

Pre-Quarterly Results Communication Q3 2018

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New information for Q3 2018

Foreign exchange

Average rates Quarterly	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018
Key currencies							
US\$	1.25	1.29	1.30	1.36	1.39	1.35	1.31
€	1.17	1.15	1.13	1.15	1.13	1.15	1.11
Yen	141	143	148	148	151	147	146
Other currencies							
Australian dollar	1.66	1.70	1.68	1.72	1.77	1.79	1.78
Brazilian real	3.96	4.16	4.15	4.37	4.53	4.89	5.10
Canadian dollar	1.66	1.72	1.66	1.72	1.76	1.74	1.72
Chinese yuan	8.60	8.80	8.76	8.84	8.82	8.68	8.90
Indian rupee	83.2	83.4	84.8	86.2	89.5	90.5	92.1
Russian rouble	73.6	74.4	77.0	77.8	79.0	83.4	84.5
FX impact on turnover	+14%	+9%	+2%	-3%	-6%	-4%	-3%
FX impact on adjusted EPS	+22%	+14%	+3%	-4%	-13%	-7%	n/a

Average rates for the quarter ended 30 September 2018 were \$1.31/£, €1.11/£ and Yen 146/£. Based on these rates, it is expected that the negative impact of foreign exchange on Q3 2018 sales will be around 3%. As a result of the mix of currency movements relative to the mix of costs, we expect that the negative impact of foreign exchange on Q3 2018 sterling Adjusted EPS will be greater than the negative impact on sales.

Average rates	3M	6M	9M	12M	3M	6M	9M
Cumulative - YTD	2017	2017	2017	2017	2018	2018	2018
Key currencies							
US\$	1.25	1.27	1.28	1.30	1.39	1.37	1.35
€	1.17	1.16	1.15	1.15	1.13	1.14	1.13
Yen	141	142	144	145	151	149	148
Other currencies							
Australian dollar	1.66	1.68	1.68	1.69	1.77	1.78	1.78
Brazilian real	3.96	4.06	4.09	4.16	4.53	4.71	4.84
Canadian dollar	1.66	1.69	1.68	1.69	1.76	1.75	1.74
Chinese yuan	8.60	8.70	8.72	8.75	8.82	8.75	8.80
Indian rupee	83.2	83.3	83.8	84.4	89.5	90.0	90.7
Russian rouble	73.6	74.0	75.0	75.7	79.0	81.2	82.3
FX impact on turnover	+ 14%	+11%	+8%	+5%	-6%	-5%	-4%
FX impact on adjusted EPS	+22%	+17%	+11%	+7%	-13%	-10%	n/a

Average rates for the nine months ended 30 September 2018 were \$1.35/£, €1.13/£ and Yen 148/£. Based on these rates, it is expected that the negative impact of foreign exchange on 9M 2018 sales will be around 4%. We also expect that the negative impact of foreign exchange on 9M 2018 sterling Adjusted EPS will likely be greater than the negative impact on sales.



Period end rates	Dec 2016	Mar 2017	June 2017	Sept 2017	Dec 2017	Mar 2018	Jun 2018	Sept 2018
Key currencies								
US\$	1.24	1.25	1.30	1.34	1.35	1.40	1.32	1.30
€	1.17	1.17	1.14	1.13	1.13	1.14	1.13	1.12
Yen	144	139	146	151	152	149	146	148

The Q3 2018 period-end rates were \$1.30/£, €1.12/£ and Yen 148/£.

Foreign exchange: Exchange Gains or (Losses)

Sharp movements and volatility in currencies during a quarter can result in Exchange Gains or Losses (EGOLs) which are recorded in SG&A. During Q3 2018 there was continued volatility in several currencies relative to Sterling.

EGOLs as reported (£m)	Q1	Q2	Q3	Q4	Full Year
2016	(3)	0	11	(42)	(34)
2017	(12)	(20)	(18)	(12)	(62)
2018	(32)	(15)			

Foreign exchange: Ready reckoner

In the 2017 FY results presentation on 7 February 2018, the following ready reckoner was provided on slide 31 to help estimate the expected impact of foreign exchange movements on adjusted EPS*:

Currency	Impact on 2018 full year adjusted EPS
US dollar	10 cents movement in average exchange rate for full year
	impacts EPS by approximately +/-4.0%
Euro	10 cents movement in average exchange rate for full year
	impacts EPS by approximately +/-2.5%
Japanese yen	10 yen movement in average exchange rate for full year
	impacts EPS by approximately +/-1.0%

*Please note that the ready reckoner does not include the impact of inter-company exchange gains or losses

The slide also included 2017 currency sales exposure for GSK:

Currency	2017 currency sales exposure
US dollar	37%
Euro	19%
Japanese yen	7%
Other‡	37%

‡The other currencies that each represent more than 1% of Group sales are: Australian dollar, Brazilian real, Canadian dollar, Chinese yuan and Indian rupee. In total, they accounted for 12% of Group revenues in 2017



Currency impact 2018

In the Q2 2018 press release we made the following comment on the potential impact of currencies on sales and EPS in 2018:

"If exchange rates were to hold at the closing rates on 30 June 2018 (\$1.32/£1, €1.13/£1 and Yen 146/£1) for the rest of 2018, the estimated negative impact on full-year 2018 Sterling turnover growth would be around 3% and if exchange gains or losses were recognised at the same level as in 2017, the estimated negative impact on 2018 Sterling Adjusted EPS growth would be around 6%"

We will update you on our latest view on the estimated impact of currencies in 2018 in our Q3 2018 press release on 31 October.

