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Pipeline assets and clinical trials appendix

Q1 2023

Contents

Innovation: pipeline growth

Overview of potential new vaccines and medicines

68 potential new vaccines and medicines in pipeline

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
Oncology
Opportunity driven

Phase I – 34 assets

2904545	adjuvanted recombinant protein*	*C. difficile*
4429016	adjuvanted bioconjugated, recombinant	*K. pneumoniae*
3993129	adjuvanted recombinant subunit	cytomegalovirus[1]
4382276	mRNA*	seasonal flu
4396687	mRNA*	COVID-19
4077164	bivalent GMMA*	invasive non-typhoidal salmonella**
3943104	adjuvanted recombinant protein*	therapeutic herpes simplex virus[1]
4348413	GMMA	gonorrhea[1]
3536867	bivalent conjugate*	salmonella (*typhoid + paratyphoid A*)
2556286	Mtb cholesterol dependent inhibitor*	tuberculosis
3186899	CRK-12 inhibitor*[8]	visceral leishmaniasis
3494245	proteasome inhibitor*	visceral leishmaniasis
3772701	*P. falciparum* whole cell inhibitor*	malaria
3882347	FimH antagonist*	uncomplicated UTI
3923868	PI4K beta inhibitor	viral COPD exacerbations
4182137 (VIR-7832)	anti-spike protein antibody*	COVID-19[1]
3965193	PAPD5/PAPD7 inhibitor	hepatitis B virus
5251738	TLR8 agonist*	hepatitis B virus
cabotegravir (1265744)	integrase inhibitor (400 mg/ml formulation)	HIV
3739937	maturation inhibitor	HIV
4004280	capsid protein inhibitor	HIV
4011499	capsid protein inhibitor	HIV
4524184	integrase inhibitor*	HIV
3888130	anti-IL7 antibody*	multiple sclerosis
3858279	anti-CCL17 antibody*	osteoarthritis pain
1070806	anti-IL18 antibody	atopic dermatitis
4527226 (AL101)	anti-sortilin antibody*	neurodegenerative diseases
4074386	anti-LAG-3 antibody*	cancer
4381562	anti-PVRIG antibody*	cancer
3745417	STING agonist	cancer
6097608	anti-CD96 antibody*	cancer
XMT-2056[9] (wholly owned by Mersana Therapeutics)	STING agonist ADC*	cancer
belantamab (2857914)	anti-BCMA antibody*	multiple myeloma[2]
4172239	DNMT1 inhibitor*	sickle cell disease[2]

Phase II – 17 assets

3437949	adjuvanted recombinant protein*	malaria fractional dose
4406371	live, attenuated	MMRV new strain
3536852	GMMA*	Shigella
3528869	viral vector with recombinent protein, adjuvanted*	therapeutic hepatitis B virus[1]**
4023393	recombinant protein, OMV, conjugated vaccine	MenABCWY, 2nd Gen[1]
41 781 16	live, attenuated	varicella, new strain
51 01 956	MAPS*	adult pneumococcal disease, 24-valent
51 01 955	MAPS*	paediatric pneumococcal disease, 24-valent
41 06647	adjuvanted recombinant protein*	human papillomavirus[1]
3036656	leucyl t-RNA synthetase inhibitor*	tuberculosis
sanfetrinem cilexetil (GV1 1 881 9)	serine beta lactamase inhibitor*	tuberculosis
BVL-GSK098	ethionamide booster*	tuberculosis
VIR-2482	neutralising monoclonal antibody*[3]	influenza
381 01 09	broadly neutralising antibody*	HIV
Benlysta (belimumab)	anti-BLys antibody	systemic sclerosis associated interstitial lung disease[4]
belrestotug (4428859)	anti-TIGIT antibody*	non-small cell lung cancer
4532990	HSD1 7B1 3 siRNA*	non-alcoholic steatohepatitis

*In-license or other alliance relationship with third party ** Additional indications or candidates also under investigation ^ In registration

