### Press release

## First quarter 2023



# GSK momentum continues with strong start to 2023

### Q1 2023 performance highlights:

- Sales performance reflected lower COVID-19 solutions sales versus Q1 2022, Excluding COVID-19 solutions. sales grew +10% CER with strong performance across Vaccines, Specialty and General Medicines
- Key growth drivers included Shingrix for shingles, meningitis vaccines, oral two-drug regimen and long-acting HIV medicines, Benlysta in immunology, Nucala and Trelegy in respiratory, which combined contributed more than 40% of sales
- Total operating profit and total EPS performance reflected the comparison to Q1 2022 which included the oneoff income benefit of the Gilead settlement and higher Xevudy sales
- Adjusted operating profit was stable at CER, predominately reflecting a 5% adverse impact following expected lower COVID-19 solutions sales and 4% from legal provisions primarily relating to royalties
- Adjusted EPS increased +7% CER due to lower non-controlling interests, a lower effective tax rate, and strong . sales growth excluding lower COVID-19 solutions (which impacted performance by 7%)
- Cash generated from operations £0.3 billion; free cash outflow (£0.7) billion lower than Q1 2022 primarily due to Gilead settlement income received in Q1 2022 and timing of profit share payments
- Full-year 2023 guidance affirmed. Dividend of 14p declared for Q1 2023. 56.5p expected for the full-year 2023 .

			Q1 2023
	£m	% AER	% CER
Vaccines	2,041	22	15
Specialty Medicines	2,236	(29)	(33)
General Medicines	2,674	12	9
Turnover	6,951	(3)	(8)
Turnover excluding COVID-19 solutions	6,819	16	10
Total operating profit	2,082	(9)	(15)
Total continuing EPS	36.8p	(1)	(8)
Total EPS	36.8p	(18)	(23)
Adjusted operating profit	2,092	8	-
Adjusted operating margin %	30.1%	3.1 ppts	2.5 ppts
Adjusted EPS	37.0p	15	7
Cash generated from operations	287	(88)	
Free cash outflow	(689)	>(100)	
(Financial Performance - 01 2023 results unless otherwise stated, growth % and commentary at CER)			

(Financial Performance - Q1 2023 results unless otherwise stated, growth % and commentary at CER)

#### R&D delivery and targeted business development support future growth

- Innovative pipeline of 68 vaccines and specialty medicines based on the science of immune system with 17 in Phase III/registration; four anticipated 2023 approvals (daprodustat in anaemia due to chronic kidney disease, RSV older adults vaccine, momelotinib in myelofibrosis and *Jemperli* in first-line endometrial cancer)
- Four positive phase III/IV data readouts in Q1 2023, including pentavalent Meningitis ABCWY vaccine candidate; • gepotidacin for uncomplicated urinary tract infections; Jemperli for first-line endometrial cancer and Cabenuva for HIV treatment
- Proposed acquisition of Bellus Health provides access to camlipixant, potential best-in-class and highly selective P2X3 antagonist currently in phase III development for treatment of refractory chronic cough; exclusive license agreement signed with Scynexis for Brexafemme, a US FDA approved, first-in-class antifungal for treatment of vulvovaginal candidiasis

### Emma Walmsley, Chief Executive Officer, GSK:

"We have made a strong start to 2023, with excellent performance across Vaccines, Specialty and General Medicines. We are very focused on our upcoming launches, including our potential RSV older adult vaccine, and on continuing to strengthen our pipeline - both organically with several positive late-stage read-outs already this year, and through targeted business development. This continued momentum is also supporting our confidence in delivering our medium and long-term growth ambitions."

The Q1 2022 comparative results are restated from those previously published to reflect the demerger of Consumer Healthcare in July 2022 see page 33.

The Total results are presented in summary above and on page 6 and Adjusted results reconciliations are presented on pages 18 and 19. Adjusted results are a non-IFRS measure excluding discontinued operations and other adjustments that may be considered in addition to, but not as a substitute for, or superior to, information presented in accordance with IFRS. Adjusted results are defined on page 16 and £% or AER% growth, CER% growth, free cash flow, turnover excluding COVID-19 solutions and other non-IFRS measures are defined on page 44, COVID-19 solutions are defined on page 44. GSK provides guidance on an Adjusted results basis only, for the reasons set out on page 16. All expectations, guidance and targets regarding future are defined or performance and dividend payments should be read together with 'Guidance, assumptions and cautionary statements' on pages 45 and 46.

### Press release

# First quarter 2023



### 2023 guidance

The Company affirms its full-year 2023 guidance at constant exchange rates (CER). All expectations and full-year growth rates exclude any contributions from COVID-19 solutions:

#### Turnover is expected to increase between 6 to 8 per cent Adjusted operating profit is expected to increase between 10 to 12 per cent Adjusted earnings per share is expected to increase between 12 to 15 per cent

Taking Q1 2023 performance and the latest expectations for Q2 2023 into account, GSK now expects first half and second half turnover growth to be broadly similar and for General Medicines to be broadly flat to slightly down this year. GSK expects Adjusted operating profit growth to be lower in the first half of 2023 and higher in the second half, relative to full-year expectations.

Despite the recovery of healthcare systems, uncertain economic conditions prevail across many markets in which GSK operates and we continue to expect to see variability in performance between quarters.

This guidance is supported by the following turnover expectations for full year 2023 at CER:

Vaccines – expected increase of mid-teens per cent in turnover Specialty Medicines – expected increase of mid to high single-digit per cent in turnover General Medicines – expected to be broadly flat to slightly down

Adjusted Operating profit is expected to grow between 10 to 12 per cent at CER reflecting Cost of sales and R&D increasing at a rate slightly below turnover, while SG&A is anticipated to increase at a rate broadly aligned to turnover, reflecting targeted support for launches and potential launches including the RSV older adult candidate vaccine. Adjusted earnings per share is expected to increase between 12 to 15 per cent at CER reflecting favourable net finance costs and non-controlling interests plus an expected lower tax rate, at around 15%.

#### **Additional commentary**

Dividend policies and expected pay-out ratios remain unchanged for GSK. The future dividend policies and guidance regarding the expected dividend pay-out in 2023 for GSK are provided on page 30.

#### **COVID-19 solutions**

In Q1 2023, turnover decreased by 8% at CER reflecting the comparison to Q1 2022, which included £1,307 million of COVID-19 solutions sales in the period. Excluding COVID-19 solutions, turnover increased by 10% at CER. In Q1 2023, Adjusted Operating profit was stable at CER reflecting a 5% adverse impact from expected lower COVID-19 solutions sales. Based on known binding agreements with governments, GSK does not anticipate further significant COVID-19 pandemic-related sales or operating profit in 2023. Consequently, the Company now expects full-year 2023 turnover growth to be impacted by approximately 9%, with Adjusted Operating profit growth being reduced between 5% to 6% versus the prior year.

All expectations, guidance and targets regarding future performance and dividend payments should be read together with 'Guidance, assumptions and cautionary statements' on pages 45 and 46. If exchange rates were to hold at the closing rates on 31 March 2023 (1.24/£1, €1.14/£1 and Yen 165/£1) for the rest of 2023, the estimated impact on 2023 Sterling turnover growth for GSK would be stable and if exchange gains or losses were recognised at the same level as in 2022, the estimated impact on 2023 Sterling Adjusted Operating Profit growth for GSK would be -1%.

#### **Results presentation**

A conference call and webcast for investors and analysts of the quarterly results will be hosted by Emma Walmsley, CEO, at 12pm GMT on 26 April 2023. Presentation materials will be published on www.gsk.com prior to the webcast and a transcript of the webcast will be published subsequently.

Notwithstanding the inclusion of weblinks, information available on the Company's website, or from non GSK sources, is not incorporated by reference into this Results Announcement.

Q1 2023

Issued: Wednesday, 26 April 2023, London, U.K.

### Press release

# First quarter 2023

### Performance: turnover

### Turnover

			QT 2023
		Growth	Growth
	£m	£%	CER%
Shingles	833	19	11
Meningitis	280	32	25
Influenza	12	(33)	(28)
Established Vaccines	815	10	4
Vaccines excluding COVID-19 solutions	1,940	16	9
COVID-19 solutions: Pandemic vaccines	101	100	100
Vaccines	2,041	22	15
HIV	1,468	24	15
Immunology/Respiratory and Other	601	16	9
Oncology	136	7	2
Specialty Medicines excluding COVID-19 solutions	2,205	21	13
COVID-19 solutions: Xevudy	31	(98)	(98)
Specialty Medicines	2,236	(29)	(33)
Respiratory	1,767	15	10
Other General Medicines	907	7	7
General Medicines	2,674	12	9
Total	6,951	(3)	(8)
Total excluding COVID-19 solutions	6,819	16	10
By Region:			
US	3,270	(9)	(17)
Europe	1,704	3	(2)
International	1,977	2	2
Total	6,951	(3)	(8)
Turnover excluding COVID-19 solutions is a non-IERS measure defined on page 44 with the reconciliation to	the IERS measure Turnover included in th	e table above	

Turnover excluding COVID-19 solutions is a non-IFRS measure defined on page 44 with the reconciliation to the IFRS measure Turnover included in the table above.

			£m	AER	CER
Vaccinco	Total	Q1 23	2,041	22%	15%
Vaccines	Excluding COVID-19 solutions	Q1 23	1,940	16%	9%

Vaccines grew in all regions. Key growth drivers were geographical expansion and market growth for *Shingrix*, and inclusion in National Immunisation Programmes for *Bexsero*. Pandemic vaccines sales reflected GSK's share of 2023 contracted European volumes related to a COVID-19 booster vaccine co-developed with Sanofi.

Shingles	Q1 23	833	19%	11%
<i>Shingrix</i> , a vaccine against herpes zoster (shingles), grew in demand and favourable pricing mix. US sales were primaril inventory movements. <i>Shingrix</i> is now available in 31 countr	y impacted by ur		•	

Meningitis	Q1 23	280	32%	25%
Strong growth in Meningitis vaccines was primarily driven by	Bexsero, our vacci	ine against me	ningitis B, whic	h grew in
Europe mainly from inclusion in National Immunisation Progra	ammes and in Inter	national due to	o an increase ir	n demand
ahead of an anticipated price increase. Menveo, our vaccine	against meningitis s	strains ACWY,	grew in the US	S primarily
due to initial public stocking of the new liquid formulation and	Center for Disease	Control (CDC)	) purchasing pa	atterns.

Established Vaccines grew mainly in Hepatitis vaccines resulting from continued travel market recovery in Europe and International, and due to CDC purchasing patterns in the US. *Rotarix*, a vaccine to protect infants against rotavirus, grew in the US primarily driven by initial stocking of the new liquid formulation by the CDC. *Synflorix*, our 10-valent vaccine for pneumococcal disease, declined in the quarter reflecting phasing of public market supply and lower demand related to decreased birth cohorts in International.



Results Summ	ary Research and development	ESG	Total and Adjusted results	Financi informat		iditor's review report
Press releas	ay, 26 April 2023, London, U.K. S <b>e</b> <b>arter 2023</b>				G	SX
				£m	AER	CER
Specialty Nedicines	Total		Q1 23	2,236	(29%)	(33%)
Specialty Med Other all grow	Excluding COVID-19 sc icines growth reflected co ving. In the quarter, there drag of 46 (CER) percenta	nsistent performan were minimal sale				
ΗV			Q1 23	1,468	24%	15%
Dral 2DR and Dral 2DR ( <i>Do</i> u	/ato, Juluca) and Long Act	ing medicines ( <i>Cal</i>				51% e total HIV
	ared to 36% in Q1 2022.	Glowin was priman	Q1 23	601	16%	9%
	area includes sales of <i>E</i> aunch in US is expected ir			or Duvioy (	Daprodustaty	in Japan.
Daprodustat la				253	18%	
Daprodustat la Benlysta Benlysta, a m nderlying dei		n the second half of nent for Lupus, co This growth was p	the year. Q1 23 Intinues to show co	253 Insistent grov	18% vth represent	9% ing strong
Daprodustat la Benlysta Benlysta, a m Inderlying den nventory mov	aunch in US is expected in nonoclonal antibody treatmand in US and Europe.	n the second half of nent for Lupus, co This growth was p	the year. Q1 23 Intinues to show co	253 Insistent grov	18% vth represent	9% ing strong
Daprodustat la Benlysta Benlysta, a m Inderlying den nventory mov Nucala Nucala, is a IL chronic rhinos syndrome (HE ndications wit	aunch in US is expected in nonoclonal antibody treatmand in US and Europe.	n the second half of ment for Lupus, co This growth was p tional regions. antibody treatmen eosinophilic granul r reflected patient growth was partially	the year. Q1 23 Intinues to show co artially offset in the Q1 23 t for severe asthma omatosis with polya demand in severe e	253 Insistent grow quarter by th 347 , with addition ngiitis (EGPA eosinophilic a	18% wth represent ne impact of v 18% nal indications and hypere- asthma and fo	9% ing strong wholesaler 11% s including osinophilic or the new
Daprodustat la Benlysta Benlysta, a m Inderlying den nventory mov Nucala Nucala, is a IL Nucala, is a IL	aunch in US is expected in nonoclonal antibody treatr mand in US and Europe. ements in US and Interna 5 antagonist monoclonal inusitis with nasal polyps, ES). Growth in the quarte h ongoing launches. This	n the second half of ment for Lupus, co This growth was p tional regions. antibody treatmen eosinophilic granul r reflected patient growth was partially	the year. Q1 23 Intinues to show co artially offset in the Q1 23 t for severe asthma omatosis with polya demand in severe e	253 Insistent grow quarter by th 347 , with addition ngiitis (EGPA eosinophilic a	18% wth represent ne impact of v 18% nal indications and hypere- asthma and fo	9% ing strong wholesaler 11% s including osinophilic or the new
Daprodustat la Benlysta Benlysta, a m Inderlying den Nucala Nucala, is a IL Indicata, is a IL Indications wit In unfavourate Dincology grov	aunch in US is expected in nonoclonal antibody treatr mand in US and Europe. ements in US and Interna 5 antagonist monoclonal inusitis with nasal polyps, ES). Growth in the quarte h ongoing launches. This	n the second half of ment for Lupus, co This growth was p tional regions. antibody treatmen eosinophilic granul r reflected patient growth was partially tment. in Europe and <i>Jen</i>	the year. Q1 23 Intinues to show co artially offset in the Q1 23 t for severe asthma omatosis with polya demand in severe e offset in the US by Q1 23	253 Insistent grow quarter by th 347 , with addition ngiitis (EGPA eosinophilic a the impact of 136	18% wth represent ne impact of w 18% nal indications and hypere- isthma and for inventory dep <b>7%</b>	9% ing strong wholesaler 11% s including osinophilic or the new oletion and <b>2%</b>
Daprodustat la Benlysta Benlysta, a m underlying den nventory mov Nucala Nucala, is a IL chronic rhinos syndrome (HE ndications wit an unfavourat <b>Dncology</b> grov	aunch in US is expected in nonoclonal antibody treatr mand in US and Europe. ements in US and Interna 5 antagonist monoclonal inusitis with nasal polyps, ES). Growth in the quarte h ongoing launches. This ole prior period RAR adjus	n the second half of ment for Lupus, co This growth was p tional regions. antibody treatmen eosinophilic granul r reflected patient growth was partially tment. in Europe and <i>Jen</i>	the year. Q1 23 Intinues to show co artially offset in the Q1 23 t for severe asthma omatosis with polya demand in severe e offset in the US by Q1 23	253 Insistent grow quarter by th 347 , with addition ngiitis (EGPA eosinophilic a the impact of 136	18% wth represent ne impact of w 18% nal indications and hypere- isthma and for inventory dep <b>7%</b>	9% ing strong wholesaler 11% s including osinophilic or the new oletion and <b>2%</b>