Basic weighted average number of shares (WANS)

The basic weighted number of shares in issue during Q3 2018 was 4,917m compared with 4,890m in Q3 2017 (an increase of 0.6%).

In millions*	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018
WANS: Quarter	4,877	4,887	4,890	4,891	4,903	4,914	4,917
WANS: Cumulative - Year to date	4,877	4,882	4,884	4,886	4,903	4,909	4,911
Period end shares	4,886	4,888	4,890	4,892	4,913	4,915	4,919

*excludes treasury shares and shares held by ESOP trusts

Dividend

In the Q2 2018 press release we made the following comment on returns to shareholders:

"GSK recognises the importance of dividends to shareholders and aims to distribute regular dividend payments that will be determined primarily with reference to the free cash flow generated by the business after funding the investment necessary to support the Group's future growth.

The Board intends to maintain the dividend for 2018 at the current level of 80p per share, subject to any material change in the external environment or performance expectations. Over time, as free cash flow strengthens, it intends to build free cash flow cover of the annual dividend to a target range of 1.25-1.50x, before returning the dividend to growth."

Dividend per share (p)	Q1	Q2	Q3	Q4	Full Year
2016	19	19	19	23	80
2017	19	19	19	23	80
2018 - expected	19	19			80†

†The actual dividend amount is determined by the Board of Directors.



Factors impacting recent quarterly comparisons

As usual there were several events in 2018 to date and during 2017 which impact the year on year comparisons for Q3 2018. This includes the following noteworthy items which you may wish to consider in your modelling.

Please note that the items listed below are not intended to be a complete list of all items that may impact the comparisons for Q3 2018 versus Q3 2017.

For further comments, please refer to quarterly press releases, presentations and transcripts.

Pharmaceuticals

Pharmaceuticals (£m)	Q1 2017	Q2 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018	Q2 2018
Total turnover	4,189	4,357	4,190	4,540	17,276	4,009	4,229
Reported growth - CER	+4%	+3%	+2%	+3%	+3%	+2%	+1%
Adjusted operating profit	1,440	1,464	1,426	1,597	5,927	1,329	1,492
Reported growth - CER	+6%	-5%	+1%	+4%	+1%	+0%	+7%
Adjusted operating margin	34.4%	33.6%	34.0%	35.2%	34.3%	33.2%	35.3%

Pharmaceuticals: Respiratory

Seretide/Advair (£m)	Q1 2017	Q2 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018	Q2 2018
US	339	476	388	407	1,610	229	260
Europe	206	182	164	184	736	166	151
International	207	190	191	196	784	171	179
Total	752	848	743	787	3,130	566	590
CER growth							
US	-12%	-11%	-15%	-22%	-16%	-25%	-43%
Europe	-17%	-21%	-18%	-10%	-17%	-21%	-17%
International	-4%	-11%	-11%	-7%	-8%	-12%	-2%
Total	-12%	-14%	-15%	-16%	-14%	-20%	-28%

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding the Respiratory business:

"Seretide/Advair continue to decline as we transition our Respiratory portfolio globally, but also impacted by the step up in US pricing pressures I highlighted in Q1. The pricing comparator for Advair should be slightly easier in the balance of the year as the increased pricing pressure really started in the second half of last year, before then again picking up in Q1. I still expect an overall decline in Advair for the year of around 30%, assuming no generic entry in 2018, although it might be a little worse, depending on how the anticipation of an imminent generic impacts year-end stocking positions.



Breo grew 4% in the quarter, with strong growth outside the US being offset by a decline in the US. This reflects another quarter of the RAR catch-up that we flagged at Q1. Overall volume growth in the US was strong at around 30%. With the catch-up now largely done, we expect to be back to good new sales growth in the second half. "

Pharmaceuticals: HIV

On the Q1 2018 results analyst/investor call on 25 April 2018, Simon Dingemans made the following comments regarding the HIV business:

"I continue to expect this business to deliver good growth this year, albeit at a lower rate than 2017, reflecting the larger base of the business."

HIV (£m)	Q1 2017	Q2 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018	Q2 2018
Tivicay	301	340	364	399	1,404	348	407
Triumeq	539	648	621	653	2,461	606	682
Juluca	-	-	-	5	5	10	24
Total dolutegravir	840	988	<i>985</i>	1,057	3,870	964	1,113
Epzicom	78	63	51	42	234	37	26
Other HIV	67	65	57	57	246	47	50
Total turnover	985	1,116	1,093	1,156	4,350	1,048	1,189
CER growth	+19%	+17%	+13%	+17%	+16%	+14%	+11%

Pharmaceuticals: Established Pharmaceuticals

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding Established Pharmaceuticals:

"Established Pharmaceuticals declined by 5%, although the quarter benefited from favourable RAR adjustments for Lamictal and some post-divestment inventory sales. I anticipate that the decline will be steeper in the second half, and overall continue to expect the performance for Established Pharmaceuticals to be a decline in sales of mid to high single-digits over the full year, including the impact of divestments."