1. In Phase I/II study 2. Imminent study start 3. GSK has exclusive option to co-develop post Phase II 4. Phase II/III study start expected in 2023 5. Phase III study start expected in 2023 6. Phase III trial in patients with progranulin gene mutation 7. Approved in US and Japan 8. Transition activities underway to enable further progression by partner 9. GSK has an exclusive global license option to co-develop and commercialise the candidate 10. Collaboration with SK Bioscience, approved in Korea and UK

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
Oncology
Opportunity driven

68 potential new vaccines and medicines in pipeline

Phase III / Registration – 17 assets

RSV vaccine - (3844766)	adjuvanted recombinant protein*	RSV older adults^
SKYCovione (COVID-19 vaccine)	recombinant protein nanoparticle, adjuvanted*[10]	COVID-19^
gepotidacin (2140944)	BTI inhibitor*	uncomplicated UTI**
bepirovirsen (3228836)	antisense oligonucleotide*	hepatitis B virus**
Bexsero (Men B vaccine)	recombinant protein	meningitis B
MenABCWY vaccine (3536819)	recombinant protein, OMV, conjugated vaccine	MenABCWY, 1st Gen
tebipenem pivoxil (3778712)	antibacterial carbapenem*	complicated UTI[5]
Nucala (mepolizumab)	anti-IL5 antibody	COPD
depemokimab (3511294)	long-acting anti-IL5 antibody*	asthma**
latozinemab (4527223)	anti-sortilin antibody*	frontotemporal dementia[6]**
momelotinib (3070785)	JAK1, JAK2 and ACVR1 inhibitor*	myelofibrosis^
Jemperli (dostarlimab)	anti-PD-1 antibody*	endometrial cancer**
Zejula (niraparib)	PARP inhibitor*	ovarian cancer**
Blenrep (belantamab mafodotin)	anti-BCMA ADC*	multiple myeloma
cobolimab (4069889)	anti-TIM-3 antibody*	non-small cell lung cancer
daprodustat (1278863)	prolyl hydroxylase inhibitor	anaemia of chronic kidney disease^[7]
linerixibat (2330672)	IBAT inhibitor	cholestatic pruritus in primary biliary cholangitis

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1. In Phase I/II study 2. Imminent study start 3. GSK has exclusive option to co-develop post Phase II 4. Phase II/III study start expected in 2023 5. Phase III study start expected in 2023 6. Phase III trial in patients with progranulin gene mutation 7. Approved in US and Japan 8. Transition activities underway to enable further progression by partner 9. GSK has an exclusive global license option to co-develop and commercialise the candidate 10. Collaboration with SK Bioscience, approved in Korea and UK

Infectious diseases pipeline

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
Oncology
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Phase I – 18 assets

2904545	adjuvanted recombinant protein*	*C. difficile*
4429016	adjuvanted bioconjugated, recombinant protein*	*K. pneumoniae*
3993129	adjuvanted recombinant subunit	cytomegalovirus[1]
4382276	mRNA*	seasonal flu
4396687	mRNA*	COVID-19
4077164	bivalent GMMA*	invasive non-typhoidal salmonella**
3943104	adjuvanted recombinant protein*	therapeutic herpes simplex virus[1]
4348413	GMMA	gonorrhea[1]
3536867	bivalent conjugate*	salmonella (*typhoid + paratyphoid A*)
2556286	Mtb cholesterol dependent inhibitor*	tuberculosis
3186899	CRK-12 inhibitor*[8]	visceral leishmaniasis
3494245	proteasome inhibitor*	visceral leishmaniasis
3772701	*P. falciparum* whole cell inhibitor*	malaria
3882347	FimH antagonist*	uncomplicated UTI
3923868	PI4K beta inhibitor	viral COPD exacerbations
4182137 (VIR-7832)	anti-spike protein antibody*	COVID-19[1]
3965193	PAPD5/PAPD7 inhibitor	hepatitis B virus
5251738	TLR8 agonist*	hepatitis B virus