Results Summary	Research and development	ESG	Total and Adjusted results	Financia informatio		ditor's review report
ssued: Wednesday, 26 Press release	) April 2023, London, U.K.					
First quarte	er 2023					<b>S</b> ł
				£m	AER	CER
General Medicine	S		Q1 23	2,674	12%	9%
in all regions in add	ooth Respiratory and dition to a strong alle and International regi	rgy season in Japai				
Respiratory			Q1 23	1,767	15%	10%
<i>Trelegy</i> <i>Trelegy</i> , is the mos	t prescribed single inh performance across a					rew in the
<i>Trelegy</i> <i>Trelegy</i> , is the mos period with strong p	t prescribed single inf performance across a		SITT) treatment for C	OPD and asth	ma. <i>Trelegy</i> g	rew in the T market.
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<i>Trelegy</i> <i>Trelegy</i> , is the mos period with strong p <i>Seretide/Advair</i> <i>Seretide/Advair</i> is International marke of generic competi	an ICS/LABA treatmets and the benefit of tion in Europe, US and	Il regions, reflecting i nent for asthma and f a favourable US pr	GITT) treatment for C increased patient de Q1 23 I COPD. Growth re for period RAR adju	COPD and asth mand and grov 339 flected targete	ma. <i>Trelegy</i> g vth of the SIT 12% ed promotion	rew in the T market. 8% in certain he impact
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Trelegy Trelegy, is the mosperiod with strong period with seretide/Advair is International market of generic competine of generic competine of the competine of the single-digit gradient of the single-d	an ICS/LABA treatments and the benefit of tion in Europe, US and the denefit of tion in Europe, US and the tion in Europe, US and the tion in Europe, US and the tion of 37% AER, 38% C	Il regions, reflecting i nent for asthma and a favourable US pr nd certain Internatio g post pandemic der ER in the quarter. T	SITT) treatment for C increased patient de Q1 23 I COPD. Growth re for period RAR adjunal markets. Q1 23 mand for anti-infection the impact of ongoin	COPD and asth mand and grov 339 flected targete ustment, partia <b>907</b> ives in Europe ng generic com ntly in the Inter	ma. <i>Trelegy</i> g wh of the SIT 12% ed promotion illy offset by t <b>7%</b> and Internati petition in th national regio	T market. 8% in certain he impact 7% onal, with is product
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period with strong p Seretide/Advair Seretide/Advair Seretide/Advair is International marked of generic competin Other General Me High single-digit gr Augmentin growth group is also offset by Region US To Ex In the quarter there solutions sales in C Vaccine market red comparator on Shir growth was driven b	an ICS/LABA treatments an ICS/LABA treatments and the benefit of tion in Europe, US an edicines rowth reflected strong of 37% AER, 38% C t by <i>Avodart</i> and dem edicines rowth <i>reflected strong</i> of 37% AER, 38% C t by <i>Avodart</i> and dem edicines rowth <i>reflected strong</i> of 37% AER, 38% C t by <i>Avodart</i> and dem edicines rowth <i>reflected strong</i> of 37% AER, 38% C t by <i>Avodart</i> and dem edicines rowth <i>reflected strong</i> of 37% AER, 38% C t by <i>Avodart</i> and dem edicines rowth <i>reflected strong</i> of 37% AER, 38% C	Il regions, reflecting i nent for asthma and a favourable US pr nd certain Internatio g post pandemic der ER in the quarter. T matological product olutions centage point drag d is effect there was g er phasing, offsetting y Medicines growth	Correlated patient for Concreased patient de Q1 23 Correlated patient de Q1 23 Correlated RAR adjunal markets. Q1 23 Mand for anti-infection The impact of ongoin growth, predominar Q1 23 Q1 23 Q1 23 ue to high sales of A rowth in all product of grimpact of wholesa was driven by strong	COPD and asth mand and grov 339 flected targete ustment, partia 907 ives in Europe ng generic com ntly in the Inter £m 3,270 3,270 Kevudy in Q1 2 groups. Vaccin iler destocking g HIV performan	ma. <i>Trelegy</i> g with of the SIT 12% ed promotion illy offset by t <b>7%</b> and International region <b>AER</b> (9%) 16% 022, with no C es grew on E and a strong nce. General	rew in the T market. 8% in certair he impac 7% onal, with is producton. CER (17%) 6% COVID-19 stablished Q1 2022

groups growing strongly excluding this effect. Vaccines double digit growth reflected *Shingrix* launches and uptake, *Bexsero* national immunisation campaigns in France and Spain and ongoing travel vaccine recovery. Specialty Medicines double digit growth was driven by HIV, *Benlysta* and *Nucala* including the impact of new indication launches. General Medicines was driven by *Trelegy* ongoing growth and *Augmentin* on strong post pandemic antibiotic demand.

			£m	AER	CER
International	Total	Q1 23	1,977	2%	2%
International	Excluding COVID-19 solutions	Q1 23	1,946	13%	14%

In the quarter there was a 12 (CER) percentage point drag due to high sales of *Xevudy* in Q1 2022, with all product groups growing strongly excluding this effect. Vaccines double digit growth was driven by *Shingrix* uptake in Japan and China and launches in certain other markets. Specialty Medicines grew in HIV, Oncology and Immunology/Respiratory and Other with *Nucala* delivering strong growth in severe eosinophilic asthma and new indications. General Medicines product group was driven by Respiratory, with *Trelegy* growth and a strong allergy season in Japan, Other General Medicines was driven by *Augmentin* on strong post pandemic antibiotic demand.

Q1 2023

Issued: Wednesday, 26 April 2023, London, U.K.

### Press release

# First quarter 2023

## **Financial performance**

	£m	% AER	% CER
<b>Turnover</b> Cost of sales Selling, general and administration Research and development Royalty income Other operating income/(expense)	6,951 (1,943) (2,143) (1,260) 180 297	(3) (28) 18 14 30	(8) (30) 12 8 28
Operating profit	2,082	(9)	(15)
Net Finance expense Share of after tax profit/(loss) of associates and joint ventures Profit/(loss) on disposal of interest in associates	(174) (2) 1		
Profit before taxation	1,907	(9)	(15)
Taxation <i>Tax rate %</i>	(276) 14.5%		
Profit after taxation	1,631	(8)	(14)
Profit attributable to non-controlling interests Profit attributable to shareholders	141 1,490		
	1,631	(8)	(14)
Earnings per share	36.8p	(1)	(8)

The Total Results are on a continuing basis. The Q1 2022 comparative results have been restated on a consistent basis from those previously published to reflect the demerger of the Consumer Healthcare business (see page 33). Financial Performance - Q1 2023 results unless otherwise stated, growth % and commentary at CER.

### Adjusted results

Reconciliations between Total results and Adjusted results for Q1 2023 and Q1 2022 are set out on pages 18 and 19.

			Q1 2023
	£m	% AER	% CER
Turnover	6,951	(3)	(8)
Cost of sales Selling, general and administration Research and development Royalty income	(1,752) (2,065) (1,222) 	(31) 17 12 30	(32) 10 6 28
Adjusted operating profit	2,092	8	
Adjusted profit before taxation Taxation	1,920 (303)	10 6	2 (2)
Adjusted profit after taxation	1,617	11	3
Adjusted profit attributable to non-controlling interests Adjusted profit attributable to shareholders	121 1,496		
	1,617	11	3
Earnings per share	37.0p	15	7_

Results Summary	Research and development	ESG	Total and Adjusted results	Financial information		uditor's review report
Issued: Wednesday, 2 Press release	6 April 2023, London, U.K.					
First quart	er 2023				J	SK
			_			Q1 2023
			_	£m	AER	CER
Cost of sales	Total			1,943	(28%)	(30%)
	% of sales			28.0%	(9.8%)	(8.9%)
	Adjusted			1,752	(31%)	(32%)
	% of sales			25.2%	(9.9%)	(9.1%)
margin Xevudy co	otal and Adjusted compared to Q1 2022. ustments in Q1 2022	This was partly offs	set by an unfavourat			

				Q1 2023
		£r	n AER	CER
Selling, general & administration	Total	2,143	3 18%	12%
	% of sales	30.89	% 5.6%	5.5%
	Adjusted	2,065	5 17%	10%
	% of sales	29.79	% 5.1%	4.9%

Growth in Total and Adjusted SG&A primarily reflected an increase in legal provisions primarily relating to the Zejula royalty dispute<sup>(1)</sup> resulting in an increase of 4 ppts and an increased level of launch investment in Specialty Medicines particularly HIV and Vaccines including Shingrix to drive post-pandemic recovery demand and support market expansion. Growth was partly offset by favourable comparison due to impairment provisions relating to Russia and Ukraine in Q1 2022 and the continuing benefit of restructuring and tight control of ongoing costs.

				Q1 2023
		£m	AER	CER
Research &	Total	1,260	14%	8%
development	% of sales	18.1%	2.8%	2.7%
	Adjusted	1,222	12%	6%
	% of sales	17.6%	2.4%	2.4%

Growth in Total and Adjusted R&D reflected increased investment across the Vaccines clinical development portfolio, particularly in pneumococcal programmes acquired as part of the Affinivax Inc (Affinivax) acquisition, mRNA technology platforms and the phase II MMR programme.

In the Specialty Medicines portfolio, there was increased investment in the early stage research portfolio, particularly CCL17 for osteo arthritic pain and IL18 for atopic dermatitis and in Jemperli, with preparation for new phase II/III trials in rectal and colon cancer as well as the ongoing trials in endometrial cancer. In addition, there was increased investment in momelotinib, a potential new treatment of myelofibrosis patients with anaemia, the phase III respiratory programme for depemokimab, a potential new medicine to treat a range of eosinophil-driven diseases and for bepirovirsen, the study in chronic hepatitis B. These increases in investment were partly offset by decreases related to the completion of late-stage clinical development programmes for otilimab and Cell & Gene therapy and reduced R&D investment in Blenrep versus Q1 2022.

				Q1 2023
		£m	AER	CER
Royalty income	Total	180	30%	28%
	Adjusted	 180	30%	28%

Growth in Total and Adjusted royalty income primarily reflected the settlement and licensing agreement with Gilead Sciences Inc. (Gilead) announced on 1 February 2022 and included Gardasil royalty income of £71 million.

(1) See update on Legal matters on page 29.

Results Summary	development	ESG	Adjusted results	information		report
Issued: Wednesday, 26	April 2023, London, U.K.					
Press release						
First quarte	er 2023					SK
•						
						Q1 2023
				£m	AER	CER
Other operating (expense)/income	Total			297	(50%)	(52%)

The decrease primarily reflected an unfavourable comparison to the upfront income in Q1 2022 of £0.9 billion received from the settlement with Gilead. Net other operating income included an accounting credit of £271 million (Q1 2022: £335 million charge) arising from the remeasurement of contingent consideration liabilities and the liabilities for the Pfizer, Inc. (Pfizer) put option and Pfizer and Shionogi & Co. Ltd (Shionogi) preferential dividends in ViiV Healthcare.

				Q1 2023
		£m	AER	CER
Operating profit	Total	2,082	(9%)	(15%)
	% of sales	30.0%	(1.9%)	(2.4%)
	Adjusted	2,092	8%	-
	% of sales	30.1%	3.1%	2.5%

Total operating profit margin was down 1.9 ppts at AER and 2.4 ppts at CER primarily reflecting an unfavourable comparison due to the £0.9 billion upfront income received from the settlement with Gilead in Q1 2022, partly offset by remeasurement credits on contingent consideration liabilities.

Adjusted profit was impacted by lower sales of COVID-19 solutions sales which led to a drag of 5% AER and CER but increased the Adjusted operating profit margin by approximately 3.9 ppts at AER and CER. Excluding COVID-19 Solutions, Adjusted operating profit benefited from strong sales across all three product areas but margin was impacted by increased legal charges in the quarter primarily relating to the *Zejula* royalty dispute and an unfavourable comparison to a one-time benefit from inventory adjustments in Q1 2022.

Contingent consideration cash payments made to Shionogi and other companies reduce the balance sheet liability. Total contingent consideration cash payments in Q1 2023 amounted to £291 million (Q1 2022: £211 million). These included cash payments made to Shionogi of £287 million (Q1 2022: £208 million).

				Q1 2023
		£m	AER	CER
Adjusted	Commercial Operations	3,375	8%	1%
operating profit by business	% of sales	48.6%	5.2%	4.3%
	R&D	(1,232)	13%	6%

Commercial Operations Adjusted operating profit reflected lower COVID-19 solutions sales, primarily *Xevudy*. Sales declined 8% with 19 ppts AER / 18 ppts CER drag from COVID-19 solutions sales. Operating profit margin benefitted from product mix upside (with minimal *Xevudy* sales) and increased royalty income, partly offset by increased investment in growth and launch assets as well as an increase in legal provisions.

The R&D segment operating expenses primarily reflected increased investment in the Vaccines clinical development portfolio, particularly in pneumococcal programmes, the mRNA technology platforms and the phase II MMR programme. This was partly offset by decreases related to the completion of late-stage clinical development programmes for otilimab and Cell & Gene therapy and reduced R&D investment in *Blenrep* versus Q1 2022.

				Q1 2023
		£m	AER	CER
Net finance costs	Total	174	(12%)	(16%)
	Adjusted	 170	(14%)	(18%)

Total net finance costs decreased by £24 million compared to Q1 2022. Adjusted net finance costs decreased by £28 million compared to Q1 2022. The decrease is mainly driven by the net savings from maturing bonds including the Sterling Notes repurchase in Q4 2022 and higher interest income on cash.

	development	ESG	Adjusted results	information	ı	report
	w 26 April 2022 London LLK					
Press releas	ay, 26 April 2023, London, U.K. S <b>C</b>					
First qua	rter 2023				- <b>F</b>	SX
i not quu						
						Q1 2023
					. = 5	
				£m	AER	CER
Taxation	Total			276	AER (15%)	CER (21%)
Taxation	Total <i>Tax rate %</i>					
Taxation				276		

Total and

Financial

Auditor's review

Research and

The effective tax rate impact is broadly in line with expectations for the quarter. Issues related to taxation are described in Note 14, 'Taxation' in the Annual Report 2022. The Group continues to believe it has made adequate provision for the liabilities likely to arise from periods that are open and not yet agreed by relevant tax authorities. The ultimate liability for such matters may vary from the amounts provided and is dependent upon the outcome of agreements with relevant tax authorities.

				Q1 2023
		£m	AER	CER
Non-controlling	Total	141	(49%)	(53%)
interests	Adjusted	121	(25%)	(32%)

The decrease in Total profit from continuing operations allocated to non-controlling interest was primarily due to lower allocation of ViiV Healthcare profits of £140 million (Q1 2022: £227 million), partly offset by decreased credits for remeasurement of contingent consideration liabilities, as well as lower net profits in some of the Group's other entities with non-controlling interests.

The decrease in Adjusted profit from continuing operations allocated to non-controlling interest primarily reflected lower profits in some of the Group's entities with non-controlling interests partly offset by an increased allocation of ViiV Healthcare profits of £120 million (Q1 2022: £113 million).

				Q1 2023
		£m	AER	CER
Earnings per	Total		(1%)	(8%)
share	Adjusted	37.0p	15%	7%

The decrease in Total EPS primarily reflected an unfavourable comparison due to upfront income received from the settlement with Gilead in Q1 2022. This was partly offset by remeasurement credits for contingent consideration liabilities compared to charges in Q1 2022, lower non-controlling interests and lower effective tax rate.

Adjusted EPS reflected strong growth in sales across all product areas excluding COVID-19 solutions, higher royalty income, lower non-controlling interests and a lower effective tax rate. This was partly offset by increased legal charges primarily relating to royalties and investment behind launches in Specialty Medicines including HIV and Vaccines plus higher supply chain costs, freight and distribution costs. Decline in lower margin COVID-19 solutions sales was a drag on Adjusted EPS growth of 7 ppts at AER and CER.

#### Currency impact on Q1 2023 results

The results for Q1 2023 are based on average exchange rates, principally £1/\$1.22, £1/€1.14 and £1/Yen 162. Comparative exchange rates are given on page 31. The period-end exchange rates were £1/\$1.24, £1/€1.14 and £1/Yen 165.

In Q1 2023, turnover was down 3% at AER and 8% at CER. Total EPS from continuing operations was 36.8p compared with 37.3p in Q1 2022. Adjusted EPS was 37.0p compared with 32.3p in Q1 2022, up 15% at AER and 7% at CER. The favourable currency impact primarily reflected the weakening of Sterling against the US Dollar and the Euro. Exchange gains or losses on the settlement of intercompany transactions had a one percent adverse impact on the eight percentage point favourable currency impact on Adjusted EPS.

Issued: Wednesday, 26 April 2023, London, U.K.

### Press release

# First quarter 2023

## Cash generation

### Cash flow

	Q1 2023 £m	Q1 2022 £m
Cash generated from operations attributable to continuing operations (£m) Cash generated from operations attributable to	287	2,352
discontinued operations (£m)	<u> </u>	403
Total cash generated from operations (£m)	287	2,755
Net cash inflow/(outflow) from operating activities from continuing operations (£m) Net cash inflow/(outflow) from operating activities from discontinued operations (£m)	53 -	2,206 336
Total net cash generated from operating activities (£m)	53	2,542
Free cash inflow/(outflow) from continuing operations* (£m) Free cash flow from continuing operations growth (%) Free cash flow conversion from continuing operations* (%) Total net debt** (£m)	(689) >(100)% 3% (17,950)	1,477 96% (19,351)

Free cash flow from continuing operations and free cash flow conversion are defined on page 44.
 Net debt is analysed on page 34.

### Q1 2023

Cash generated from operating activities from continuing operations was £287 million (Q1 2022: £2,352 million). The decrease primarily reflected an unfavourable comparison due to the upfront income from the settlement with Gilead received in Q1 2022, unfavourable timing of profit share payments for *Xevudy*, increase in seasonal inventory and lower payable balances reflecting increased investment in 2022.

Total cash payments to Shionogi in relation to the ViiV Healthcare contingent consideration liability in the quarter were £287 million (Q1 2022: £208 million), all of which was recognised in cash flows from operating activities. These payments are deductible for tax purposes.

Free cash outflow was £689 million for the quarter (Q1 2022: £1,477 million inflow). The decrease primarily reflected an unfavourable comparison due to the upfront income from the settlement with Gilead received in Q1 2022, unfavourable timing of profit share payments for *Xevudy*, increase in seasonal inventory, lower payable balances reflecting increased investment in 2022 and higher tax payments.

### **Total Net debt**

At 31 March 2023, net debt was £17,950 million, compared with £17,197 million at 31 December 2022, comprising gross debt of £20,905 million and cash and liquid investments of £2,955 million.