Established Pharmaceuticals (£m)	Q1 2017	Q2 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018	Q2 2018
Total turnover	1,429	1,347	1,391	1,391	5,558	1,286	1,230
CER growth	-6%	-7%	-4%	-5%	-5%	-5%	-5%

Vaccines

Sales of vaccines are vulnerable to volatility on a quarterly basis – particularly in emerging markets. Since quarterly sales can be very lumpy due in part to the impact of large tenders as well as competitor outages we highlight in the table overleaf the 2017 and 2018 quarterly results for the Vaccines business.



GSK Vaccines	Q1	Q2	Q3	Q4	FY	Q1	Q2
(£m)	2017	2017	2017	2017	2017	2018	2018
US	363	316	816	374	1,869	489	486
Europe	389	394	431	386	1,600	389	393
International	400	401	442	448	1,691	360	374
Total turnover	1,152	1,111	1,689	1,208	5,160	1,238	1,253
Adjusted operating	341	374	698	231	1,644	339	357
profit							
Adjusted operating	29.6%	33.7%	41.3%	19.1%	31.9%	27.4%	28.5%
margin							
CER growth							
US	+21%	+12%	+6%	+16%	+12%	+50%	+61%
Europe	+4%	+10%	+6%	+2%	+6%	-3%	+0%
International	+25%	-5%	-14%	+9%	+1%	-6%	-3%
Total turnover	+16%	+5%	+0%	+9%	+6%	+13%	+16%
Adjusted operating profit	+22%	+30%	+5%	-3%	+11%	+18%	+3%

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding Vaccines revenues:

"Turning to Vaccines, sales up 16%, primarily driven by further acceleration of Shingrix, as well as growth in hepatitis, which benefited from a competitor being out of stock.

Emma highlighted earlier the successful Shingrix launch, and we continue to work on increasing supply, but I can confirm that we have plans now in place to deliver sufficient doses to fulfil Shingrix sales in the range of £600 to £650 million for 2018 as a whole. Previous vaccination patterns for Shingles vaccines suggest we will see stronger seasonal demand in Q3 than Q4, and I expect to see this reflected in the phasing of sales in the second half.

The meningitis franchise remains an important growth driver for the business, even though this quarter saw a decline of 3%. Bexsero was particularly impacted by the completion of cohort catch-up vaccination programmes in Europe, while Menveo was impacted by minor supply constraints that have now been resolved. I expect a positive second half and we are well prepared as we head into the back to school season.

As a reminder, Q3 last year was very strong, driven by flu sales, and it is difficult to predict precise ordering patterns between Q3 and Q4, but current bookings suggest it might be a bit more weighted to Q4 than last year."

Consumer Healthcare

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding Consumer Healthcare revenues:

"Turning to Consumer, sales up 3%, despite a one percentage drag from the combined impact of the divestment of non-strategic brands GST in India and generic competition for TDS in the US. Quarter 3



is expected to be the last quarter impacted by GST, and although the decline in TDS may spread into next year, it will no longer be a material factor in 2019.

Power brand growth dipped in the quarter due to stocking patterns and the phasing of some promotional activities. We remain confident in delivering low single-digit growth for Consumer for 2018."

GSK Consumer Healthcare (£m)	Q1 2017	Q2 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018	Q2 2018
Turnover	2,043	1,852	1,964	1,891	7,750	1,975	1,828
CER growth	+2%	+0%	+2%	+4%	+2%	+2%	+3%
Adjusted operating profit	351	328	392	302	1,373	384	352
CER growth	-2%	+16%	+19%	+12%	+11%	+18%	+13%
Adjusted operating margin	17.2%	17.7%	20.0%	16.0%	17.7%	19.4%	19.3%

Corporate and other unallocated and costs

Adjusted corporate and other unallocated operating profit (costs) (£m)	Q1	Q2	Q3	Q4	Full Year
2016	(168)	(31)	(35)	(128)	(362)
2017	(153)	(83)	(48)	(92)	(376)
2018	(129)	(99)			



Operating and financial performance

Operating performance

Year-on-year annual cost savings

Existing Major Restructuring programme (per Q4 2017 results presentation)

Annual savings: (£bn)*	2017 December achieved	2018 December expected	2019 December expected	2020 December expected
Annual savings at 2015 FX	3.3	3.5	3.7	4.0
Cumulative FX benefit	0.4	0.4	0.4	0.4
Total savings delivered/expected	3.7	3.9	4.1	4.4

* Expected phasing of annual savings. All expectations and targets regarding future performance should be read together with "Assumptions related to 2018 guidance and 2016-2020 outlook" and "Assumptions and cautionary statement regarding forward-looking statements" on page 40 of our Q2 2018 earnings release dated 25 July 2018.

In the Q2 2018 press release we made the following comments on restructuring:

"Cash payments made in the six months were £213 million (H1 2017: £332 million) including the settlement of certain charges accrued in previous quarters. The programme delivered incremental annual cost savings in the six months of £0.2 billion.

Charges for the combined restructuring and integration programme to date are £5.0 billion, of which cash charges were £3.6 billion. Cash payments of £3.3 billion have been made to date. Non-cash charges were £1.4 billion.

Estimated charges for 2018 under the existing programmes are £0.5 billion, with cash charges of around £0.3 billion and non-cash charges of around £0.2 billion.