Phase II - 13 assets

3437949	adjuvanted recombinant protein*	malaria fractional dose
4406371	live, attenuated	MMRV new strain
3536852	GMMA*	Shigella
3528869	viral vector with recombinent protein, adjuvanted*	therapeutic hepatitis B virus[1]**
4023393	recombinant protein, OMV, conjugated vaccine	MenABCWY, 2nd Gen[1]
4178116	live, attenuated	varicella, new strain
5101956	MAPS*	adult pneumococcal disease, 24-valent
5101955	MAPS*	paediatric pneumococcal disease, 24-
4106647	adjuvanted recombinant protein*	human papillomavirus[1]
3036656	leucyl t-RNA synthetase inhibitor*	tuberculosis
sanfetrinem cilexetil (GV118819)	serine beta lactamase inhibitor*	tuberculosis
BVL-GSK098	ethionamide booster*	tuberculosis
VIR-2482	neutralising monoclonal antibody*[3]	influenza

Phase III & Registration - 7 assets

RSV vaccine - (3844766)	adjuvanted recombinant protein*	RSV older adults^
SKYCovione (COVID-19 vaccine)	recombinant protein nanoparticle, adjuvanted*[10]	COVID-19^
gepotidacin (2140944)	BTI inhibitor*	uncomplicated UTI**
bepirovirsen (3228836)	antisense oligonucleotide*	hepatitis B virus**
Bexsero (Men B vaccine)	recombinant protein	meningitis B
MenABCWY vaccine (3536819)	recombinant protein, OMV, conjugated vaccine	MenABCWY, 1st Gen
tebipenem pivoxil (3778712)	antibacterial carbapenem*	complicated UTI[5]

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1. In Phase I/II study 3. GSK has exclusive option to co-develop post Phase II 5. Phase III study start expected in 2023 10. Collaboration with SK Bioscience, approved in Korea and UK

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
Oncology
Opportunity driven

HIV pipeline

Phase I – 5 assets

cabotegravir (1265744)	integrase inhibitor (400 mg/ml formulation)	HIV
3739937	maturation inhibitor	HIV
4004280	capsid protein inhibitor	HIV
4011499	capsid protein inhibitor	HIV
4524184	integrase inhibitor*	HIV

Phase II - 1 asset

3810109	broadly neutralising antibody*	HIV

*In-license or other alliance relationship with third party

Immunology / Respiratory pipeline

Phase I – 4 assets

3888130	anti-IL7 antibody*	multiple sclerosis
3858279	anti-CCL17 antibody*	osteoarthritis pain
1070806	anti-IL18 antibody	atopic dermatitis
4527226 (AL101)	anti-sortilin antibody*	neurodegenerative diseases

Phase II - 1 asset

Benlysta (belimumab)	anti-BLys antibody	systemic sclerosis associated interstitial lung disease[4]

Phase III - 3 assets

Nucala (mepolizumab)	anti-IL5 antibody	COPD
depemokimab (3511294)	long-acting anti-IL5 antibody*	asthma**
latozinemab (4527223)	anti-sortilin antibody*	frontotemporal dementia[6]**

*In-license or other alliance relationship with third party ** Additional indications or candidates also under investigation
4. Phase II/III study start expected in 2023 6. Phase III trial in patients with progranulin gene mutation

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
Oncology
Opportunity driven

Oncology pipeline

Phase I – 6 assets

4074386	anti-LAG-3 antibody*	cancer
4381562	anti-PVRIG antibody*	cancer
3745417	STING agonist	cancer
6097608	anti-CD96 antibody*	cancer
XMT-2056[9] (wholly owned by Mersana	STING agonist ADC*	cancer
belantamab (2857914)	anti-BCMA antibody*	multiple myeloma[2]

Phase II - 1 asset

belrestotug (4428859)	anti-TIGIT antibody*	non-small cell lung cancer

Phase III / Registration - 5 assets

momelotinib (3070785)	JAK1, JAK2 and ACVR1 inhibitor*	myelofibrosis^
Jemperli (dostarlimab)	anti-PD-1 antibody*	endometrial cancer**
Zejula (niraparib)	PARP inhibitor*	ovarian cancer**
Blenrep (belantamab mafodotin)	anti-BCMA ADC*	multiple myeloma
cobolimab (4069889)	anti-TIM-3 antibody*	non-small cell lung cancer