Net debt increased by £0.8 billion primarily due to £0.7 billion free cash outflow and dividends paid to shareholders of £0.6 billion. This was partly offset by net favourable exchange impacts of £0.4 billion from the translation of non-Sterling denominated debt and exchange on other financing items and £0.1 billion of income received from equity investments.

At 31 March 2023, GSK had short-term borrowings (including overdrafts and lease liabilities) repayable within 12 months of £4,261 million with loans of £1,682 million repayable in the subsequent year.

Press release

# First quarter 2023

# **Q1 2023 pipeline highlights (since 1 February 2023)**

	Medicine/vaccine	Trial (indication, presentation)	Event	
Regulatory approvals or other regulatory action	Jesduvroq	ASCEND-D (anaemia of chronic kidney disease on dialysis)	Regulatory approval (US)	
	Jemperli	GARNET (2L endometrial cancer)	Conversion to regular (full) approval (US)	
Regulatory submissions	Nucala	Severe asthma	Regulatory acceptance (CN)	
or acceptances	Jemperli	RUBY (1L mismatch repair- deficient/microsatellite instability-high (dMMR/MSI- H) endometrial cancer)	Regulatory acceptance (EU)	
Phase III data readouts or other significant events	Benlysta	Paediatric systemic lupus erythematosus (sub- cutaneous administration)	Positive phase II data readout	
	Jemperli	Rectal cancer	US FDA Advisory Committee vote to support phase II trial design	
	Jemperli	RUBY (1L endometrial cancer)	Phase III data presentation	
	gepotidacin	EAGLE-2/3 (uncomplicated urinary tract infection)	Phase III data presentation	
	RSV older adult vaccine candidate	RSV, older adults aged 60+ years	US FDA Advisory Committee vote	
	MenABCWY (gen 1) vaccine candidate	Meningitis ABCWY	Positive phase III data readout	

### Anticipated news flow

Timing	Medicine/vaccine	Trial (indication, presentation)	Event
H1 2023	daprodustat	ASCEND (anaemia of chronic kidney disease)	Regulatory decision (EU)
	Jemperli	RUBY (1L endometrial cancer)	Regulatory submission (US)
	momelotinib	MOMENTUM (myelofibrosis with anaemia)	Regulatory decision (US)
	RSV older adult vaccine candidate	RSV, older adults aged 60+ years	Regulatory decision (US)
	Shingrix	Shingles, at-risk adults aged 18+ years	Regulatory decision (JP)
H2 2023	bepirovirsen	B-Together (hepatitis B virus)	Phase IIb data readout
	Nucala	Nasal polyposis	Regulatory submission (CN, JP)
	Blenrep	DREAMM-7 (2L+ multiple myeloma)	Phase III data readout
	Blenrep	DREAMM-8 (2L+ multiple myeloma)	Phase III data readout
	Blenrep	DREAMM-7 (2L+ multiple myeloma)	Regulatory submission (US, EU)
	Blenrep	DREAMM-8 (2L+ multiple myeloma)	Regulatory submission (US, EU)
	Jemperli	RUBY (1L endometrial cancer)	Regulatory decision (US)
	Zejula	FIRST (1L maintenance ovarian cancer)	Phase III data readout
	cabotegravir	Pre-exposure prophylaxis, long-acting injectable	Regulatory decision (EU)
	Vocabria	HIV	Regulatory decision (CN)
	gepotidacin	EAGLE-1 (urogenital gonorrhoea)	Phase III data readout
	gepotidacin	EAGLE-2/3 (uncomplicated urinary tract infection)	Regulatory submission (EU)



### Press release

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Timing	Medicine/vaccine	Trial (indication, presentation)	Event
	MenABCWY (gen 2) vaccine candidate	Meningitis ABCWY	Phase II data readout
	RSV older adult vaccine candidate	RSV, older adults aged 60+ years	Regulatory decision (EU, JP)
	RSV older adult vaccine candidate	RSV, older adults aged 50-59 years	Phase III data readout
	RSV older adult vaccine candidate	RSV, older adults aged 50-59 years	Regulatory submission (US, EU, JP)
	SKYCovione COVID-19 vaccine	COVID-19	Regulatory decision (EU)
2024	linerixibat	GLISTEN (cholestatic pruritus in primary biliary cholangitis)	Phase III data readout
	linerixibat	GLISTEN (cholestatic pruritus in primary biliary cholangitis)	Regulatory submission (US, EU)
	Nucala	Severe asthma	Regulatory decision (CN)
	Nucala	Nasal polyposis	Regulatory decision (JP)
	Nucala	MATINEE (chronic obstructive pulmonary disease)	Phase III data readout
	Nucala	MATINEE (chronic obstructive pulmonary disease)	Regulatory submission (US, EU, CN, JP)
	Blenrep	DREAMM-7 (2L+ multiple myeloma)	Regulatory decision (US, EU)
	Blenrep	DREAMM-8 (2L+ multiple myeloma)	Regulatory decision (US, EU)
	cobolimab	COSTAR (non-small cell lung cancer)	Phase III data readout
	Jemperli	RUBY (1L dMMR/MSI-H endometrial cancer)	Regulatory decision (EU)
	Jemperli	RUBY part 2 (1L endometrial cancer)	Phase III data readout
	Jemperli	RUBY part 2 (1L endometrial cancer)	Regulatory submission (US, EU)
	momelotinib	MOMENTUM (myelofibrosis with anaemia)	Regulatory decision (EU)
	Zejula	ZEAL (1L maintenance NSCLC)	Phase III data readout
	gepotidacin	EAGLE-2/3 (uncomplicated urinary tract infection)	Regulatory decision (US, EU)
	gepotidacin	EAGLE-2/3 (uncomplicated urinary tract infection)	Regulatory submission (JP)
	gepotidacin	EAGLE-1 (urogenital gonorrhoea)	Regulatory submission (US)
	MenABCWY (gen 1) vaccine candidate	Meningitis ABCWY	Regulatory submission (US)
	RSV older adult vaccine candidate	RSV, older adults aged 50-59 years	Regulatory decision (US, EU, JP)

Refer to pages 35 to 43 for further details on several key medicines and vaccines in development by therapy area.

Issued: Wednesday, 26 April 2023, London, U.K. Press release

# First quarter 2023

### Trust: progress on our six priority areas for responsible business

Building Trust by operating responsibly is integral to GSK's strategy and culture. This will support growth and returns to shareholders, reduce risk, and help GSK's people thrive while delivering sustainable health impact at scale. The Company has identified six Environmental, Social, and Governance (ESG) focus areas that address what is most material to GSK's business and the issues that matter the most to its stakeholders. Highlights below include activity since Full-year and Q4 2022 results. For a full list of progress in 2022, please see the 2022 ESG Performance Report at: https://gsk.to/3V1hwFk.

### Access

Commitment: to make GSK's vaccines and medicines available at value-based prices that are sustainable for the business and implement access strategies that increase the use of GSK's vaccines and medicines to treat and protect underserved people.

### Progress to date:

- GSK continues to collaborate to support access to its HIV portfolio. For example, following the signing of a voluntary licensing agreement for cabotegravir for HIV pre-exposure prophylaxis (PrEP) between ViiV Healthcare and the Medicines Patent Pool (MPP) in July 2022, the MPP signed subsequent sub-licence agreements in March 2023 with Aurobindo Pharma Limited, Cipla, Inc. and Viatris, Inc. through its subsidiary Mylan to manufacture generic versions of cabotegravir long-acting for PrEP. More information can be found at: https://gsk.to/3LsG72L
- Working with GSK's partners, more than 1.2 million children in Ghana, Kenya and Malawi have received at least one dose of the Company's malaria vaccine, *Mosquirix* (RTS,S/AS01 E). In March 2023, Kenya expanded vaccine use beyond the communities involved in the Malaria Vaccine Immunisation Programme (MVIP), almost doubling the number of areas where children can access it. All three countries that were part of the MVIP have now expanded the rollout.

### **Global health and health security**

**Commitment:** develop novel products and technologies to treat and prevent priority diseases, including pandemic threats.

### Progress to date:

- GSK remains committed to innovation across medicines and vaccines to help get ahead of antimicrobial resistance, with a number of R&D projects targeting pathogens deemed 'critical' or 'urgent' by the WHO and US Centers for Disease Control and Prevention. GSK reinforced its commitment to developing new antibiotics in high unmet medical need areas when it presented positive results from the pivotal EAGLE-2 and EAGLE-3 phase III trials for gepotidacin, an investigational, first-in-class oral antibiotic with a novel mechanism of action for uncomplicated urinary tract infections (uUTI) in female adults and adolescents. Escherichia coli (e. coli) bacteria are the main cause of uUTI but it is showing increasing resistance to antibiotics currently used<sup>(1)</sup>. The data were disclosed in an oral presentation at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Copenhagen, Denmark. More information can be found at: https://gsk.to/40yA5lq.
- GSK continued to expand its industry-leading infectious diseases portfolio. In March 2023, the Company entered an
  exclusive licence agreement for *Brexafemme* (ibrexafungerp tablets), a US FDA-approved, first-in-class antifungal for
  treating vulvovaginal candidiasis and for a reduction in the incidence of recurrent VVC. *Brexafemme* complements
  GSK's late-stage antibiotics gepotidacin, and tebipenem, a potential new treatment for complicated urinary tract
  infections. With rates of multi-drug resistant fungal infections rising, this agreement strengthens the Company's
  position as an innovation leader in antimicrobial resistance. More information can be found at: https://gsk.to/30HAlkx

#### **Environment**

Commitment: committed to a net zero, nature-positive, healthier planet with ambitious goals set for 2030 and 2045.

### Progress to date:

- The Company has clear and measurable targets to achieve its climate and nature goals and shared its annual progress
  as part of GSK's <u>ESG Performance Report</u>. The Company also published more detail on its carbon reduction pathway
  and use of carbon credits, which can be found at: https://gsk.to/3LtovDT.
- The Taskforce on Nature-related Financial Disclosures (TNFD) recently released its final beta framework for naturerelated risk management and disclosure. GSK sits on the Taskforce, and to pilot the recommendations ahead of the
  final framework expected later this year, the Company made an initial disclosure, focusing on strategy, metrics and
  targets in its 2022 <u>Annual Report</u> (page 62). In addition, GSK was included in the TNFD (section 3.1) <u>scenario</u>
  guidance as an example of a multinational company taking an advanced approach.

#### Diversity, equity and inclusion

**Commitment:** create a diverse, equitable and inclusive workplace; enhance recruitment of diverse patient populations in GSK clinical trials; and support diverse communities.

#### Progress to date:

 Appropriate clinical research representation is critical for advancing the Company's understanding of new vaccines and medicines to ensure they positively impact patients' lives. GSK announced results from a 17-year retrospective study on US clinical trial diversity in February 2023. Results of the study demonstrate real-world disease epidemiology



### Press release

# First quarter 2023



data, compared to the conventional standard of US Census data, is a better benchmark to ensure clinical trial enrolment reflects the populations affected by diseases. GSK has committed to applying insights from the study and collaborating with regulators, patients, academics, and other biopharmaceutical companies to make meaningful progress on clinical trial diversity. As a result, 100% of phase III trials now include a demographic plan. More information can be found at: https://gsk.to/40IAGkE.

- GSK is committed to equality of representation so that its workforce reflects the communities in which it operates and hires, and that GSK leadership reflects the Company's workforce. In February 2023, GSK communicated its 2022 progress which was also highlighted in the ESG Performance Report:
  - Women held 42% of Vice President (VP) and above roles globally, compared with 40% in 2021, bringing the Company closer to its 2025 aspirational target of 45%; Women made up 47% of all employees in 2022 and 50% of all management roles.
  - In the US, GSK has 31.3% of ethnically diverse leaders at the VP level and above and has met its 2025 aspirational target of at least 30%.
  - In the UK, the Company has 14.3% of ethnically diverse leaders at VP and above, progressing towards its 2025 aspirational target of reaching at least 18%.

### Ethical standards

Commitment: promote ethical behaviour across GSK's business by supporting its employees to do the right thing and working with suppliers that share the Company's standards and operate responsibly.

Performance metrics related to ethical standards are updated annually with details from the most recent year on page 26 of GSK's ESG Performance Report 2022.

#### Product governance

Commitment: maintain robust quality and safety processes and responsibly use data and new technologies.

Performance metrics related to product governance are updated annually with details from the most recent year on page 30 of GSK's ESG Performance Report 2022.

### ESG rating performance

Detailed below is how GSK performs in key ESG ratings.

External benchmark	2020	2021	2022	Comments
S&P Global's Corporate	87	88	86	
Sustainability Assessment <sup>(2)</sup>				
	2nd in Pharma	1st in Pharma	2nd in Pharma	
	industry	industry	industry <sup>(2)</sup>	
Access to Medicines Index	4.23	n/a	4.06	Led the bi-annual index
				since its inception in 2008
	Ranked 1st		Ranked 1st	
Antimicrobial resistance	86%	84%	n/a	Led the bi-annual
benchmark				benchmark since
	Ranked 1st	Ranked 1st		inception
CDP Climate Change	A-	A-	A-	
CDP Water Security	A	В	В	
CDP Forests <sup>(3)</sup> (palm oil)	n/a	В	A-	
CDP Forests <sup>(3)</sup> (timber)	n/a	В	В	
CDP supplier engagement rating	Leader	Leader	Leader	
Sustainalytics	21.3	18.9	18.8	Lower score represents lower risk
	8th in Pharma	5th in Pharma	3rd in Pharma	
	sub-industry group	sub-industry group	sub-industry group	
MSCI	AA	AA	AA	
Moody's ESG solutions	62	61	n/a	
	2nd in Pharma	2nd in Pharma		
	and Biotech sector	and Biotech sector		
ISS Corporate Rating	В	B+	B+	
FTSE4Good	Member	Member	Member	Member since 2004
ShareAction's Workforce	68%	75%	77%	
Disclosure Initiative (WDI)				
	Sector average:	Sector average:	Sector average:	
	65%	70%	66%	

(1) WHO. Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. 2017; CDC. Antibiotic resistance threats in the United States 2019. Available from: https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf (Accessed October 2022) As at 31 March 2023.

CDP Forests assessments introduced in 2021 (3)

Results Summary	Research and development	ESG	Total and Adjusted results	Financial information	Auditor's review report				
Issued: Wednesday, 26 April 2023, London, U.K. Press release First quarter 2023									
Sales tables – three Segment information Legal matters Returns to sharehow Additional information Net assets Discontinued operation Reconciliation of car Net debt analysis Free cash flow record R&D commentary Reporting definition	results rehensive income ges in equity nt – three months er e months ended 31 on olders ion ations ash flow to movemer onciliation	March 2023 nts in net debt			Page 11 13 16 21 22 23 24 25 26 28 29 30 31 32 33 34 34 34 34 34 35 44				
	tions and cautionary or's review report to				45 47				

### **Contacts**

GSK plc (LSE/NYSE:GSK) is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at <u>www.gsk.com</u>.

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# Press release

## First quarter 2023



## **Total and Adjusted results**

Total reported results represent the Group's overall performance.

GSK also uses a number of adjusted, non-IFRS, measures to report the performance of its business. Adjusted results and other non-IFRS measures may be considered in addition to, but not as a substitute for or superior to, information presented in accordance with IFRS. Adjusted results are defined below and other non-IFRS measures are defined on page 44.

GSK believes that Adjusted results, when considered together with Total results, provide investors, analysts and other stakeholders with helpful complementary information to understand better the financial performance and position of the Group from period to period, and allow the Group's performance to be more easily compared against the majority of its peer companies. These measures are also used by management for planning and reporting purposes. They may not be directly comparable with similarly described measures used by other companies.

GSK encourages investors and analysts not to rely on any single financial measure but to review GSK's quarterly results announcements, including the financial statements and notes, in their entirety.

GSK is committed to continuously improving its financial reporting, in line with evolving regulatory requirements and best practice. In line with this practice, GSK expects to continue to review and refine its reporting framework.

Adjusted results exclude the profits from discontinued operations from the Consumer Healthcare business (see details on page 33) and the following items in relation to our continuing operations from Total results, together with the tax effects of all of these items:

- amortisation of intangible assets (excluding computer software and capitalised development costs)
- impairment of intangible assets (excluding computer software) and goodwill
- major restructuring costs, which include impairments of tangible assets and computer software, (under specific Board approved programmes that are structural, of a significant scale and where the costs of individual or related projects exceed £25 million), including integration costs following material acquisitions
- transaction-related accounting or other adjustments related to significant acquisitions
- proceeds and costs of disposal of associates, products and businesses; significant settlement income; significant legal charges (net of insurance recoveries) and expenses on the settlement of litigation and government investigations; other operating income other than royalty income, and other items

Costs for all other ordinary course smaller scale restructuring and legal charges and expenses from continuing operations are retained within both Total and Adjusted results.

As Adjusted results include the benefits of Major restructuring programmes but exclude significant costs (such as significant legal, major restructuring and transaction items) they should not be regarded as a complete picture of the Group's financial performance, which is presented in Total results. The exclusion of other Adjusting items may result in Adjusted earnings being materially higher or lower than Total earnings. In particular, when significant impairments, restructuring charges and legal costs are excluded, Adjusted earnings will be higher than Total earnings.