Total cash charges for the existing programme are now expected to be approximately £4.1 billion with non-cash charges up to £1.6 billion. The programme has now delivered approximately £3.8 billion of annual savings, including a currency benefit of £0.4 billion. The programme is now expected to deliver by 2020 total annual savings of £4.0 billion on a constant currency basis, together with an estimated benefit of £0.4 billion from currency on the basis of H1 2018 average exchange rates."

New Major Restructuring programme (per Q2 2018 results presentation)

Annual savings: (£bn)*	2019E	2020E	2021E
Annual savings at 2017 FX	0.25	0.35	0.40

* Expected phasing of annual savings. All expectations and targets regarding future performance should be read together with "Assumptions related to 2018 guidance and 2016-2020 outlook" and "Assumptions and cautionary statement regarding forward-looking statements" on page 40 of our Q2 2018 earnings release dated 25 July 2018.

In the Q2 2018 press release we made the following comments on the new major restructuring programme:



The Board has approved a new major restructuring programme, which is designed to significantly improve the competitiveness and efficiency of the Group's cost base with savings delivered primarily through supply chain optimisation and reductions in administrative costs. The new programme is expected to cost £1.7 billion over the period to 2021, comprising cash costs of £0.8 billion and non-cash costs of £0.9 billion, and is expected to deliver annual savings of around £400 million by 2021. These savings will be fully re-invested in the Group to help fund targeted increases in R&D and commercial support of new products.

Estimated charges under the new programme for 2018 are £0.4 billion, with cash charges of around £0.3 billion and non-cash charges of around £0.1 billion."

Selling, General and Administration

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding SG&A costs:

"SG&A was up by 6% in the quarter as we invested significantly behind driving new products in Respiratory, HIV and Vaccines, particularly Shingrix. This was partly offset by reductions in back office and other non-customer facing resources, and I would expect SG&A growth to slow over the second half, although we need to continue to support key seasonable products in Q3. "

Adjusted SG&A costs (£m)	Q1 2017	Q2 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018	Q2 2018
SG&A	2,347	2,294	2,280	2,420	9,341	2,286	2,334
Reported growth - CER	+0%	+2%	+2%	+2%	+1%	+2%	+6%

Research and development

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding R&D costs:

"R&D costs down 15%, down 6% excluding the impact of the PRV, and as I mentioned at Q1, the first half was expected to see reduced spend as the savings from last year's portfolio choices kicked in, but we also still expect to see those savings start going back into R&D over the second half, when we should see Pharma R&D spend start to grow again, accelerating into Q4."

Adjusted R&D costs (£m)	Q1 2017	Q2* 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018	Q2 2018
R&D	919	1,053	898	992	3,862	887	868
Reported growth - CER	+8%	+24%	+1%	+0%	+8%	+2%	-15%

*R&D in Q2 2017 includes £106m cost of the Priority Review Voucher.

Royalty income

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding royalty income:



"Royalties were down 23%, due to payment from the sales of Cialis, which ended in 2017 and we continue to expect around £200 million for the full year"

Adjusted royalties (£m)	Q1	Q2	Q3	Q4	Full Year
2016	91	83	107	117	398
2017	82	98	107	69	356
2018 outlook	53	73			Around £200m

Financial performance

Net finance costs

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding net finance costs:

"With the additional debt funding for the buy-in, and some of our older debt now refinanced at lower rates, I except funding costs for the year as a whole to be around £725 million."

Adjusted net finance costs (£m)	Q1	Q2	Q3	Q4	Full Year
2016	(159)	(163)	(160)	(170)	(652)
2017	(169)	(176)	(177)	(135)*	(657)
2018	(139)**	(165)			Around £725m

*includes £23m credits for interest on tax resulting from a number of settlements during the year ** includes the benefit of a one-off accounting adjustment to the amortisation of long term bond interest charges of £20 million

Associates and joint ventures

Adjusted associates and joint ventures (£m)	Q1	Q2	Q3	Q4	Full Year
2016	0	(2)	6	1	5
2017	5	(1)	7	2	13
2018	9	2			

Taxation

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding taxation:

"On tax, the adjusted rate was 20% in the quarter, and we continue to expect a rate of 19-20% for the full year. "

Adjusted tax rate (%)	Q1	Q2	Q3	Q4	Full Year
2016	21.4%	21.3%	20.8%	21.9%	21.3%
2017	22.0%	21.2%	21.0%	20.0%	21.0%
2018 outlook	20.2%	20.0%			19% to 20%



Profit / (loss) attributable to non-controlling interests (minority interests)

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding minority interests:

"The charge for minorities in the quarter was £170 million, compared to £174 million a year ago. The ViiV minority interest increased due to the share of the PRV costs that impacted the minority last year, and this was offset by 2 months' saving on the Consumer Healthcare minority interest, as we recognised 100% of the profits from when the agreement to acquire full ownership became unconditional on approval of shareholders on 3 May."