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2. Imminent study start 9. GSK has an exclusive global license option to co-develop and commercialise the candidate

Opportunity driven pipeline

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
Oncology
Opportunity driven

Phase I – 1 asset

4172239	DNMT1 inhibitor*	sickle cell disease[2]

Phase II - 1 asset

4532990	HSD17B13 siRNA*	non-alcoholic steatohepatitis

Phase III / Registration - 2 assets

daprodustat (1278863)	prolyl hydroxylase inhibitor	anaemia of chronic kidney disease^[7]
linerixibat (2330672)	IBAT inhibitor	cholestatic pruritus in primary biliary cholangitis

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2. Imminent study start 7. Approved in US and Japan

Q1 2023 changes since 2022

Phase II
Phase III

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
Oncology
Opportunity driven

Changes on pipeline

New to Phase I

belantamab - anti-BCMA antibody - multiple myeloma

Removed from Phase II

3640254 - maturation inhibitor - HIV

Removed from Registration

Xevudy - anti-spike protein antibody - COVID-19*

Achieved pipeline catalysts

Regulatory submission & acceptances

Nucala - severe asthma	CN
Jemperli - RUBY dMMR/MSI-H 1L endometrial cancer	EU

Regulatory decision

Jesduvroq - ASCEND, anaemia of CKD	US
Jemperli - GARNET dMMR recurrent or advanced endometrial cancer**	US

Late stage readouts

- MenABCWY vaccine
- *Benlysta* - SLE paediatrics subcut administration (registrational Phase II)

Other events

- *Jemperli* dMMR/MSI-H locally advanced rectal cancer^
- *Jemperli* RUBY 1L endometrial cancer - Phase III data presentation
- gepotidacin EAGLE-2/3 uUTI - Phase III data presentation
- RSV older adults vaccine => 60YoA - US FDA Advisory Committee vote

GSK

* Marketed product in EU ** conversion to full approval ^ US FDA Advisory Committee voted to support Phase II trial design

Upcoming pipeline catalysts: 2023 and 2024

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
Oncology
Opportunity driven

	H1 2023		H2 2023		2024	
Regulatory decision	RSV older adults vaccine – ≥60 YoA	US	RSV older adults vaccine – ≥60 YoA	EU, JP	RSV older adults vaccine – 50-59 YoA	US, EU, JP
	Shingrix – 18+ at increased risk of HZ	JP	*SKYCovione* COVID-19 vaccine	EU[2]	gepotidacin – EAGLE-2/3, uUTI	US, EU
	momelotinib – MOMENTUM, myelofibrosis	US	cabotegravir (long-acting) pre-exposure	EU	*Nucala* – severe asthma	CN
	daprodustat – ASCEND, anaemia of CKD	EU	*Vocabria* – HIV treatment	CN	*Nucala* – nasal polyposis	JP
			Jemperli[1] – RUBY, 1L endometrial cancer‡	US	*Jemperli*[1] – RUBY, 1L dMMR/MSI-H endometrial cancer	EU
					Blenrep – DREAMM-7, 2L+ multiple myeloma	US, EU
					Blenrep – DREAMM-8, 2L+ multiple myeloma	US, EU
					momelotinib – MOMENTUM, myelofibrosis	EU
Regulatory submission & acceptance	gepotidacin – EAGLE-2/3, uUTI	US	RSV older adults vaccine – 50-59 YoA	US, EU, JP	gepotidacin – EAGLE-2/3, uUTI	JP
	Jemperli[1] – RUBY, 1L endometrial cancer	US	gepotidacin – EAGLE-2/3, uUTI	EU	gepotidacin – EAGLE-1, GC	US
			Nucala – nasal polyposis	CN, JP	MenABCWY vaccine 1st Gen	US
			Blenrep – DREAMM-7, 2L+ multiple myeloma	US, EU	*Nucala* – MATINEE, COPD	US, EU, CN, JP
			Blenrep – DREAMM-8, 2L+ multiple myeloma	US, EU	linerixibat – GLISTEN, cholestatic pruritus in PBC	US, EU
					Jemperli[1] - RUBY part 2, IL endometrial cancer	US, EU
Late stage readouts – *Phase III*			gepotidacin – EAGLE-1, GC		*Nucala* – MATINEE, COPD	
			RSV older adults vaccine – 50-59 YoA		*Zejula*[1] – ZEAL, 1L maintenance NSCLC	
			Blenrep – DREAMM-7, 2L+ multiple myeloma		cobolimab[1] – COSTAR, NSCLC	
			Blenrep – DREAMM-8, 2L+ multiple myeloma		linerixibat – GLISTEN, cholestatic pruritus in PBC	
			Zejula[1] – FIRST, 1L maintenance ovarian cancer		*Jemperli*[1] - RUBY part 2, IL endometrial cancer	
Late stage readouts – *Phase II*			bepirovirsen – B-TOGETHER, HBV			
			MenABCWY vaccine 2nd gen			