GSK has undertaken a number of Major restructuring programmes in response to significant changes in the Group's trading environment or overall strategy or following material acquisitions. Within the Pharmaceuticals sector, the highly regulated manufacturing operations and supply chains and long lifecycle of the business mean that restructuring programmes, particularly those that involve the rationalisation or closure of manufacturing or R&D sites are likely to take several years to complete. Costs, both cash and non-cash, of these programmes are provided for as individual elements are approved and meet the accounting recognition criteria. As a result, charges may be incurred over a number of years following the initiation of a Major restructuring programme.

Significant legal charges and expenses are those arising from the settlement of litigation or government investigations that are not in the normal course and materially larger than more regularly occurring individual matters. They also include certain major legacy matters.

### Press release

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GSK

Reconciliations between Total and Adjusted results, providing further information on the key Adjusting items, are set out on pages 18 and 19.

GSK provides earnings guidance to the investor community on the basis of Adjusted results. This is in line with peer companies and expectations of the investor community, supporting easier comparison of the Group's performance with its peers. GSK is not able to give guidance for Total results as it cannot reliably forecast certain material elements of the Total results, particularly the future fair value movements on contingent consideration and put options that can and have given rise to significant adjustments driven by external factors such as currency and other movements in capital markets.

### ViiV Healthcare

ViiV Healthcare is a subsidiary of the Group and 100% of its operating results (turnover, operating profit, profit after tax) are included within the Group income statement.

Earnings are allocated to the three shareholders of ViiV Healthcare on the basis of their respective equity shareholdings (GSK 78.3%, Pfizer 11.7% and Shionogi 10%) and their entitlement to preferential dividends, which are determined by the performance of certain products that each shareholder contributed. As the relative performance of these products changes over time, the proportion of the overall earnings allocated to each shareholder also changes. In particular, the increasing proportion of sales of dolutegravir and cabotegravir-containing products has a favourable impact on the proportion of the preferential dividends that is allocated to GSK. Adjusting items are allocated to shareholders based on their equity interests. GSK was entitled to approximately 83% of the Total earnings and 82% of the Adjusted earnings of ViiV Healthcare for 2022.

As consideration for the acquisition of Shionogi's interest in the former Shionogi-ViiV Healthcare joint venture in 2012, Shionogi received the 10% equity stake in ViiV Healthcare and ViiV Healthcare also agreed to pay additional future cash consideration to Shionogi, contingent on the future sales performance of the products being developed by that joint venture, dolutegravir and cabotegravir. Under IFRS 3 'Business combinations', GSK was required to provide for the estimated fair value of this contingent consideration at the time of acquisition and is required to update the liability to the latest estimate of fair value at each subsequent period end. The liability for the contingent remeasurements are reflected within other operating income/(expense) and within Adjusting items in the income statement in each period.

Cash payments to settle the contingent consideration are made to Shionogi by ViiV Healthcare each quarter, based on the actual sales performance and other income of the relevant products in the previous quarter. These payments reduce the balance sheet liability and hence are not recorded in the income statement. The cash payments made to Shionogi by ViiV Healthcare in Q1 2023 were £287 million.

As the liability is required to be recorded at the fair value of estimated future payments, there is a significant timing difference between the charges that are recorded in the Total income statement to reflect movements in the fair value of the liability and the actual cash payments made to settle the liability.

Further explanation of the acquisition-related arrangements with ViiV Healthcare are set out on pages 71 and 72 of the Annual Report 2022.

Press release

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## Adjusting items

The reconciliations between Total results and Adjusted results for Q1 2023 and Q1 2022 are set out below.

### Three months ended 31 March 2023

	Total results £m	Intangible amort- isation £m	Intangible impair- ment £m	Major restruct- uring £m	Trans- action- related £m	Divest- ments, significant legal and other items £m	Adjusted results £m
Turnover Cost of sales	<b>6,951</b> (1,943)	151		35		5	<b>6,951</b> (1,752)
Gross profit	5,008	151		35		5	5,199
Selling, general and administration Research and development Royalty income Other operating income/(expense)	(2,143) (1,260) 180 297	18	16	69 4	(271)	9 (26)	(2,065) (1,222) 180
Operating profit	2,082	169	16	108	(271)	(12)	2,092
Net finance cost Share of after tax profit/(loss) of associates and joint venture	(174) (2)					4	(170) (2)
Profit/(loss) on disposal of interest in associates	(2)					(1)	(2)
Profit before taxation	1,907	169	16	108	(271)	(9)	1,920
Taxation <i>Tax rate %</i>	(276) 14.5%	(36)	(4)	(22)	15	20	(303) 15.8%
Profit after taxation from continuing operations	1,631	133	12	86	(256)	11	1,617
Profit attributable to non-controlling interests from continuing operations	141	-	-	-	(20)	-	121
Profit attributable to shareholders from	4 400	400	40	96	(000)		4 400
continuing operations	1,490	133	<u> </u>	86	(236)	11	1,496
<b>_</b>	1,631	133		86	(256)		1,617
Earnings per share from continuing operations	36.8p	3.3p	0.3p	2.1p	(5.8)p	0.3p	37.0p
Weighted average number of shares (millions)	4,044						4,044

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### Three months ended 31 March 2022<sup>(a)</sup>

	Total results £m	Profit from discon- tinued operations £m	Intangible amort- isation £m	Intangible impair- ment £m	Major restruct- uring £m	Trans- action- related £m	Divest- ments, significant legal and other items £m	Adjusted results £m
Turnover Cost of sales	<b>7,190</b> (2,717)		163		15	12		<b>7,190</b> (2,527)
Gross profit	4,473		163		15	12		4,663
Selling, general and administration Research and development Royalty income Other operating income/(expense)	(1,812) (1,103) 138 597		23	(16)	28 8	335	14 (932)	(1,770) (1,088) 138
Operating profit	2,293		186	(16)	51	347	(918)	1,943
Net finance cost Share of after tax profit/(loss) of	(198)							(198)
associates and joint venture Profit before taxation	<u> </u>		186	(16)	51	347	(918)	<u> </u>
Taxation Tax rate %	(323) 15.4%		(39)	3	(12)	(53)	137	(287) 16.5%
Profit after taxation from continuing operations	1,771		147	(13)	39	294	(781)	1,457
Profit after taxation from discontinued operations and other gains/(losses) from the demerger	396	(396)						
Profit after taxation from discontinued operations	396	(396)						
Total profit after taxation for the period	2,167	(396)	147	(13)	39	294	(781)	1,457
Profit attributable to non-controlling interest from continuing operations	275					(114)		161
Profit attributable to shareholders from continuing operations	1,496		147	(13)	39	408	(781)	1,296
Profit attributable to non-controlling interest from discontinued operations	90	(90)						-
Profit attributable to shareholders		(00)						
from discontinued operations	306	(306)						
	2,167	(396)	147	(13)	39	294	(781)	1,457
Total profit attributable to non-controlling interests	365	(90)				(114)		161
Total profit attributable to shareholders	1,802	(306)	147	(13)	<u> </u>	408	(781)	1,296
Earnings par abore from continuing	2,167	(396)	147	(13)	39	294	(781)	1,457
Earnings per share from continuing operations	37.3p		3.7p	(0.3)p	1.0p	10.2p	(19.6)p	32.3p
Earnings per share from discontinued operations	7.6p	(7.6)p						
Total earnings per share	44.9p	(7.6)p	3.7p	(0.3)p	1.0p	10.2p	(19.6)p	32.3p
Weighted average number of shares (millions)	4,016							4,016

(a) The Q1 2022 comparative results have been restated on a consistent basis from those previously published to reflect the demerger of the Consumer Healthcare business (see page 33) and the impact of Share Consolidation implemented on 18 July 2022 (see page 33).

Results Summary	Research and development	ESG	Total and Adjusted results	Financial information	Auditor's review report

#### Press release

## First quarter 2023



### Major restructuring and integration

Total Major restructuring charges from continuing operations incurred in Q1 2023 were £108 million (Q1 2022: £51 million), analysed as follows:

			Q1 2023			Q1 2022
	Cash £m	Non- cash £m	Total £m	Cash £m	Non- cash £m	Total £m
Separation Preparation restructuring programme	37	47	84	11	37	48
Significant acquisitions	21	1	22	-	-	-
Legacy programmes		2	2	2	1	3
	58	50	108	13	38	51

The Separation Preparation programme incurred cash charges of £37 million primarily from the restructuring of some administrative functions as well as Global Supply Chain and R&D. The non-cash charges of £47 million primarily reflected the write-down of assets in administrative as well as manufacturing locations.

The benefit in Q1 2023 from restructuring programmes was £0.1 billion, primarily relating to the Separation Preparation restructuring programme. The programme has delivered £0.9 billion of annual savings to date and targets to deliver £1.0 billion by 2023, with total costs estimated at £2.4 billion, of which £1.6 billion is expected to be cash costs.

Costs of significant acquisitions relate to integration costs of Sierra Oncology Inc. (Sierra) and Affinivax which were acquired in Q3 2022.

### **Transaction-related adjustments**

Transaction-related adjustments from continuing operations resulted in a net credit of £271 million (Q1 2022: £347 million charge) all of which related to accounting (credits)/charge for the remeasurement of contingent consideration liabilities and the liabilities for the Pfizer put option and Pfizer and Shionogi preferential dividends in ViiV Healthcare.

Charge/(credit)	Q1 2023 £m	Q1 2022 £m
Contingent consideration on former Shionogi-ViiV Healthcare joint Venture (including Shionogi preferential dividends) ViiV Healthcare put options and Pfizer preferential dividends Contingent consideration on former Novartis Vaccines business Contingent consideration on acquisition of Affinivax Other adjustments	(64) (105) (69) (33)	256 32 44 - 15
Total transaction-related charges	(271)	347

The £64 million credit relating to the contingent consideration for the former Shionogi-ViiV Healthcare joint venture represented a reduction in the valuation of the contingent consideration due to Shionogi, as a result of a credit of £172 million primarily from exchange rates as well as sales forecasts, partly offset by the unwind of the discount for £108 million. The £105 million credit relating to the ViiV Healthcare put option and Pfizer preferential dividends represented a reduction in the valuation of the put option primarily as a result of updated exchange rates as well as updated sales forecasts and lower cash balances.

The ViiV Healthcare contingent consideration liability is fair valued under IFRS. An explanation of the accounting for the non-controlling interests in ViiV Healthcare is set out on page 17.

The £69 million credit relating to the contingent consideration on the former Novartis Vaccines business primarily relates to changes to future sales forecasts.

### Divestments, significant legal charges, and other items

Divestments, significant legal charges and other items primarily included dividend and distribution income received from investments partly offset by fair value loss of £65 million on the retained stake in Haleon.

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### Press release

# First quarter 2023

## **Financial information**

### **Income statements**

	Q1 2023 £m	Q1 2022 <sup>(a)</sup> £m
TURNOVER	6,951	7,190
Cost of sales	(1,943)	(2,717)
Gross profit	5,008	4,473
Selling, general and administration Research and development Royalty income Other operating income/(expense)	(2,143) (1,260) 180 297	(1,812) (1,103) 138 597
	2,082	2,293
Finance income Finance expense Share of after tax profit/(loss) of associates and joint ventures Profit/(loss) on disposal of interests in associates	29 (203) (2) 1	7 (205) (1)
PROFIT BEFORE TAXATION	1,907	2,094
Taxation	(276)	(323)
Tax rate %	14.5%	15.4%
PROFIT AFTER TAXATION FROM CONTINUING OPERATIONS	1,631	1,771
Profit after taxation from discontinued operations and other gains from the demerger PROFIT AFTER TAXATION FROM DISCONTINUED		396
OPERATIONS	-	396
PROFIT AFTER TAXATION FOR THE PERIOD	1,631	2,167
Profit attributable to non-controlling interests from continuing operations	141	275
Profit attributable to shareholders from continuing operations	1,490	1,496
Profit attributable to non-controlling interests from discontinued operations	-	90
Profit attributable to shareholders from discontinued operations	-	306
	1,631	2,167
Profit attributable to non-controlling interests	141	365
Profit attributable to shareholders	1,490	1,802
	1,631	2,167
EARNINGS PER SHARE FROM CONTINUING OPERATIONS	36.8p	37.3p
EARNINGS PER SHARE FROM DISCONTINUED OPERATIONS	-	7.6p
TOTAL EARNINGS PER SHARE	36.8p	44.9p
Diluted earnings per share from continuing operations	36.5p	36.9p
Diluted earnings per share from discontinued operations	-	7.5p
Total diluted earnings per share	36.5p	44.4p

(a) The Q1 2022 comparative results have been restated on a consistent basis from those previously published to reflect the demerger of the Consumer Healthcare business (see page 33) and the impact of Share Consolidation implemented on 18 July 2022 (see page 33).

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### Press release

# First quarter 2023

## Statement of comprehensive income

	Q1 2023 £m	Q1 2022 <sup>(a)</sup> £m
Total profit for the period	1,631	2,167
Items that may be reclassified subsequently to continuing operations income statement:		
Exchange movements on overseas net assets and net investment hedges Reclassification of exchange movements on liquidation or disposal	87	(19)
of overseas subsidiaries and associates Fair value movements on cash flow hedges	(3)	- 2
Reclassification of cash flow hedges to income statement	1	(1)
	85	(18)
Items that will not be reclassified to continuing operations income statement:		
Exchange movements on overseas net assets of non-controlling interests	(14)	3
Fair value movements on equity investments Tax on fair value movements on equity investments	(168) 22	(543) 47
Remeasurement gains/(losses) on defined benefit plans Tax on remeasurement losses/(gains) on defined benefit plans	350 (87)	313 (73)
	103	(253)
Other comprehensive expense for the period from continuing operations	188	(271)
Other comprehensive income for the period from discontinued operations	<u> </u>	435
Total comprehensive income for the period	1,819	2,331
Total comprehensive income for the period attributable to:		
Shareholders Non-controlling interests	1,692 127	1,962 369
	1,819	2,331

(a) The Q1 2022 comparative results have been restated on a consistent basis from those previously published to reflect the demerger of the Consumer Healthcare business (see page 33).

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### Press release

# First quarter 2023

## Balance sheet

	31 March 2023	31 December 2022
	£m	£m
ASSETS		
Non-current assets	0.750	0.000
Property, plant and equipment	8,758	8,933
Right of use assets Goodwill	656 6,857	687 7 046
Other intangible assets	14,160	7,046 14,318
Investments in associates and joint ventures	70	74
Other investments	1,270	1,467
Deferred tax assets	5,610	5,658
Other non-current assets	1,496	1,194
Total non-current assets	38,877	39,377
Current assets Inventories	5 255	E 1/6
Current tax recoverable	5,355 296	5,146 405
Trade and other receivables	6,833	7,053
Derivative financial instruments	125	190
Current equity investments	4,020	4,087
Liquid investments	65	67
Cash and cash equivalents	2,890	3,723
Assets held for sale	135	98
Total current assets	19,719	20,769
TOTAL ASSETS	58,596	60,146
LIABILITIES		
Current liabilities		
Short-term borrowings	(4,261)	(3,952)
Contingent consideration liabilities	(962)	(1,289)
Trade and other payables	(14,268)	(16,263)
Derivative financial instruments	(98)	(183)
Current tax payable	(424)	(471)
Short-term provisions	(683)	(652)
Total current liabilities	(20,696)	(22,810)
Non-current liabilities		
Long-term borrowings	(16,644)	(17,035)
Corporation tax payable	(123)	(127)
Deferred tax liabilities	(290)	(289)
Pensions and other post-employment benefits	(2,480)	(2,579)
Other provisions	(537)	(532)
Contingent consideration liabilities	(5,622)	(5,779)
Other non-current liabilities	(892)	(899)
Total non-current liabilities	(26,588)	(27,240)
TOTAL LIABILITIES	(47,284)	(50,050)
NET ASSETS	11,312	10,096
EQUITY		
Share capital	1,348	1,347
Share premium account	3,449	3,440
Retained earnings	5,655	4,363
Other reserves	1,368	1,448
Shareholders' equity	11,820	10,598
Non-controlling interests	(508)	(502)
TOTAL EQUITY	11,312	10,096
	;	

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### Press release

# First quarter 2023

## Statement of changes in equity

_	Share capital £m	Share premium £m	Retained earnings £m	Other reserves £m	Share- holder's equity £m	Non- controlling interests £m	Total equity £m
At 1 January 2023	1,347	3,440	4,363	1,448	10,598	(502)	10,096
Profit for the period			1,490		1,490	141	1,631
Other comprehensive income/(expense) for the period			336	(134)	202	(14)	188
Total comprehensive income/(expense) for the period			1,826	(134)	1,692	127	1,819
Distributions to non-controlling interests Contributions from non-controlling						(140)	(140)
interests						7	7
Dividends to shareholders Realised after tax losses on disposal			(555)		(555)		(555)
or liquidation of equity investments Share of associates and joint ventures			(13)	13			-
realised profit/(loss) on disposal of equity investments			2	(2)			-
Shares issued Write-down on shares held by ESOP	1	7			8		8
Trusts			(48)	48			-
Shares acquired by ESOP Trusts		2	1	(3)	70		-
Share-based incentive plans Hedging gain/loss after taxation			79		79		79
transferred to non-financial assets				(2)	(2)		(2)
At 31 March 2023	1,348	3,449	5,655	1,368	11,820	(508)	11,312
At 1 January 2022	1,347	3,301	7,944	2,463	15,055	6,287	21,342
Profit for the period			1,802		1,802	365	2,167
Other comprehensive income/(expense) for the period			507	(347)	160	4	164
Total comprehensive income/(expense) for the period			2,309	(347)	1,962	369	2,331
Distributions to non-controlling interests Contributions from non-controlling						(213)	(213)
interests						8	8
Dividends to shareholders Realised after tax losses on disposal			(952)		(952)		(952)
of equity investments			(10)	10			-
Shares issued Write-down on shares held by ESOP		17			17		17
Trusts			(457)	457			-
Shares acquired by ESOP Trusts Share-based incentive plans		118	704 99	(822)	99		- 99
At 31 March 2022	1,347	3,436	9,637	1,761	16,181	6,451	22,632
-	.,			.,			,