Adjusted profit/(loss) attributable to non- controlling interests (£m)	FY 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018	Q2 2018
ViiV	324	113	81	117	103	414	111	135
Novartis Consumer Healthcare	288	74	80	105	85	344	102	16
Other	25	12	13	6	4	35	11	19
Total	637	199	174	228	192	793	224	170

Free cash flow

Free cash flow* (£m)	Q1	Q2	H1	Q3	9М	Q4	FY
2016 - revised	(240)	365	125	1,433	1,558	1,739	3,297
2017 – revised	650	(264)	386	1,282	1,668	1,817	3,485
2018	329	492	821				

*With the introduction of the new R&D strategy in Q2 2018, GSK has revised its definition of free cash flow, a non-IFRS measure, to include proceeds from the sale of intangible assets.

On the Q2 2018 results analyst/investor call on 25 July 2018, Simon Dingemans made the following comments regarding Cashflow:

"Moving to cash generation and net debt, we remain very focused on driving greater cash discipline across the group and improving cash conversion.

Free cash flow for the Group during the first half of the year was £0.8bn, up £0.4bn compared with last year. This increase was driven by improved operating profit, reduced restructuring spend and tighter control of capital expenditures, as well as the comparison with the cost of the PRV in Q2 2017. This progress was partly offset by the Vaccines milestone payment to Novartis at the beginning of this year, foreign currency movements and a greater increase in working capital than the first half last year.

The working capital increase reflected the usual seasonal build we see in the first half but also additional inventories going in behind new products in Respiratory, HIV and Shingrix, and the rapid take-up of Shingrix has also led to a step up in receivables which we would expect to collect during the balance of the year. Like last year, I expect cash flows overall to be weighted to the second half."



Contingent consideration

In the Q2 2018 press release we made the following comments:

"Contingent consideration amounted to £6,170 million at 30 June 2018 (31 December 2017: £6,172 million), of which £5,879 million (31 December 2017: £5,542 million) represented the estimated present value of amounts payable to Shionogi relating to ViiV Healthcare and £243 million (31 December 2017: £584 million) represented the estimated present value of contingent consideration payable to Novartis related to the Vaccines acquisition following a milestone payment of \$450 million made to Novartis in January 2018. The liability due to Shionogi included £234 million in respect of preferential dividends. The liability for preferential dividends due to Pfizer at 30 June 2018 was £16 million (31 December 2017: £17 million)."

Contingent consideration (£m)	31 Dec 2016	31 Mar 2017	30 Jun 2017	30 Sep 2017	31 Dec 2017	31 Mar 2018	30 June 2018
Shionogi – relating to ViiV Healthcare	5,304	5,193	5,351	5,224	5,542	5,314	5,879
Novartis – relating to Vaccines acquisition	545	554	646	648	584	251	243
Other	47	47	46	45	46	45	48
Total	5,896	5,794	6,043	5,917	6,172	5,610	6,170



Historic London Stock Exchange announcements (LSE announcements) and press releases

Acquisitions and divestments

Roivant subsidiary Dermavant Sciences signs agreement with GSK to purchase rights to tapinarof

 GSK today announced that Dermavant Sciences, a subsidiary of Roivant Sciences, has agreed to purchase the rights to tapinarof, an investigational therapeutic aryl hydrocarbon receptor modulating agent (TAMA) for the treatment of psoriasis and atopic dermatitis and back-up programmes for a total consideration of £250 million, including an initial payment of £150 million and a potential future milestone payment of £100 million.

The transaction is anticipated to complete during the second half of 2018, subject to necessary approvals, anti-trust and regulatory clearances. As part of the transaction, GSK, Roivant and Dermavant will enter into agreements for supply of the investigational medicine for the phase III programme and commercial supply. At closing of the transaction, Dermavant will acquire all global rights to tapinarof, except in China. Dermavant will acquire global rights to the preclinical topical back-up programme to tapinarof and will assume responsibility for all development milestones owed to third parties. (Press Release 12 July 2018)

GSK completes Consumer Healthcare buyout

• GlaxoSmithKline plc (LSE/NYSE: GSK) today announces that it has completed the buyout of Novartis' 36.5% stake in its Consumer Healthcare Joint Venture for \$13 billion (£9.3 billion).

The transaction, which was previously announced on 27 March 2018 and described in the circular published on 13 April 2018, was approved by shareholders on 3 May 2018. **(LSE announcement 01 June 2018)**

News flow on key assets during the quarter and to date

Since the beginning of Q3 2018 we have issued several LSE announcements and press releases, each of which can be accessed using the following links: <u>http://www.gsk.com/en-gb/media/press-releases/</u> <u>http://us.gsk.com/en-us/media/press-releases/</u>

GSK updates policy for working with healthcare professionals

We are updating our policy on working with healthcare professionals (HCPs). This policy update is being made to ensure we continue to operate responsibly and improve how we help prescribers to understand new data and clinical experience with our innovative products, so they can deliver better outcomes for patients.

These changes are being made for a select number of innovative products in a limited number of countries and apply to restricted time periods in a product's lifecycle. The updated policy means GSK will in certain circumstances:

• Allow payments to global expert practitioners who speak about the new science behind our innovative products, their associated diseases and clinical practice in promotional settings.



- Pay reasonable travel costs (except in the US) for an HCP to attend a GSK-organized standalone meeting to learn about data and clinical expertise.
- Directly pay registration fees for HCPs to attend remote congress webinars/webcasts. We will continue to not sponsor HCPs to attend local and international conferences.
- These changes are effective from today, apply to GSK's Pharmaceuticals and Vaccines businesses, and ViiV Healthcare, and are in full compliance with applicable regulations and laws.