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### Press release

# First quarter 2023

## Cash flow statement – three months ended 31 March 2023

	Q1 2023	Q1 2022 <sup>(a)</sup>
Profit after tax from continuing operations	<u> </u>	<u>£m</u> 1,771
Tax on profits	276	323
Share of after tax loss/(profit) of associates and joint ventures	2	1
(Profit)/loss on disposal of interest in associates and joint ventures	(1)	-
Net finance expense	174	198
Depreciation, amortisation and other adjusting items Decrease/(Increase) in working capital	640 (840)	418 (479)
Contingent consideration paid	(290)	(185)
Increase/(decrease) in other net liabilities (excluding contingent consideration paid)	(1,305)	305
Cash generated from operations attributable to continuing operations	287	2,352
Taxation paid	(234)	(146)
Net cash inflow/(outflow) from continuing operating activities	53	2,206
Cash generated from operations attributable to discontinued operations	-	403
Taxation paid from discontinued operations		(67)
Net operating cash flows attributable to discontinued operations	<u> </u>	336
Total net cash inflows/(outflows) from operating activities	53	2,542
Cash flow from investing activities	(222)	(100)
Purchase of property, plant and equipment	(233)	(193)
Proceeds from sale of property, plant and equipment Purchase of intangible assets	7 (296)	6 (377)
Proceeds from sale of intangible assets	(200)	(377)
Purchase of equity investments	(56)	(45)
Proceeds from sale of equity investments	10	-
Contingent consideration paid	(1)	(26)
Disposal of businesses	(6)	1
Interest received Proceeds from disposal of associates and joint ventures	29 1	8
Dividend and distributions from investments	132	-
Dividends from associates and joint ventures	1	-
Net cash inflow/(outflow) from continuing investing activities	(408)	(621)
Net investing cash flows attributable to discontinued operations	<u>-</u>	(2,972)
Total net cash inflow/(outflow) from investing activities	(408)	(3,593)
Cash flow from financing activities		
Issue of share capital	8	17
Decrease in long-term loans	(144)	-
Net increase/(repayment) of short-term loans	552	(249)
Repayment of lease liabilities Interest paid	(47) (120)	(51) (82)
Dividends paid to shareholders	(555)	(952)
Shares acquired by ESOP Trusts	(2)	(7)
Distribution to non-controlling interests	(140)	(78)
Contributions from non-controlling interests	7	8
Other financing items	123	91
Net cash inflow/(outflow) from continuing financing activities	(318)	(1,303)
Net financing cash flows attributable to discontinued operations	- (240)	9,276
Total net cash inflow/(outflow) from financing activities	(318)	7,973
Increase/(decrease) in cash and bank overdrafts in the period	(673)	6,922
Cash and bank overdrafts at beginning of the period Exchange adjustments	3,425 (31)	3,817 12
Increase/(decrease) in cash and bank overdrafts	(673)	6,922
Cash and bank overdrafts at end of the period	2,721	10,751
Cash and bank overdrafts at end of the period comprise:		
Cash and cash equivalents	2,890	10,967
Overdrafts	(169)	(216)
	2,721	10,751

(a) The Q1 2022 comparative results have been restated on a consistent basis from those previously published to reflect the demerger of the Consumer Healthcare business (see page 33).

Press release

# First quarter 2023



## Vaccines turnover – three months ended 31 March 2023

			Total			US			Europe		Inte	rnational
			Growth			Growth			Growth			Growth
	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%
Shingles	833	19	11	508	4	(5)	214	34	27	111	>100	>100
Shingrix	833	19	11	508	4	(5)	214	34	27	111	>100	>100
Meningitis	280	32	25	119	20	10	115	39	33	46	53	50
Bexsero	218	34	26	74	12	3	110	39	34	34	89	78
Menveo	59	40	31	45	36	24	4	33	-	10	67	83
Other	3	(57)	(57)	-	-	-	1	-	-	2	(67)	(67)
Influenza	12	(33)	(28)	1						11	(35)	(29)
Fluarix, FluLaval	12	(33)	(28)	1	-	-	-	-	-	11	(35)	(29)
Established Vaccines	815	10	4	353	17	7_	193	16	12	269	(1)	(4)
Infanrix, Pediarix	177	1	(5)	108	(4)	(12)	33	14	14	36	6	-
Boostrix	139	10	3	92	31	20	31	(6)	(9)	16	(30)	(30)
Hepatitis	170	39	31	98	26	15	46	59	52 <sup>´</sup>	26	<b>7</b> 3	<b>`</b> 73 <sup>´</sup>
Rotarix	138	18	14	47	34	23	33	3	-	58	16	16
Synflorix	62	(23)	(26)	-	-	-	8	33	33	54	(28)	(31)
Priorix, Priorix Tetra,												
Varilrix	53	13	9	2	-	-	33	18	7	18	(5)	-
Cervarix	27	(7)	(7)	-	-	-	9	>100	>100	18	(28)	(24)
Other	49	11		6	(14)	(43)		(100)	(80)	43	34	22
Vaccines excluding												
COVID-19 solutions	1,940	16	9	981	10	1	522	28	22	437	19	17
Pandemic vaccines	101	100	100	-	-	-	101	100	100	-	-	-
Pandemic adjuvant	101	100	100				101	100	100			_
Vaccines	2,041	22	15	981	10	1	623	52	45	437	19	17

## Specialty Medicines turnover – three months ended 31 March 2023

1			Total			US			Europe		Inte	ernational
-			Growth			Growth			Growth			Growth
<u> </u>	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%
HIV	1,468	24	15	917	32	20	346	16	11	205	11	5
Dolutegravir products	1,277	16	8	760	19	8	319	11	7	198	14	7
Tivicay	357	12	3	185	16	6	66	2	(2)	106	12	-
Triumeq	374	(5)	(11)	249	2	(7)	75	(20)	(23)	50	(6)	(8)
Juluca	150	13	5	111	12	3	35	17	10	4	-	-
Dovato	396	54	44	215	57	43	143	46	40	38	73	73
Rukobia	25	56	44	23	53	40	2	100	100	-	-	-
Cabenuva	127	>100	>100	103	>100	>100	20	>100	>100	4	>100	>100
Apretude	24	>100	>100	24	>100	>100	-	-	-	-	-	-
Other	15	(35)	(35)	7	-	(14)	5	-	(20)	3	(73)	(55)
Immunology/												
Respiratory and Other	601	16	9	393	13	4	108	29	23	100	12	15
Benlysta	253	18	9	204	20	10	23	21	16	26	-	-
Nucala	347	18	11	189	7	(2)	89	37	31	69	30	32
Other	1	(90)	(80)	-	-	-	(4)	-	-	5	(50)	(40)
Oncology	136	7	2	55	(20)	(28)	72	33	28	9	>100	>100
Zejula	114	16	10	50	(2)	(10)	55	28	21	9	>100	>100
Blenrep	11	(56)	(56)	-	(100)	(100)	11	22	22	-	-	-
Jemperli	11	>100	>100	5	>100	>100	5	>100	>100	1	>100	>100
Other	-						1			(1)		
Specialty Medicines excluding COVID-19												
solutions	2,205	21	13	1,365	23	12	526	20	15	314	13	10
Pandemic	31	(98)	(98)		(100)	(100)		(100)	(100)	31	(86)	(87)
Xevudy	31	(98)	(98)		(100)	(100)		(100)	(100)	31	(86)	(87)
Specialty Medicines	2,236	(29)	(33)	1,365	(28)	(34)	526	(30)	(33)	345	(32)	(34)

### Press release

# First quarter 2023



### General Medicines turnover – three months ended 31 March 2023

			Total			US			Europe	International		
			Growth			Growth			Growth			Growth
	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%
Respiratory	1,767	15	10	832	15	5	372	12	8	563	17	18
Arnuity Ellipta	8	(38)	(38)	6	(45)	(45)	-	-	-	2	-	-
Anoro Ellipta	120	22	<b>`</b> 16	51	24	Ì15	46	21	18	23	21	16
Avamys/Veramyst	124	32	31	-	-	-	18	12	6	106	36	36
Flixotide/Flovent	157	24	16	106	25	14	21	17	11	30	25	25
Incruse Ellipta	35	(30)	(34)	13	(50)	(54)	16	-	(6)	6	(25)	(25)
Relvar/Breo Ellipta	274	-	(5)	100	(17)	(23)	98	18	13	76	6	6
Seretide/Advair	339	12	<b>`</b> 8	120	`43 <sup>´</sup>	<b>`</b> 30	71	(3)	(7)	148	2	2
Trelegy Ellipta	465	37	28	327	37	26	67	26	23	71	45	47
Ventolin	205	2	(3)	108	(8)	(15)	28	(7)	(10)	69	28	28
Other Respiratory	40	14	17	1	-	-	7	17	17	32	10	17
Other General Medicines	907	7	7	92	3	(6)	183	8	4	632	7	10
Dermatology	97	5	8	-	-	-	28	4	-	69	6	11
Augmentin	177	37	38	-	-	-	56	56	50	121	30	33
Avodart	92	14	9	-	-	-	29	7	4	63	17	11
Lamictal	129	8	2	66	12	2	28	8	8	35	-	(3)
Other	412	(4)	-	26	(13)	(20)	42	(22)	(28)	344	-	6
General Medicines	2,674	12	9	924	14	4	555	10	6	1,195	11	14

## Commercial Operations turnover – three months ended 31 March 2023

	Total		US			Europe			International			
		Growth		Growth		Growth				Growth		
	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%
Three months ended 31 March 2023	6,951	(3)	(8)	3,270	(9)	(17)	1,704	3	(2)	1,977	2	2

## Commercial Operations turnover excluding COVID-19 solutions

		Total			US			Europe			International		
		Growth		Growth		Growth		Growth	G		Growth		
	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%	£m	£%	CER%	
Three months ended 31 March 2023	6,819	16	10	3,270	16	6	1,603	19	14	1,946	13	14	

### Press release

# First quarter 2023



## Segment information

Operating segments are reported based on the financial information provided to the Chief Executive Officer and the responsibilities of the GSK Leadership Team (GLT). GSK reports results under two segments: Commercial Operations and Total R&D. Members of the GLT are responsible for each segment. The Consumer Healthcare segment is presented as discontinued operations in Q1 2022 for comparative purposes and therefore no segment information is presented.

R&D investment is essential for the sustainability of the business. However, for segment reporting the Commercial operating profits exclude allocations of globally funded R&D.

The Total R&D segment is the responsibility of the Chief Scientific Officer and is reported as a separate segment. The operating costs of this segment includes R&D activities across Specialty Medicines, including HIV and Vaccines. It includes R&D and some SG&A costs relating to regulatory and other functions.

The Group's management reporting process allocates intra-Group profit on a product sale to the market in which that sale is recorded, and the profit analyses below have been presented on that basis.

## Turnover by segment

	Q1 2023	Q1 2022 <sup>(a)</sup>	Growth	Growth
	£m	£m	£%	CER%
Commercial Operations (total turnover)	6,951	7,190	(3)	(8)

### Operating profit by segment

	Q1 2023 £m	Q1 2022 £m	Growth £%	Growth CER%
Commercial Operations Research and Development	3,375 (1,232)	3,117 (1,095)	8 13	1 6
Segment profit Corporate and other unallocated costs	2,143 (51)	2,022 (79)	6	(2)
Adjusted operating profit Adjusting items	2,092 (10)	1,943 350	8	-
Total operating profit	2,082	2,293	(9)	(15)
Finance income Finance costs Share of after tax profit/(loss) of associates	29 (203)	7 (205)		
and joint ventures Profit on disposal of associates and joint ventures	(2) 1	(1)		
Profit before taxation from continuing operations	1,907	2,094	(9)	(15)

(a) The Q1 2022 comparative results have been restated on a consistent basis from those previously published to reflect the demerger of the Consumer Healthcare business (see page 33).

### Press release

# First quarter 2023



### Legal matters

The Group is involved in significant legal and administrative proceedings, principally product liability, intellectual property, tax, anti-trust, consumer fraud and governmental investigations, which are more fully described in the 'Legal Proceedings' note in the Annual Report 2022. At 31 March 2023, the Group's aggregate provision for legal and other disputes (not including tax matters described on page 9) was £0.3 billion (31 December 2022: £0.2 billion).

The Group may become involved in significant legal proceedings in respect of which it is not possible to meaningfully assess whether the outcome will result in a probable outflow, or to quantify or reliably estimate the liability, if any, that could result from ultimate resolution of the proceedings. In these cases, the Group would provide appropriate disclosures about such cases, but no provision would be made.

The ultimate liability for legal claims may vary from the amounts provided and is dependent upon the outcome of litigation proceedings, investigations and possible settlement negotiations. The Group's position could change over time, and, therefore, there can be no assurance that any losses that result from the outcome of any legal proceedings will not exceed by a material amount the amount of the provisions reported in the Group's financial accounts.

Significant legal developments since the date of the Annual Report 2022:

### **Intellectual Property**

#### Coreg

On 29 March 2023, the US Solicitor General filed a brief with the US Supreme Court expressing the view that Teva's petition for certiorari should be granted. GSK filed a reply to the US Solicitor General's brief on 11 April 2023, again arguing that Teva's petition for certiorari be denied.

### Tivicay

In September 2021, ViiV Healthcare received a paragraph IV letter from Lupin Ltd. (Lupin) relating to the *Tivicay* 5mg dosage for oral suspension, challenging only the crystal form patent. On 2 November 2021, ViiV Healthcare filed suit against Lupin in the US District Court for the District of Delaware. In March 2023, the parties reached a settlement, thereby concluding the matter.

### Juluca

On 12 June 2020, ViiV Healthcare received a paragraph IV letter from Cipla Ltd. (Cipla) relating to *Juluca*. On 22 July 2020, ViiV Healthcare filed suit against Cipla in the US District Court for the District of Delaware. In March 2023, the parties reached a settlement, thereby concluding the matter.

### Product Liability

### <u>Zantac</u>

On 23 March 2023, the court presiding over the California *Zantac* litigation cases issued a Sargon ruling in the first case scheduled for trial (*Goetz*). The court found that the plaintiff's experts' causation opinions are admissible and can be presented to a jury. This ruling does not mean that the Court agrees with plaintiff's experts' scientific conclusions as plaintiff must still prove his case at trial. The ruling applies only to the *Goetz* case and does not affect any other state cases or the December 2022 MDL Daubert ruling. The *Goetz* trial is scheduled to begin on 24 July 2023.

Two cases have been set for trial in 2024 in the Cook County, Illinois proceedings.

GSK will continue to defend itself vigorously against all claims.

### Sales and marketing and regulation

### US electronic health records subpoena

On 19 March 2023, the Group received a subpoena from the United States Attorney's Office for the Western District of Virginia, which is working with the United States Department of Justice Civil Division, seeking documents relating to the Group's electronic health record programmes. The Group is cooperating with this enquiry.

### Commercial and corporate

### Zejula Royalty Dispute

Trial was held the week of 6 March 2023 and judgment was entered against the Group on 5 April 2023. The Court upheld AstraZeneca's interpretation that all current uses of *Zejula* generate royalty-bearing sales under the wording of the two license agreements. Accordingly, GSK will owe back royalties to AstraZeneca in an amount to be determined in a separate phase of the proceedings. The Group will also be responsible for paying on this same basis going forward. The Group is considering an appeal.

### Press release

## First quarter 2023

## **Returns to shareholders**

### **Quarterly dividends**

The Board has declared a first interim dividend for Q1 2023 of 14p per share (Q1 2022: 17.50p<sup>(1)</sup> per share retrospectively adjusted for the Share Consolidation).

Dividends remain an essential component of total shareholder return and GSK recognises the importance of dividends to shareholders. On 23 June 2021, at the GSK Investor Update, GSK set out that from 2022 a progressive dividend policy will be implemented guided by a 40 to 60 percent pay-out ratio through the investment cycle. The dividend policy, the total expected cash distribution, and the respective dividend pay-out ratios for GSK remain unchanged. GSK expects to declare a dividend of 56.5p per share for 2023.

#### Payment of dividends

The equivalent interim dividend receivable by ADR holders will be calculated based on the exchange rate on 11 July 2023. An annual fee of \$0.03 per ADS (or \$0.0075 per ADS per quarter) is charged by the Depositary. The exdividend date will be 18 May 2023, with a record date of 19 May 2023 and a payment date of 13 July 2023.