Under the new policy we will expand our reporting of payments to individual HCPs as part of our commitment to transparency and responsible disclosure. Beginning in 2019, we will, where legally permitted, disclose individual level payments annually in the US, Japan and other major developed markets in Europe, North America and Asia. (Press release 02 October 2018)

Positive results from Harmony Outcomes study of albiglutide published in The Lancet

GSK and the Duke Clinical Research Institute (DCRI) today announced publication of positive results from the Harmony Outcomes study which assessed the cardiovascular (CV) safety and efficacy of albiglutide, a GLP-1 receptor agonist, in patients with type 2 diabetes and cardiovascular disease. Results were presented at the European Association for the Study of Diabetes congress 2018 with simultaneous publication in The Lancet. (Press release 02 October 2018)

GSK candidate vaccine helps prevent active pulmonary tuberculosis in HIV negative adults in phase II study

• Publication of primary results in the New England Journal of Medicine shows positive impact of innovative vaccine technology in clinical trial conducted in tuberculosis endemic regions

Today, GSK and Aeras reported that GSK's M72/AS01E candidate vaccine significantly reduced the incidence of pulmonary tuberculosis disease in HIV-negative adults with latent tuberculosis infection in an ongoing phase IIb clinical trial testing. These primary results published in the New England Journal of Medicine after two years of trial demonstrate an overall vaccine efficacy of 54%, with varied response rates observed in different demographic sub-groups. The canidate vaccine had an acceptable safety and reactogenicity profile. (Press release 25 September 2018)

Trelegy Ellipta receives positive CHMP opinion supporting expanded COPD indication in Europe

 GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion today supporting the use of Trelegy Ellipta (fluticasone furoate/umeclidinium/ vilanterol 'FF/UMEC/VI') in a broader group of patients with moderate to severe chronic obstructive pulmonary disease (COPD) and that labelling, if approved, will be updated to further reflect its effect on exacerbations of COPD.

The expanded indication for the once-daily single inhaler triple therapy would enable use by patients not adequately treated by a long-acting muscarinic receptor antagonist (LAMA) and long-acting β 2-agonist (LABA). It would also reference the effect on exacerbations based on data from the InforMing the PAthway of COPD Treatment (IMPACT) study.

(LSE announcement 21 September 2018)



ViiV Healthcare submits regulatory application to European Medicines Agency for single-tablet, two-drug regimen of dolutegravir and lamivudine for treatment of HIV

ViiV Healthcare today announced submission of a marketing authorisation application (MAA) to the European Medicines Agency (EMA) for a single-tablet, two-drug regimen of dolutegravir (DTG) and lamivudine (3TC) for the treatment of HIV-1 infection.

The submission is based on the global GEMINI 1 & 2 studies that included more than 1400 HIV-1 infected adults with baseline viral loads up to 500,000 c/mL. The results of these studies were presented at the 2018 International AIDS Society meeting in July.

(LSE announcement 14 September 2018)

GSK data presented at ERS further supports its industry-leading respiratory medicines portfolio

• GlaxoSmithKline plc (GSK) will profile the growing evidence base that supports its broad respiratory medicines portfolio at the European Respiratory Society (ERS) congress in Paris, France, 15-19 September 2018.

Data presented in 50 abstracts will underscore the therapeutic value of key medicines across a spectrum of patients with asthma and chronic obstructive pulmonary disease (COPD). Data presented will include new analyses from clinical studies across the medicines portfolio. These data provide evidence of the role different treatments have in optimising the management of respiratory diseases by addressing the main areas of individual patient need. Findings include the effect on exacerbations, or worsening of the condition, that many COPD and asthma patients suffer, as well as on lung function, symptoms such as breathlessness and quality of life. Data will also be presented assessing the benefit of treatments across disease severities and age groups. (Press release 10 September 2018)

GSK announces results of indirect treatment comparisons of Nucala to benralizumab and reslizumab for severe eosinophilic asthma

• Nucala demonstrated greater reduction in exacerbations and improved asthma control. GlaxoSmithKline plc (LSE/NYSE: GSK) today announced results from an indirect treatment comparison of the licensed doses of Nucala (mepolizumab), versus benralizumab and reslizumab in patients with severe eosinophilic asthma. The data, published today in The Journal of Allergy and Clinical Immunology (JACI), showed that in patients with similar blood eosinophil counts, mepolizumab significantly reduced clinically significant exacerbations and improved asthma control compared with both benralizumab and reslizumab. (LSE announcement 10 September 2018)

GSK receives complete response letter from US FDA for use of mepolizumab in COPD patients

GlaxoSmithKline plc (LSE/NYSE: GSK) today received a complete response letter (CRL) from the US FDA regarding its application for mepolizumab as an add-on treatment to inhaled corticosteroidbased maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD), guided by blood eosinophil counts.