	Paid/ Payable	Pence per share/ pre share consolidation	Pence per share/ post share consolidation	£m
<b>2023</b> First interim	13 July 2023	-	14	567
2022 First interim	1 July 2022	14	17.50	704
Second interim	6 October 2022	13	16.25	654
Third interim	12 January 2023	11	13.75	555
Fourth interim	13 April 2023	11	13.75	557
		49	61.25	2,470

(1) Adjusted for the Share Consolidation on 18 July 2022. For details of the Share Consolidation see page 33.

### Weighted average number of shares

	Q1 2023 millions	Q1 2022 millions <sup>(a)</sup>
Weighted average number of shares – basic Dilutive effect of share options and share awards	4,044 41	4,016 50
Weighted average number of shares – diluted	4,085	4,066

(a) See page 33 for details of the Share Consolidation.

At 31 March 2023, 4,052 million shares (Q1 2022: 4,024 million) were in free issue (excluding Treasury shares and shares held by the ESOP Trusts). No Treasury shares have been repurchased since 2014. The Company issued 0.7 million shares under employee share schemes in the period for proceeds of £8 million (Q1 2022: £17 million).

At 31 March 2023, the ESOP Trusts held 42.7 million GSK shares against the future exercise of share options and share awards. The carrying value of £293 million has been deducted from other reserves. The market value of these shares was £615 million.

At 31 March 2023, the Company held 217 million Treasury shares at a cost of £3,796 million which has been deducted from retained earnings.



### Press release

# First quarter 2023



## Additional information

### Disposal group and discontinued operations accounting policy

Disposal groups are classified as held for distribution if their carrying amount will be recovered principally through a distribution to shareholders rather than through continuing use, they are available for distribution in their present condition and the distribution is considered highly probable. They are measured at the lower of their carrying amount and fair value less costs to distribute.

Non-current assets included as part of a disposal group are not depreciated or amortised while they are classified as held for distribution. The assets and liabilities of a disposal group classified as held for distribution are presented separately from the other assets and liabilities in the balance sheet.

A discontinued operation is a component of the entity that has been disposed of or distributed or is classified as held for distribution and that represents a separate major line of business. The results of discontinued operations are presented separately in the statement of profit or loss and comparatives are restated on a consistent basis.

The Q1 2022 comparative figures have been restated on a consistent basis in the first quarter 2023 from those previously published to reflect the demerger of the Consumer Healthcare business in July 2022.

### Accounting policies and basis of preparation

This unaudited Results Announcement contains condensed financial information for the three months ended 31 March 2023 and should be read in conjunction with the Annual Report 2022, which was prepared in accordance with United Kingdom adopted International Financial Reporting Standards. This Results Announcement has been prepared applying consistent accounting policies to those applied by the Group in the Annual Report 2022.

The Group has not identified any changes to its key sources of accounting judgements or estimations of uncertainty compared with those disclosed in the Annual Report 2022.

This Results Announcement does not constitute statutory accounts of the Group within the meaning of sections 434(3) and 435(3) of the Companies Act 2006. The full Group accounts for 2022 were published in the Annual Report 2022, which has been delivered to the Registrar of Companies and on which the report of the independent auditor was unqualified and did not contain a statement under section 498 of the Companies Act 2006.

#### Exchange rates

GSK operates in many countries and earns revenues and incurs costs in many currencies. The results of the Group, as reported in Sterling, are affected by movements in exchange rates between Sterling and other currencies. Average exchange rates, as modified by specific transaction rates for large transactions, prevailing during the period, are used to translate the results and cash flows of overseas subsidiaries, associates and joint ventures into Sterling. Period-end rates are used to translate the net assets of those entities. The currencies which most influenced these translations and the relevant exchange rates were:

	Q1 2023	Q1 2022	2022
Average rates:			
US\$/£	1.22	1.34	1.24
Euro/£	1.14	1.19	1.17
Yen/£	162	156	161
Period-end rates:			
US\$/£	1.24	1.31	1.20
Euro/£	1.14	1.18	1.13
Yen/£	165	160	159

### Press release

# First quarter 2023



### Net assets

The book value of net assets increased by £1,216 million from £10,096 million at 31 December 2022 to £11,312 million at 31 March 2023. This primarily reflected contribution from Total comprehensive income for the period partly offset by dividend paid to shareholders.

At 31 March 2023, the net deficit on the Group's pension plans was £966 million compared with £1,355 million at 31 December 2022. This decrease in the net deficit is primarily driven by higher asset values in the UK.

The estimated present value of the potential redemption amount of the Pfizer put option related to ViiV Healthcare, recorded in Other payables in Current liabilities, was £988 million (31 December 2022: £1,093 million).

Contingent consideration amounted to £6,584 million at 31 March 2023 (31 December 2022: £7,068 million), of which £5,539 million (31 December 2022: £5,890 million) represented the estimated present value of amounts payable to Shionogi relating to ViiV Healthcare, £587 million (31 December 2022: £673 million) represented the estimated present value of contingent consideration payable to Novartis related to the Vaccines acquisition and £455 million (31 December 2022: £501 million) represented the estimated present value of contingent consideration payable to Affinivax.

Of the contingent consideration payable (on a post-tax basis) to Shionogi at 31 March 2023, £925 million (31 December 2022: £940 million) is expected to be paid within one year.

Movements in contingent consideration are as follows:

<u>Q1 2023</u>	ViiV Healthcare £m	Group £m
Contingent consideration at beginning of the period Remeasurement through income statement and other movements Cash payments: operating cash flows Cash payments: investing activities	5,890 (64) (287) -	7,068 (193) (290) (1)
Contingent consideration at end of the period	5,539	6,584
<u>Q1 2022</u>	ViiV Healthcare £m	Group £m
Contingent consideration at beginning of the period Remeasurement through income statement and other movements Cash payments: operating cash flows Cash payments: investing activities	5,559 256 (183) (25)	6,076 304 (185) (26)
Contingent consideration at end of the period	5,607	6,169

### **Contingent liabilities**

There were contingent liabilities at 31 March 2023 in respect of guarantees and indemnities entered into as part of the ordinary course of the Group's business. No material losses are expected to arise from such contingent liabilities. Provision is made for the outcome of legal and tax disputes where it is both probable that the Group will suffer an outflow of funds and it is possible to make a reliable estimate of that outflow. Descriptions of the significant legal disputes to which the Group is a party are set out on page 29 and on pages 265 to 267 of the 2022 Annual Report.

#### **Business acquisitions**

On 18 April 2023, GSK announced it had reached agreement to acquire late-stage biopharmaceutical company Bellus Health for US\$14.75 per share of common stock in cash representing an approximate total equity value of US \$2.0 billion (£1.6 billion). The acquisition provides GSK access to camlipixant, a potential best-in-class and highly selective P2X3 antagonist currently in phase III development for the first-line treatment of adult patients with refractory chronic cough (RCC). Under the terms of the agreement, the acquisition will be effected through a Plan of Arrangement pursuant to the Canada Business Corporations Act in which the shares of Bellus outstanding will be acquired by GSK in consideration of US\$14.75 per share in cash. Subject to customary conditions, including court approval, the approval of the acquisition by at least 66.67% of the votes cast at a meeting of Bellus' shareholders and a majority of the votes cast by non-interested shareholders at such meeting, and approval by the appropriate regulatory agencies, the transaction is expected to close in the third quarter of 2023 or earlier.

### Press release

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### **Discontinued operations**

Consumer Healthcare was presented as a discontinued operation from Q2 2022. The demerger of Consumer Healthcare was completed on 18 July 2022. Financial information relating to the operations of Consumer Healthcare for the period ended 31 March 2022 is set out below. In Q1 2023, the Q1 2022 comparative figures are restated on a consistent basis from the previously published figures. The Group Income Statement and Group Cash Flow Statement distinguish discontinued operations from continuing operations.

Total Results	Q1 2022 £m
Turnover Other income/(expense)	2,590 (2,086)
Profit before tax Taxation <i>Tax rate%</i>	504 (108) <u>21.4%</u>
Profit/(loss) after taxation from discontinued operations: Consumer Healthcare	396
Other gains/(losses) from the demerger Remeasurement of discontinued operations distributed to shareholders on demerger	-
Profit after taxation from discontinued operations	396
Non-controlling interest in discontinued operations Earnings attributable to shareholders from discontinued operations	90 306
Earnings per share from discontinued operations	7.6p

### Share Consolidation

Following completion of the Consumer Healthcare business demerger on 18 July 2022, GSK plc Ordinary shares were consolidated to maintain share price comparability before and after demerger. The consolidation was approved by GSK shareholders at a General Meeting held on 6 July 2022. Shareholders received 4 new Ordinary shares with a nominal value of 31<sup>1</sup>/<sub>4</sub> pence each for every 5 existing Ordinary shares which had a nominal value of 25 pence each. Earnings per share, diluted earnings per share, adjusted earnings per share and dividends per share were retrospectively adjusted to reflect the Share Consolidation in all the periods presented.

### **Related party transactions**

Details of GSK's related party transactions are disclosed on page 236 of our 2022 Annual Report.

Issued: Wednesday, 26 April 2023, London, U.K.

### Press release

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## Reconciliation of cash flow to movements in net debt

	Q1 2023 £m	Q1 2022 £m
Total Net debt at beginning of the period	(17,197)	(19,838)
Increase/(decrease) in cash and bank overdrafts Net decrease/(increase) in short-term loans Net decrease/(increase) in long-term loans Repayment of lease liabilities	(673) (552) 144 47	282 249 - 51
Exchange adjustments Other non-cash movements	322 (41)	(356) (52)
Decrease/(increase) in net debt from continuing operations Decrease/(increase) in net debt from discontinued operations	(753)	174 313
Total Net debt at end of the period	(17,950)	(19,351)

### Net debt analysis

	31 March 2023 £m	31 December 2022 £m
Liquid investments	65	67
Cash and cash equivalents	2,890	3,723
Short-term borrowings Long-term borrowings	(4,261) (16,644)	(3,952) (17,035)
Total Net debt at the end of the period	(17,950)	(17,197)

## Free cash flow reconciliation from continuing operations

	Q1 2023 £m	Q1 2022 £m
Net cash inflow/(outflow) from continuing operating activities	53	2,206
Purchase of property, plant and equipment	(233)	(193)
Proceeds from sale of property, plant and equipment	7	6
Purchase of intangible assets	(296)	(377)
Proceeds from disposals of intangible assets	4	5
Net finance costs	(91)	(74)
Dividends from joint ventures and associates	1	-
Contingent consideration paid (reported in investing activities)	(1)	(26)
Distributions to non-controlling interests	(140)	(78)
Contributions from non-controlling interests	7	8
Free cash inflow from continuing operations	(689)	1,477

### Press release

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## **R&D commentary**

## **Pipeline overview**

Medicines and vaccines in phase III development (including major lifecycle innovation or under regulatory review)	17	<ul> <li>Infectious Diseases (7)         <ul> <li>RSV older adult vaccine candidate</li> <li>SKYCovione (SK) COVID-19</li> <li>gepotidacin (bacterial topoisomerase inhibitor) uncomplicated urinary tract infection and urogenital gonorrhoea</li> <li>bepirovirsen (HBV ASO) hepatitis B virus</li> <li><i>Bexsero</i> infants vaccine (US)</li> <li>MenABCWY (gen 1) vaccine candidate</li> <li>tebipenem pivoxil (antibacterial carbapenem) complicated urinary tract infection</li> </ul> </li> <li>Immunology/Respiratory (3)         <ul> <li>Nucala chronic obstructive pulmonary disease</li> <li>depemokimab (long acting anti-IL5) severe eosinophilic asthma, eosinophilic granulomatosis with polyangiitis, chronic rhinosinusitis with nasal polyps, hyper-eosinophilic syndrome</li> <li>latozinemab (AL001, anti-sortilin) frontotemporal dementia</li> </ul> </li> <li>Oncology (5)         <ul> <li>momelotinib (JAK1, JAK2 and ACVR1 inhibitor) myclofibracis with appomia</li> </ul> </li> </ul>
		<ul> <li>myelofibrosis with anaemia</li> <li><i>Blenrep</i> (anti-BCMA ADC) multiple myeloma</li> <li><i>Jemperli</i> (anti-PD-1) 1L endometrial cancer</li> </ul>
		<ul> <li>Zejula (PARP inhibitor) 1L ovarian, and lung cancer</li> <li>cobolimab (anti-TIM-3) non-small cell lung cancer</li> </ul>
		<ul> <li>Opportunity driven (2)</li> <li>Jesduvroq (HIF-PHI) anaemia of chronic kidney disease</li> <li>linerixibat (IBATi) cholestatic pruritus in primary biliary cholangitis</li> </ul>
Total vaccines and medicines in all phases of clinical development	68	
Total projects in clinical development (inclusive of all phases and indications)	86	



### Press release

# First quarter 2023

## Our key growth assets by therapy area

The following outlines several key vaccines and medicines by therapy area that will help drive growth for GSK to meet its outlooks and ambition for 2021-2026 and beyond.

### **Infectious Diseases**

### bepirovirsen (HBV ASO)

Bepirovirsen is a potential new treatment option for people with chronic hepatitis B being evaluated a monotherapy or combination therapy with both existing and novel treatments. Two randomised, double-blind, placebo-controlled phase III trials (B-Well 1 and B-Well 2) evaluating the safety and efficacy of bepirovirsen started in Q1 2023 and are actively recruiting patients.

Key trials for bepirovirsen:

Trial name (population)	Phase	Design	Timeline	Status
B-Well 1 bepirovirsen in nucleos(t)ide treated patients (chronic hepatitis B)		A multi-centre, randomised, double-blind, placebo-controlled trial to confirm the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus	Trial Start: Q1 2023	Recruiting
NCT05630807			T : LOL I	<b>D</b>
B-Well 2 bepirovirsen in nucleos(t)ide treated patients (chronic hepatitis B)		A multi-centre, randomised, double-blind, placebo-controlled trial to confirm the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus	Trial Start: Q1 2023	Recruiting
NCT05630820	llb	A multi control randomicad partial blind	Trial start:	Completer
B-Clear bepirovirsen monotherapy (chronic hepatitis B) NCT04449029	dil	A multi-centre, randomised, partial-blind parallel cohort trial to assess the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus	Q3 2020	Complete; full data presented
B-Together bepirovirsen sequential combination therapy with Peg-interferon (chronic hepatitis B) NCT04676724	llb	A multi-centre, randomised, open label trial to assess the efficacy and safety of sequential treatment with bepirovirsen followed by Pegylated Interferon Alpha 2a in participants with chronic hepatitis B virus	Trial start: Q1 2021	Active, not recruiting
bepirovirsen sequential combination therapy with targeted immunotherapy (chronic hepatitis B) NCT05276297	11	A trial on the safety, efficacy and immune response following sequential treatment with an anti-sense oligonucleotide against chronic hepatitis B (CHB) and chronic hepatitis B targeted immunotherapy (CHB-TI) in CHB patients receiving nucleos(t)ide analogue (NA) therapy	Trial start: Q2 2022	Recruiting

#### gepotidacin (bacterial topoisomerase inhibitor)

In April 2023, GSK presented positive results from the pivotal EAGLE-2 and EAGLE-3 phase III trials on 15 April 2023 for gepotidacin as a potential treatment for uncomplicated urinary tract infections (uUTI) in an oral presentation at the European Congress of Clinical Microbiology and Infectious Diseases in Copenhagen, Denmark. In the EAGLE-2 and EAGLE-3 phase III trials, gepotidacin demonstrated non-inferiority to nitrofurantoin, an existing first-line treatment for uUTI, in patients with a confirmed uUTI and a uropathogen susceptible to nitrofurantoin. Additionally, in the EAGLE-3 phase III trial, gepotidacin demonstrated statistically significant superiority versus nitrofurantoin. These results are based on a primary efficacy endpoint of therapeutic success, an endpoint comprised of combined clinical resolution and microbiological eradication of bacteria at the Test-of-Cure (ToC) visit 10-13 days after initiation of treatment. In the EAGLE-2 phase III trial, gepotidacin demonstrated therapeutic success in 50.6% of patients compared to 47% for nitrofurantoin. In the EAGLE-3 phase III trial, gepotidacin demonstrated therapeutic success in 58.5% of patients compared to 43.6% for nitrofurantoin. The safety and tolerability profile of gepotidacin in the EAGLE-2 and EAGLE-3 phase III trials.



# Press release

First quarter 2023



The presentation follows the decision to stop the EAGLE-2 and EAGLE-3 pivotal trials early for efficacy following a recommendation made by the Independent Data Monitoring Committee in November 2022. The full results will be submitted for publication in a peer-reviewed scientific journal later this year.

Key phase III trials for gepotidacin:

Trial name (population)	Phase	Design	Timeline	Status
EAGLE-1 (uncomplicated urogenital gonorrhoea) NCT04010539	111	A randomised, multi-centre, open-label trial in adolescent and adult participants comparing the efficacy and safety of gepotidacin to ceftriaxone plus azithromycin in the treatment of uncomplicated urogenital gonorrhoea caused by <i>Neisseria gonorrhoeae</i>	Trial start: Q4 2019	Recruiting
EAGLE-2 (females with uUTI / acute cystitis) NCT04020341	111	A randomised, multi-centre, parallel-group, double-blind, double-dummy trial in adolescent and adult female participants comparing the efficacy and safety of gepotidacin to nitrofurantoin in the treatment of uncomplicated urinary tract infection (acute cystitis)	Trial start: Q4 2019	Complete; primary endpoint met
EAGLE-3 (females with uUTI / acute cystitis) NCT04187144	111	A randomised, multi-centre, parallel-group, double-blind, double-dummy trial in adolescent and adult female participants comparing the efficacy and safety of gepotidacin to nitrofurantoin in the treatment of uncomplicated urinary tract infection (acute cystitis)	Trial start: Q2 2020	Complete; primary endpoint met

## MenABCWY vaccine candidate

GSK's MenABCWY combination vaccine candidate met all primary endpoints of the pivotal phase III clinical trial and was well tolerated with a safety profile consistent with *Bexsero* and *Menveo*. The primary endpoint data demonstrated statistical non-inferiority compared to *Bexsero* and *Menveo* in individuals 10-25 years old, eliciting a clinically meaningful immune response. If approved, this five-in-one vaccine candidate could provide the broadest meningococcal serogroup coverage and could lead to a simplified immunisation schedule. Detailed results from this phase III trial will be presented in a peer-reviewed publication and at upcoming scientific meetings. Based on these results, GSK intends to submit a Biologics License Application to the US Food and Drug Administration (FDA) to approve of its MenABCWY combination vaccine candidate.

Key trials for MenABCWY vaccine candidate:

Trial name (population)	Phase	Design	Timeline	Status
MenABCWY – 019	IIIb	A randomised, controlled, observer-blind trial	Trial start:	Active, not
NCT04707391		to evaluate safety and immunogenicity of GSK's meningococcal ABCWY vaccine when administered in healthy adolescents and adults, previously primed with meningococcal ACWY vaccine	Q1 2021	recruiting
MenABCWY – V72 72 NCT04502693	111	A randomised, controlled, observer-blind trial to demonstrate effectiveness, immunogenicity, and safety of GSK's meningococcal Group B and combined ABCWY vaccines when administered to healthy adolescents and	Trial start: Q3 2020	Complete; primary endpoints met
		young adults		

#### RSV vaccine candidates

In March 2023, the US FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted that the available data supported the safety and effectiveness of GSK's respiratory syncytial virus (RSV) older adult vaccine candidate for the prevention of lower respiratory tract disease caused by RSV in adults aged 60 years and older. The Committee voted unanimously 12-0 on effectiveness and 10-2 on safety. The US FDA has assigned a Prescription Drug User Fee Act action date of 3 May 2023. Regulatory reviews are ongoing elsewhere, including in the EU and Japan.

The VRBPAC vote followed the publication of positive phase III trial results for the vaccine candidate in *The New England Journal of Medicine*.



# Press release

# First quarter 2023

Key phase III trials for RSV older adult vaccine candidates:

Trial name (population)	Phase	Design	Timeline	Status
RSV OA=ADJ-004 (Adults ≥ 60 years old) NCT04732871	111	A randomised, open-label, multi-country trial to evaluate the immunogenicity, safety, reactogenicity and persistence of a single dose of the RSVPreF3 OA investigational vaccine and different revaccination schedules in adults aged 60 years and above	Trial start: Q1 2021	Active, not recruiting; primary endpoint met
RSV OA=ADJ-006 (ARESVI-006; Adults ≥ 60 years old) NCT04886596	111	A randomised, placebo-controlled, observer- blind, multi-country trial to demonstrate the efficacy of a single dose of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above	Trial start: Q2 2021	Active, not recruiting; primary endpoint met
RSV OA=ADJ-007 (Adults ≥ 60 years old) NCT04841577	III	An open-label, randomised, controlled, multi- country trial to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU-QIV vaccine in adults aged 60 years and above	Trial start: Q2 2021	Complete; primary endpoint met
RSV OA=ADJ-008 (Adults ≥ 65 years old) NCT05559476	III	A phase III, open-label, randomised, controlled, multi country trial to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU HD vaccine in adults aged 65 years and above	Trial start: Q4 2022	Active, not recruiting
RSV OA=ADJ-009 (Adults ≥ 60 years old) NCT05059301	III	A randomised, double-blind, multi-country trial to evaluate consistency, safety, and reactogenicity of 3 lots of RSVPreF3 OA investigational vaccine administrated as a single dose in adults aged 60 years and above	Trial start: Q4 2021	Complete; primary endpoint met
RSV OA=ADJ-017 (Adults ≥ 65 years old) NCT05568797	111	A phase III, open-label, randomised, controlled, multi-country trial to evaluate the immune response, safety and reactogenicity of an RSVPreF3 OA investigational vaccine when co-administered with FLU aQIV (inactivated influenza vaccine – adjuvanted) in adults aged 65 years and above	Trial start: Q4 2022	Active, not recruiting
RSV OA=ADJ-018 (Adults 50-59 years) NCT05590403	III	A phase III, observer-blind, randomised, placebo-controlled trial to evaluate the non- inferiority of the immune response and safety of the RSVPreF3 OA investigational vaccine in adults 50 59 years of age, including adults at increased risk of respiratory syncytial virus lower respiratory tract disease, compared to older adults ≥60 years of age.	Trial start: Q4 2022	Active, not recruiting

#### ΗIV

#### cabotegravir

In February 2023, ViiV Healthcare announced positive 12-month findings from the SOLAR phase IIIb trial, presented at the 30th Conference on Retroviruses and Opportunistic Infections, in Seattle, Washington. SOLAR is the first head-to-head, phase IIIb trial of the first and only complete long-acting injectable regimen *Cabenuva* (cabotegravir, rilpivirine) compared against complete daily oral regimen bictegravir/emtricitabine/tenofovir alafenamide.

The trial showed that *Cabenuva* dosed every two months achieved the primary endpoint of non-inferior virologic efficacy versus daily oral bictegravir/emtricitabine/tenofovir alafenamide. At the same time, 90% of participants who switched to *Cabenuva* from bictegravir/emtricitabine/tenofovir alafenamide, and who completed a survey (n=425), preferred the long-acting regimen. Switching to *Cabenuva* from bictegravir/emtricitabine/tenofovir alafenamide, and who completed a survey (n=425), preferred the long-acting regimen. Switching to *Cabenuva* from bictegravir/emtricitabine/tenofovir alafenamide during the SOLAR trial was efficacious, well-tolerated, and improved treatment satisfaction from baseline based on adjusted HIV Treatment Satisfaction Questionnaire status version scores.

# Press release

# First quarter 2023



Additionally, together with the Medicines Patent Pool (MPP), ViiV announced that MPP has signed sublicence agreements with Aurobindo Pharma, Cipla Inc. and Viatris Inc – through its subsidiary Mylan – to manufacture generic versions of cabotegravir long-acting (LA) for HIV pre-exposure prophylaxis (PrEP). This is enabled by signing a voluntary licensing agreement for patents relating to cabotegravir LA for PrEP with MPP in July 2022. Through the MPP-ViiV Healthcare agreement, the selected generic manufacturers will be able to develop, manufacture, and supply generic versions of cabotegravir LA for PrEP, in 90 countries, subject to required regulatory approvals being obtained.

Key phase III trials for cabotegravir:

Trial name (population)	Phase	Design	Timeline	Status
HPTN 083 (HIV uninfected cisgender men and transgender women who have sex with men) NCT02720094	IIb/III	A double-blind safety and efficacy trial of injectable cabotegravir compared to daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-uninfected cisgender men and transgender women who have sex with men	Trial start: Q4 2016	Active; not recruiting; primary endpoint met (superiority)
HPTN 084 (HIV uninfected women who are at high risk of acquiring HIV) NCT03164564	111	A double-blind safety and efficacy trial of long- acting injectable cabotegravir compared to daily oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected women	Trial start: Q4 2017	Active; not recruiting; primary endpoint met (superiority)
ATLAS NCT02951052	111	A randomised, multi-centre, parallel-group, non-inferiority, open-label trial evaluating the efficacy, safety, and tolerability of switching to long-acting cabotegravir plus long-acting rilpivirine from current INI- NNRTI-, or PI- based antiretroviral regimen in HIV-1-infected adults who are virologically suppressed	Trial start: Q4 2016	Active; not recruiting; primary endpoint met (non-inferiority)
ATLAS-2M NCT03299049	IIIb	A randomised, multi-centre, parallel-group, non-inferiority, open-label trial evaluating the efficacy, safety, and tolerability of long-acting cabotegravir plus long-acting rilpivirine administered every 8 weeks or every 4 weeks in HIV-1-infected adults who are virologically suppressed	Trial start: Q4 2017	Active; not recruiting; primary endpoint met (non-inferiority)
FLAIR NCT02938520	111	A randomised, multi-centre, parallel-group, open-label trial evaluating the efficacy, safety, and tolerability of long-acting intramuscular cabotegravir and rilpivirine for maintenance of virologic suppression following switch from an integrase inhibitor single tablet regimen in HIV- 1 infected antiretroviral therapy naïve adult participants	Trial start: Q4 2016	Active; not recruiting; primary endpoint met (non-inferiority)

# Immunology/Respiratory

depemokimab (ultra-long-acting anti-IL5)

The phase III programme for our ultra-long-acting IL5 inhibitor, depemokimab continues to make progress across a range of eosinophil-driven diseases. Phase III trials of depemokimab were initiated in the second half of 2022 in indications for chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic granulomatosis with polyangiitis (EGPA) and hypereosinophilic syndrome (HES). Trials of depemokimab in severe eosinophilic asthma which started in 2021 continued throughout 2022 with the open label extension of these trials starting recruitment in Q1 of 2022. Depemokimab is a unique and distinct monoclonal antibody developed specifically for its affinity for IL-5 and long duration of inhibition.

# Press release

# First quarter 2023

Key phase III trials for depemokimab:

Trial name (population)	Phase	Design	Timeline	Status
SWIFT-1 (severe	111	A 52-week, randomised, double-blind,	Trial start:	Active, not
eosinophilic asthma;		placebo-controlled, parallel-group, multi-centre	Q1 2021	recruiting
SEA)		trial of the efficacy and safety of depemokimab		
NCT04719832		adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma		
110104/19032		with an eosinophilic phenotype		
SWIFT-2 (SEA)	111	A 52-week, randomised, double-blind,	Trial start:	Recruiting
		placebo-controlled, parallel-group, multi-centre	Q1 2021	rtooraning
NCT04718103		trial of the efficacy and safety of depemokimab		
		adjunctive therapy in adult and adolescent		
		participants with severe uncontrolled asthma		
		with an eosinophilic phenotype		
AGILE (SEA)	111	A 52-week, open label extension phase of	Trial start:	Recruiting
	(extension)	SWIFT-1 and SWIFT-2 to assess the long-	Q1 2022	
NCT05243680		term safety and efficacy of depemokimab		
		adjunctive therapy in adult and adolescent		
		participants with severe uncontrolled asthma with an eosinophilic phenotype		
NIMBLE (SEA)	111	A 52-week, randomised, double-blind, double-	Trial start:	Recruiting
		dummy, parallel group, multi-centre, non-	Q1 2021	Recluling
NCT04718389		inferiority trial assessing exacerbation rate,	Q12021	
		additional measures of asthma control and		
		safety in adult and adolescent severe		
		asthmatic participants with an eosinophilic		
		phenotype treated with depemokimab		
		compared with mepolizumab or benralizumab		
ANCHOR-1	111	Efficacy and safety of depemokimab in	Trial start:	Recruiting
(CRSwNP)		participants with CRSwNP	Q2 2022	
NCT05274750				
ANCHOR-2	111	Efficacy and safety of depemokimab in	Trial start:	Recruiting
(CRSwNP)		participants with CRSwNP	Q2 2022	Recluling
			QL LULL	
NCT05281523				
OCEAN (EGPA)	111	Efficacy and safety of depemokimab compared	Trial start:	Recruiting
		with mepolizumab in adults with relapsing or	Q3 2022	, , , , , , , , , , , , , , , , , , ,
NCT05263934		refractory EGPA		
DESTINY (HES)	Ш	A 52-week, randomised, placebo-controlled,	Trial start:	Recruiting
		double-blind, parallel group, multicentre trial of	Q4 2022	
NCT05334368		depemokimab in adults with uncontrolled HES		
		receiving standard of care (SoC) therapy		

## Oncology

# Blenrep (belantamab mafodotin)

Trials within the DREAMM (DRiving Excellence in Approaches to Multiple Myeloma) clinical trial programme are ongoing, evaluating belantamab mafodotin in earlier lines of therapy and in combination. We anticipate data from DREAMM-7 and DREAMM-8 in the second-line setting in the second half of 2023.

Key phase III trials for Blenrep:

Trial name (population)	Phase	Design	Timeline	Status
DREAMM-7 (2L+ MM pts)	111	A multi-centre, open-label, randomised trial to evaluate the efficacy and safety of the combination of belantamab mafodotin,	Trial start: Q2 2020	Active, not recruiting
NCT04246047		bortezomib, and dexamethasone (B-Vd) compared with the combination of daratumumab, bortezomib and dexamethasone (D-Vd) in participants with relapsed/refractory multiple myeloma		



Results Summary	development	ESG	Adjusted results	information	report	
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DREAMM-8 (2L+ MM pts)		A multi-centre, open-labe evaluate the efficacy and			nrolment omplete	

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Auditor's review

DREAMM-8 (2L+ MM	111	A multi-centre, open-label, randomised trial to	Trial start:	Enrolment
pts)		evaluate the efficacy and safety of belantamab	Q4 2020	complete
		mafodotin in combination with pomalidomide		
NCT04484623		and dexamethasone (B-Pd) versus		
		pomalidomide plus bortezomib and		
		dexamethasone (P-Vd) in participants with		
		relapsed/refractory multiple myeloma		

#### Jemperli (dostarlimab)

In February 2023, the US FDA Oncologic Drugs Advisory Committee voted in support of trials designed to evaluate *Jemperli* as a potential treatment for mismatch repair-deficient/microsatellite instability-high (dMMR/MSI-H) locally advanced rectal cancer. Following the committee's positive vote, in March 2023, GSK initiated a global, open-label, phase II clinical trial to investigate the efficacy and safety of dostarlimab as monotherapy – as a replacement for chemotherapy, radiation and/or surgery – for treatment-naïve patients with dMMR/MSI-H locally advanced rectal cancer. The first patient was dosed in April 2023. GSK intends to use data from this trial, alongside data from Memorial Sloan Kettering Cancer Center's ongoing trial of 30 patients, to support a supplemental Biologics License Application (sBLA) for accelerated regulatory approval in this indication. Earlier in Q1 2023, the US FDA granted dostarlimab Fast Track designation for the treatment of dMMR/MSI-H locally advanced rectal cancer.

In February 2023, the US FDA granted full approval for *Jemperli* for the treatment of adult patients with dMMR recurrent or advanced endometrial cancer, as determined by a US FDA-approved test, that has progressed on or following a prior platinum-containing regimen in any setting and are not candidates for curative surgery or radiation. This approval was based on additional data collected from the A1 expansion cohort of the ongoing GARNET phase I trial, a multicentre, open-label, single-arm trial of *Jemperli* monotherapy in patients with advanced or recurrent solid tumours. Long-term outcomes from GARNET demonstrated an overall response rate of 45.4%.

In March 2023, GSK announced interim results from Part 1 of the RUBY/ENGOT-EN6/GOG3031/NSGO phase III trial investigating dostarlimab plus standard-of-care chemotherapy (carboplatin-paclitaxel) followed by dostarlimab compared to chemotherapy plus placebo followed by placebo in adult patients with primary advanced or recurrent endometrial cancer. The results demonstrated the potential of dostarlimab plus chemotherapy to redefine the treatment of primary advanced or recurrent endometrial cancer versus chemotherapy alone. A 72% and 36% reduction in the risk of disease progression or death were observed in the dMMR/MSI-H and overall patient populations, respectively. A clinically meaningful overall survival trend was also observed at the interim analysis.

In April 2023, GSK announced that the European Medicines Agency (EMA) validated the marketing authorisation application (MAA) for *Jemperli* plus chemotherapy for the treatment of dMMR/MSI-H primary advanced or recurrent endometrial cancer.

Key trials for Jemperli:

Trial name (population)	Phase	Design	Timeline	Status
RUBY ENGOT-EN6 GOG-3031 (1L Stage III or IV endometrial cancer) NCT03981796	111	A randomised, double-blind, multi-centre trial of dostarlimab plus carboplatin-paclitaxel with and without niraparib maintenance versus placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced endometrial cancer	Trial start: Q3 2019	Active, not recruiting; primary endpoint met in RUBY Part 1
PERLA (1L metastatic non-small cell lung cancer) NCT04581824	11	A randomised, double-blind trial to evaluate the efficacy of dostarlimab plus chemotherapy versus pembrolizumab plus chemotherapy in metastatic non-squamous non-small cell lung cancer	Trial start: Q4 2020	Active, not recruiting; primary endpoint met
GARNET (advanced solid tumours) NCT02715284	1/11	A multi-center, open-label, first-in-human trial evaluating dostarlimab in participants with advanced solid tumors who have limited available treatment options	Trial start: Q1 2016	Recruiting
AZUR-1 (locally advanced rectal cancer)	11	A single-arm, open-label trial with dostarlimab monotherapy in participants with untreated stage II/III dMMR/MSI-H locally advanced rectal cancer	Trial start: Q1 2023	Recruiting
NCT05723562				

# Press release

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# momelotinib (JAK1/2 and ACVR1/ALK2 inhibitor)

A European Union MAA for momelotinib, a potential new oral treatment for myelofibrosis, is currently under review with the EMA. A Committee for Medicinal Products for Human Use (CHMP) regulatory action is anticipated by year-end 2023. A New Drug Application (NDA) for momelotinib is also currently under regulatory review by the US FDA with a Prescription Drug User Fee Act action date of 16 June 2023.