The CRL states that more clinical data are required to support an approval. GSK will work closely with the FDA to determine the appropriate next steps for the supplementary biologics licence application (sBLA). (LSE announcement 07 September 2018)



European Commission approves Nucala (mepolizumab) for the treatment of children with severe asthma

• First anti-IL-5 biologic treatment for paediatric patients with severe eosinophilic asthma in Europe

GlaxoSmithKline (LSE/NYSE: GSK) today announced that the European Commission has granted marketing authorisation for Nucala (mepolizumab) as an add-on treatment for severe refractory eosinophilic asthma in paediatric patients aged six up to 17 years. As a result of this licence extension Nucala is now approved for use for severe refractory eosinophilic asthma in both adult and paediatric patients in the 31 European countries covered by the European Medicines Agency (EMA). (LSE announcement 30 August 2018)

ViiV Healthcare reports positive 48-week results for first pivotal, phase III study for novel, longacting, injectable HIV-treatment regimen

- ATLAS study meets primary endpoint, showing similar efficacy of a once-a-month, investigational, injectable two-drug regimen of cabotegravir and rilpivirine compared to a standard of care, daily, oral three-drug regimen.
- Full results from the study will be presented at an upcoming scientific meeting.

ViiV Healthcare today announced positive headline results from its global, phase III ATLAS study of a long-acting, injectable two-drug regimen (2DR) for the treatment of HIV. ATLAS (Antiretroviral Therapy as Long-Acting Suppression) was designed to establish if HIV-1-infected adult participants who had maintained viral suppression for at least six months, on a daily oral regimen comprised of two nucleoside reverse transcriptase inhibitors (NRTIs) plus a third agent, maintained similar rates of viral suppression upon switching to the investigational, two-drug, long-acting, injectable regimen of cabotegravir and rilpivirine, compared with continuing the three-drug oral regimen.

The study showed long-acting cabotegravir and rilpivirine, injected once a month, had similar efficacy to a standard of care, daily, oral three-drug regimen at Week 48. The injectable treatment regimen met the primary endpoint for non-inferiority (the proportion of participants with plasma HIV-1 RNA ≥50 copies per milliliter [c/mL] using the FDA Snapshot algorithm at Week 48). Overall safety, virologic response and drug resistance results for the injectable regimen were consistent with results from the phase II LATTE and LATTE-2 studies.

Detailed results from the study will be presented at an upcoming scientific meeting. Headline results from FLAIR, a second pivotal trial designed to evaluate a long-acting, injectable regimen of cabotegravir and rilpivirine in treatment-naïve individuals, are expected later this year. **(LSE announcement 15 August 2018)**

- GSK ships 2018-19 seasonal influenza vaccines for US market
- Company to deliver up to 40 to 45 million doses, GSK's highest volume to date
- Annual vaccination best way to help prevent and reduce severity of influenza

GSK today announced it will begin shipping its quadrivalent influenza vaccines to US healthcare providers and pharmacies for the 2018-19 flu season, immediately following licensing and lot-release approval from the US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research. (Press release 08 August 2018)



CHMP recommend Nucala (mepolizumab) for the treatment of severe eosinophilic asthma paediatric patients in Europe

GlaxoSmithKline (LSE/NYSE: GSK) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending Nucala (mepolizumab) as an add-on treatment for severe refractory eosinophilic asthma in paediatric patients aged six up to 17 years. If approved, it would be the first targeted biologic therapy for the treatment of severe eosinophilic asthma in paediatric patients in Europe. (LSE announcement 27 July 2018)

GSK reports on outcome of the FDA Advisory Committee on mepolizumab for the treatment of COPD patients on maximum inhaled therapy

• Advisory Committee provide non-binding recommendation for consideration by the FDA GlaxoSmithKline plc (LSE/NYSE: GSK) today announced the outcome of the Pulmonary Allergy Drugs Advisory Committee of the United States (US) Food and Drug Administration (FDA) meeting on the use of mepolizumab as an add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD) guided by blood eosinophil counts. The committee voted on the basis of data presented that the risk-benefit profile was not adequate to support approval (3 for, 16 against).

The committee also voted that there was not substantial evidence of the efficacy (3 for, 16 against) but there was adequate evidence of the safety (17 for, 2 against) of mepolizumab in this population and the committee suggested further data to characterise the patient population that would be most likely to benefit from this targeted biologic therapy. **(LSE announcement 25 July 2018)**

GSK and 23andMe sign agreement to leverage genetic insights for the development of novel medicines

• Multi-year collaboration expected to identify novel drug targets, tackle new subsets of disease and enable rapid progression of clinical programmes

GSK and 23andMe today unveiled an exclusive four-year collaboration that will focus on research and development of innovative new medicines and potential cures, using human genetics as the basis for discovery. The collaboration will combine 23andMe's large-scale genetic resources and advanced data science skills, with the scientific and medical knowledge and commercialisation expertise of GSK. The goal of the collaboration is to gather insights and discover novel drug targets driving disease progression and develop therapies for serious unmet medical needs based on those discoveries. (LSE announcement 25 July 2018)

GSK and Adaptimmune complete transition of NY-ESO SPEAR T-cell therapy programme to GSK

• GlaxoSmithKline plc and Adaptimmune Therapeutics plc (Nasdaq:ADAP), today announced the transition of the development programme for GSK3377794 (GSK '794), an NY-ESO SPEAR T-cell therapy, to GSK.

Dr. Hal Barron, President R&D, GSK said, "The data we've seen for GSK '794 point to the potentially transformational nature of this T-cell therapy, as this is the first cell therapy to show clinical response in solid tumours. The concept of cells as medicines is an exciting component of our immuno-oncology portfolio and leverages our expertise in manufacturing T-cell therapies. This has been a



productive collaboration on GSK '794 and we look forward to continued collaboration with Adaptimmune."

"This is a turning point for Adaptimmune. We are extremely proud of the partnership with GSK and the pioneering work we have led over the years with NY-ESO SPEAR T-cells, as the foundation of our targeted TCR therapies, showing responses in two solid tumours and treating more than 80 patients in six different indications," said James Noble, Chief Executive Officer at Adaptimmune. "With the NY-ESO programme transitioned, Adaptimmune can focus its clinical, regulatory and manufacturing resources on the development of our wholly owned therapies MAGE-A4, MAGE-A10, and AFP. We will continue the pre-clinical work with GSK on its next target, PRAME." (Press Release 24 July 2018)

ViiV Healthcare announces SWORD 100-week data for Juluca (dolutegravir/rilpivirine) at AIDS 2018

• Juluca, the first 2-drug regimen, once daily, single pill regimen, maintains viral suppression through 100 weeks.

ViiV Healthcare today presented 100-week results from its phase III programme evaluating the safety and efficacy of switching virologically-suppressed people living with HIV from a three or four-drug antiretroviral regimen to a 2-drug regimen of dolutegravir (ViiV Healthcare) and rilpivirine (Janssen Sciences Ireland UC, part of the Janssen Pharmaceutical Companies of Johnson & Johnson.) These results were presented at the 22nd International AIDS Conference taking place 23-27 July 2018 in Amsterdam. (LSE announcement 24 July 2018)

ViiV Healthcare presents phase III data at AIDS 2018 from landmark GEMINI studies showing twodrug regimen of dolutegravir and lamivudine has similar efficacy to a three-drug regimen in treatment naïve HIV patients, with no emergence of resistance

• GEMINI 1 & 2 studies meet primary endpoint, showing two-drug regimen to be effective across high and low viral loads.

ViiV Healthcare today presented at the 22nd International AIDS conference in Amsterdam 48-week results from the phase III GEMINI 1 & 2 studies, assessing the safety and efficacy of a two-drug regimen (2DR) of dolutegravir (DTG) and lamivudine (3TC) compared to a three-drug regimen of dolutegravir and two nucleoside reverse transcriptase inhibitors (NRTIs), tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), in treatment-naïve, HIV-1 infected adults with baseline viral loads up to 500,000 copies per millilitre (c/mL).

The studies met their primary endpoint for non-inferiority based on plasma HIV-1 RNA <50c/mL, a standard measure of HIV control, at Week 48. In a pooled analysis, 91% (655/716) of patients taking DTG + 3TC had HIV-1 RNA<50 copies/mL compared with 93% (669/717) of patients taking DTG +TDF/FTC [adjusted difference -1.7% (95% CI: -4.4%, 1.1%)]. (LSE announcement 24 July 2018)

US FDA approves Krintafel (tafenoquine) for the radical cure of P. vivax malaria

• First single-dose medicine to prevent the relapse of P. vivax malaria marks a major contribution towards malaria eradication efforts

GSK and Medicines for Malaria Venture (MMV) today announced that the United States Food and Drug Administration (FDA) has approved, under Priority Review, single-dose Krintafel (tafenoquine) for the radical cure (prevention of relapse) of Plasmodium vivax (P. vivax) malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute P. vivax infection. (Press release 20 July 2018)



ViiV Healthcare shares data from landmark 2-drug regimen trials at AIDS 2018

ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer Inc. and Shionogi Limited as shareholders, will be presenting over 20 abstracts, including data from the landmark GEMINI 1 & 2 clinical trials, at the 22nd International AIDS Conference (AIDS 2018), 23-27 July 2018, in Amsterdam, The Netherlands. The data being presented this year has a strong focus on novel exploratory therapeutic options and innovative treatment strategies, as well as improving awareness and understanding of key issues that continue to affect the HIV community. (Press release 18 July 2018)

Other news flow during the quarter and to date

Iain Mackay appointed GSK Chief Financial Officer

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that Iain Mackay has been appointed GSK's next Chief Financial Officer (CFO). He has also been appointed as an Executive Director to the GSK Board. Mr Mackay will join the company on 14 January 2019.

Mr Mackay joins GSK from the global bank HSBC, where he has been Group Finance Director for the last 8 years. GSK announced in May that the Company's CFO, Simon Dingemans, is to retire from the Company in May 2019.

A chartered accountant, Mr Mackay has worked in Asia, the US and Europe and before HSBC was at General Electric, Schlumberger Dowell and Price Waterhouse. He is a trustee of the British Heart Foundation and a member of the Court of the University of Aberdeen.

(LSE announcement 07 August 2018)

James Ford appointed GSK General Counsel

GSK today announced that James Ford, currently SVP and General Counsel for Global Pharma, will succeed Dan Troy as General Counsel, GSK. James will join the Corporate Executive Team (CET) on 1 August.

Through his 23-year career with GSK, James has gained wide-ranging legal experience including investigations, complex corporate transactions and litigation in senior roles across the USA, Asia and UK.

James replaces Dan Troy who will leave GSK after 10 years as General Counsel.

(Press release 12 July 2018)



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. All commentaries are presented in terms of CER growth, unless otherwise stated.

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