Key phase III trial for momelotinib:

Trial name (population)	Phase	Design	Timeline	Status
MOMENTUM		A randomised, double-blind, active control	Trial start:	Active, not
(myelofibrosis)		phase III trial intended to confirm the	Q1 2020	recruiting;
		differentiated clinical benefits of the		primary
NCT04173494		investigational drug momelotinib (MMB) versus		endpoint met
		danazol (DAN) in symptomatic and anaemic		
		subjects who have previously received an		
		approved Janus kinase inhibitor (JAKi) therapy		
		for myelofibrosis (MF)		

# *Zejula* (niraparib)

Zejula is approved in more than 40 countries as a maintenance treatment for certain types of ovarian, fallopian tube and primary peritoneal cancer. The ongoing development programme includes several combination trials, including the FIRST phase III trial assessing niraparib in combination with dostarlimab as a potential treatment for first-line ovarian cancer maintenance and the phase III ZEAL trial assessing niraparib in combination with standard of care for the maintenance treatment of first-line advanced non-small cell lung cancer.

In April 2023, GSK took the decision to permanently discontinue enrolment in the ZEST phase III 800-patient trial, initiated in 2021. This decision was due to eligibility challenges impacting the ability to fully enrol patients with early-stage breast cancer. During the conduct of the trial, GSK learned that the prevalence of a radiologically detectable metastatic disease among patients who are ctDNA positive is much higher than expected. This enabled patients to be referred for treatment of metastatic cancer ahead of clinical symptoms. Consequently, because these patients were ineligible for the ZEST phase III trial, it has made enrolment in the trial much more challenging than previously thought.

## Key phase III trials for Zejula:

Trial name (population)	Phase	Design	Timeline	Status
ZEAL-1L	III	A randomised, double-blind, placebo-	Trial start:	Active, not
(maintenance for 1L		controlled, multi-centre trial comparing	Q4 2020	recruiting
advanced NSCLC)		niraparib plus pembrolizumab versus placebo		
		plus pembrolizumab as maintenance therapy		
NCT04475939		in participants whose disease has remained		
		stable or responded to first-line platinum-based		
		chemotherapy with pembrolizumab for Stage		
		IIIB/IIIC or IV non-small cell lung cancer		
FIRST (1L ovarian	III	A randomised, double-blind, comparison of	Trial start:	Active, not
cancer maintenance)		platinum-based therapy with dostarlimab	Q4 2018	recruiting
		(TSR-042) and niraparib versus standard of		
NCT03602859		care platinum-based therapy as first-line		
		treatment of stage III or IV non-mucinous		
		epithelial ovarian cancer		

# **Opportunity driven**

## Jesduvrog (daprodustat)

In February 2023, the US FDA approved *Jesduvroq* (daprodustat) for the treatment of anaemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four months. *Jesduvroq* is the first innovative medicine for anaemia treatment in over 30 years and the only hypoxia-inducible factor prolyl hydroxylase inhibitor approved in the US, providing a new oral, convenient option for patients in the US with anaemia of CKD on dialysis and for healthcare providers. *Jesduvroq* is currently under regulatory review with the EMA, with a regulatory decision anticipated in the first half of 2023.

When left untreated or undertreated, anaemia of CKD is associated with poor clinical outcomes and leads to a substantial burden on patients and healthcare systems. There remains an unmet need for convenient treatment options with efficacy and safety comparable to current treatments.

# Press release

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Key phase III trials for daprodustat:

Trial name (population)	Phase	Design	Timeline	Status
ASCEND-D (Dialysis subjects with anaemia of CKD) NCT02879305	III	A randomised, open-label (sponsor-blind), active-controlled, parallel-group, multi-centre, event driven trial in dialysis subjects with anaemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to recombinant human erythropoietin, following a switch from erythropoietin-stimulating agents	Reported	Complete; primary endpoint met
ASCEND-ID (Incident Dialysis subjects with anaemia of CKD) NCT03029208	111	A 52-week open-label (sponsor-blind), randomised, active-controlled, parallel-group, multi-centre trial to evaluate the efficacy and safety of daprodustat compared to recombinant human erythropoietin in subjects with anaemia of chronic kidney disease who are initiating dialysis	Reported	Complete; primary endpoint met
ASCEND-TD (Dialysis subjects with anaemia of CKD) NCT03400033	111	A randomised, double-blind, active-controlled, parallel-group, multi-centre trial in haemodialysis participants with anaemia of chronic kidney disease to evaluate the efficacy, safety, and pharmacokinetics of three-times weekly dosing of daprodustat compared to recombinant human erythropoietin, following a switch from recombinant human erythropoietin or its analogues	Reported	Complete; primary endpoint met
ASCEND-ND (Non- dialysis subjects with anaemia of CKD) NCT02876835	111	A randomised, open-label (sponsor-blind), active-controlled, parallel-group, multi-centre, event driven trial in non-dialysis subjects with anaemia of chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa	Reported	Complete; primary endpoint met
ASCEND-NHQ (Non- dialysis subjects with anaemia of CKD) NCT03409107	111	A 28-week, randomised, double-blind, placebo-controlled, parallel-group, multi- centre, trial in recombinant human erythropoietin (rhEPO) naïve non-dialysis participants with anaemia of chronic kidney disease to evaluate the efficacy, safety, and effects on quality of life of daprodustat compared to placebo	Reported	Complete; primary endpoint met



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# GSK

# **Reporting definitions**

#### Total, Continuing and Adjusted results

Total reported results represent the Group's overall performance including discontinued operations. Continuing results represents performance excluding discontinued operations.

GSK also uses a number of adjusted, non-IFRS, measures to report the performance of its business. Adjusted results and other non-IFRS measures may be considered in addition to, but not as a substitute for or superior to, information presented in accordance with IFRS. Adjusted results are defined on page 16 and other non-IFRS measures are defined below and are based on continuing operations.

#### Free cash flow from continuing operations

Free cash flow is defined as the net cash inflow/outflow from continuing operating activities less capital expenditure on property, plant and equipment and intangible assets, contingent consideration payments, net finance costs, and dividends paid to non-controlling interests, contributions from non-controlling interests plus proceeds from the sale of property, plant and equipment and intangible assets, and dividends received from joint ventures and associates (all attributable to continuing operations). It is used by management for planning and reporting purposes and in discussions with and presentations to investment analysts and rating agencies. Free cash flow growth is calculated on a reported basis. A reconciliation of net cash inflow from continuing operations to free cash flow from continuing operations is set out on page 34.

#### Free cash flow conversion

Free cash flow conversion is free cash flow from continuing operations as a percentage of profit attributable to shareholders from continuing operations.

#### Working capital

Working capital represents inventory and trade receivables less trade payables.

#### **CER and AER growth**

In order to illustrate underlying performance, it is the Group's practice to discuss its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates used to determine the results of overseas companies in Sterling had remained unchanged from those used in the comparative period. CER% represents growth at constant exchange rates. £% or AER% represents growth at actual exchange rates.

#### **Total Net debt**

Net debt is defined as total borrowings less cash, cash equivalents, liquid investments, and short-term loans to third parties that are subject to an insignificant risk of change in value.

#### **Share Consolidation**

Shareholders received 4 new Ordinary shares with a nominal value of 31<sup>1</sup>/<sub>4</sub> pence each for every 5 existing Ordinary shares which had a nominal value of 25 pence each. Earnings per share, diluted earnings per share, adjusted earnings per share and dividends per share were retrospectively adjusted to reflect the Share Consolidation in all the periods presented.

#### Earnings per share

Earnings per share has been retrospectively adjusted for the Share Consolidation on 18 July 2022, applying a ratio of 4 new Ordinary shares for every 5 existing Ordinary shares.

#### **Total Earnings per share**

Unless otherwise stated, Total earnings per share refers to Total basic earnings per share.

#### **Total Operating Margin**

Total Operating margin is operating profit divided by turnover.

#### **COVID-19 solutions**

COVID-19 solutions include the sales of pandemic adjuvant and other COVID-19 solutions including vaccine manufacturing and *Xevudy* and the associated costs but does not include reinvestment in R&D. This categorisation is used by management and we believe is helpful to investors through providing clarity on the results of the Group by showing the contribution to growth from COVID-19 solutions.

# **Turnover excluding COVID-19 solutions**

Turnover excluding COVID-19 solutions excludes the impact of sales of pandemic adjuvant within Vaccines and *Xevudy* within Specialty Medicines related to the COVID-19 pandemic. Management believes that the exclusion of the impact of these COVID-19 solutions sales aids comparability in the reporting periods and understanding of GSK's growth including by region versus prior periods and also 2023 Guidance which excludes any contributions from COVID-19 solutions.

#### **General Medicines**

General Medicines are usually prescribed in the primary care or community settings by general healthcare practitioners. For GSK, this includes medicines in inhaled respiratory, dermatology, antibiotics and other diseases.

#### **Specialty Medicines**

Specialty Medicines are typically prescription medicines used to treat complex or rare chronic conditions. For GSK, this comprises medicines in infectious diseases, HIV, oncology, immunology/respiratory and Other.

#### Percentage points

Percentage points of growth which is abbreviated to ppts.

#### Brand names and partner acknowledgements

Brand names appearing in italics throughout this document are trademarks of GSK or associated companies or used under licence by the Group.

# Press release

# First quarter 2023



# **Guidance, assumptions and cautionary statements**

# 2023 guidance

GSK expects 2023 turnover to increase between 6 to 8 per cent, Adjusted operating profit to increase between 10 to 12 per cent and Adjusted earnings per share to increase between 12 to 15 per cent. This guidance is provided at CER and excludes any contributions from COVID-19 solutions.

# Assumptions related to 2023 guidance

In outlining the guidance for 2023, the Group has made certain assumptions about the healthcare sector, the different markets in which the Group operates and the delivery of revenues and financial benefits from its current portfolio, pipeline and restructuring programmes. Taking Q1 2023 performance and the latest expectations for Q2 2023 into account, GSK now expects first half and second half turnover growth to be broadly similar and for General Medicines to be broadly flat to slightly down this year. GSK expects Adjusted operating profit growth to be lower in the first half of 2023 and higher in the second half, relative to full-year expectations. Despite the recovery of healthcare systems, uncertain economic conditions prevail across many markets in which GSK operates and we continue to expect to see variability in performance between quarters.

We expect sales of Vaccines to increase mid-teens per cent, Specialty Medicines to increase mid to high singledigit per cent, and sales of General Medicines to be broadly flat to slightly down.

These planning assumptions as well as operating profit guidance and dividend expectations assume no material interruptions to supply of the Group's products, no material mergers, acquisitions or disposals, no material litigation or investigation costs for the Company (save for those that are already recognised or for which provisions have been made) and no change in the Group's shareholdings in ViiV Healthcare. The assumptions also assume no material changes in the healthcare environment or unexpected significant changes in pricing as a result of government or competitor action. The 2023 guidance factors in all divestments and product exits announced to date.

The Group's guidance assumes successful delivery of the Group's integration and restructuring plans. Material costs for investment in new product launches and R&D have been factored into the expectations given. Given the potential development options in the Group's pipeline, the outlook may be affected by additional data-driven R&D investment decisions. The guidance is given on a constant currency basis.

# Assumptions and cautionary statement regarding forward-looking statements

The Group's management believes that the assumptions outlined above are reasonable, and that the guidance, outlooks, ambitions and expectations described in this report are achievable based on those assumptions. However, given the forward-looking nature of these guidance, outlooks, ambitions and expectations, they are subject to greater uncertainty, including potential material impacts if the above assumptions are not realised, and other material impacts related to foreign exchange fluctuations, macro-economic activity, the impact of outbreaks, epidemics or pandemics, such as the COVID-19 pandemic and ongoing challenges and uncertainties posed by the COVID-19 pandemic for businesses and governments around the world, changes in legislation, regulation, government actions or intellectual property protection, product development and approvals, actions by our competitors, and other risks inherent to the industries in which we operate.

This document contains statements that are, or may be deemed to be, "forward-looking statements". Forward-looking statements give the Group's current expectations or forecasts of future events. An investor can identify these statements by the fact that they do not relate strictly to historical or current facts. They use words such as 'anticipate', 'estimate', 'expect', 'intend', 'will', 'project', 'plan', 'believe', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, the outcome of contingencies such as legal proceedings, dividend payments and financial results. Other than in accordance with its legal or regulatory obligations (including under the Market Abuse Regulation, the UK Listing Rules and the Disclosure and Transparency Rules of the Financial Conduct Authority), the Group undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. The reader should, however, consult any additional disclosures that the Group may make in any documents which it publishes and/or files with the SEC. All readers, wherever located, should take note of these disclosures. Accordingly, no assurance can be given that any particular expectation will be met and investors are cautioned not to place undue reliance on the forward-looking statements.

## Press release

# First quarter 2023



All guidance, outlooks, ambitions and expectations should be read together with the guidance, assumptions and cautionary statements in this Q1 2023 earnings release and the 2022 Annual Report.

Forward-looking statements are subject to assumptions, inherent risks and uncertainties, many of which relate to factors that are beyond the Group's control or precise estimate. The Group cautions investors that a number of important factors, including those in this document, could cause actual results to differ materially from those expressed or implied in any forward-looking statement. Such factors include, but are not limited to, those discussed under Item 3.D 'Risk Factors' in the Group's Annual Report on Form 20-F for 2022 and any impacts of the COVID-19 pandemic. Any forward looking statements made by or on behalf of the Group speak only as of the date they are made and are based upon the knowledge and information available to the Directors on the date of this report.

# Press release

# First quarter 2023



# Independent review report to GSK plc

# Conclusion

We have been engaged by GSK plc ("the Company") to review the condensed financial information in the Results Announcement of the Company for the three months ended 31 March 2023.

The condensed financial information comprises:

- the income statement and statement of comprehensive income for three month period ended 31 March 2023 on page 21 to 22;
- the balance sheet as at 31 March 2023 on page 23;
- the statement of changes in equity for the three month period then ended on page 24;
- the cash flow statement for the three month period then ended on page 25; and
- the accounting policies and basis of preparation and the explanatory notes to the condensed financial information on pages 26 to 34 that have been prepared applying consistent accounting policies to those applied by the Group in the Annual Report 2022, which was prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the United Kingdom.

We have read the other information contained in the Results Announcement, including the non-IFRS measures contained on pages 26 to 34 and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial information.

Based on our review, nothing has come to our attention that causes us to believe that the condensed financial information in the Results Announcement for the three months ended 31 March 2023 is not prepared, in all material respects in accordance with the accounting policies set out in the accounting policies and basis of preparation section on page 31.

# **Basis for Conclusion**

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Financial Reporting Council for use in the United Kingdom (ISRE(UK)2410). A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

As disclosed on page 31, the annual financial statements of the Company are prepared in accordance with United Kingdom adopted international accounting standards. The condensed set of financial statements included in this Results Announcement have been prepared in accordance with the accounting policies set out in the accounting policies and basis of preparation section on page 31.

# **Conclusion Relating to Going Concern**

Based on our review procedures, which are less extensive than those performed in an audit as described in the Basis for Conclusion section of this report, nothing has come to our attention to suggest that the directors have inappropriately adopted the going concern basis of accounting or that the directors have identified material uncertainties relating to going concern that are not appropriately disclosed.

This Conclusion is based on the review procedures performed in accordance with ISRE (UK) 2410, however future events or conditions may cause the entity to cease to continue as a going concern.

# **Responsibilities of the directors**

The directors are responsible for preparing the Results Announcement of the Company in accordance with the Disclosure Guidance and Transparency Rules of the United Kingdom's Financial Conduct Authority.

In preparing the Results Announcement, the directors are responsible for assessing the Company's ability to continue as a going concern, disclosing as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

GSK

## Issued: Wednesday, 26 April 2023, London, U.K.

# Press release

# First quarter 2023

# Auditor's Responsibilities for the review of the financial information

In reviewing the Results Announcement, our responsibility is to express to the Company a conclusion on the condensed financial information in the Results Announcement based on our review. Our conclusion, including our Conclusions Relating to Going Concern, are based on procedures that are less extensive than audit procedures, as described in the Basis of Conclusion paragraph of this report.

## Use of our report

This report is made solely to the Company in accordance with International Standard on Review Engagements (UK and Ireland) 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Financial Reporting Council (ISRE (UK) 2410). Our work has been undertaken so that we might state to the Company those matters we are required to state to it in an independent review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company, for our review work, for this report, or for the conclusions we have formed.

**Deloitte LLP** Statutory Auditor London, United Kingdom 26 April 2023