1. Tesaro asset 2. Approved in South Korea and United Kingdom ‡ date subject to FDA priority review

Designations in our pipeline

Infectious Diseases
HIV (ViiV)
Immunology / Respiratory
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Opportunity driven

Accelerated Assessment — 1

RSV vaccine (3844766)	adjuvanted recombinant protein*	RSV older adults^

Breakthrough Designation — 1

5101956	MAPS*	adult pneumococcal disease, 24-valent

Orphan Drug Designation — 4

Benlysta (belimumab) US	anti-BLys antibody	systemic sclerosis associated interstitial lung
momelotinib (3070785) US, EU	JAK1, JAK2 and ACVR1 inhibitor*	myelofibrosis^
linerixibat (2330672) US, EU	IBAT inhibitor	cholestatic pruritus in primary biliary
latozinemab (4527223) US, EU	anti-sortilin antibody*	frontotemporal dementia[6]**

Fast Track — 8

Jemperli (dostarlimab)	anti-PD-1 antibody*	endometrial cancer**
Jemperli (dostarlimab)	anti-PD-1 antibody*	locally advanced dMMR/MSI-H rectal cancer
RSV vaccine (3844766)	adjuvanted recombinant protein*	RSV older adults^
BVL-GSK098	ethionamide booster	tuberculosis
4348413	GMMA	gonorrhea[1]
gepotidacin	BTI inhibitor*	GC
latozinemab (4527223)	anti-sortilin antibody*	frontotemporal dementia[6]**
4172239	DNMT1 inhibitor*	sickle cell disease[2]

Priority Review — 1

RSV vaccine (3844766)	adjuvanted recombinant protein*	RSV older adults^

ACCELERATED ASSESSMENT (EU): – If granted EMA will accelerate the review timelines of the marketing authorisation application for products expected to be of major public health interest, particularly from the point of view of therapeutic innovation.

BREAKTHROUGH DESIGNATION (US) – a process designed to expedite the development and review of medicines intended to treat serious condition, where preliminary clinical evidence indicates the drug may demonstrate substantial improvement over available therapy

FAST TRACK (US) – a program designed to facilitate the expedited development and review of medicines to treat serious conditions and fill an unmet medical need

PRIORITY REVIEW (US) – the US FDA's goal to take action on an application within 6 months (compared to 10 months under standard review)

OPHAN DRUG DESIGNATION – intended for treatment, diagnosis or prevention of rare disease/disorders that affect fewer than 200,000 patients in the US, or not more than 5 in 10,000 in the EU or that affect more than this number of patients but are not expected to recover the costs of developing and marketing a treatment drug

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Clinical Trials

Infectious Diseases

Infectious diseases

gepotidacin (GC)

NCT04010539 - EAGLE 1

Phase	III
Patient	Uncomplicated urogenital gonorrhea infection caused by *Neisseria gonorrhoeae*
Subjects	620
Treatment arms	**Arm A:** 2 X 3000 mg gepotidacin for one day **Arm B:** ceftriaxone (500mg IM), 1g azithromycin
Description	A Phase III randomised, multicenter, open-label study in adolescent and adult participants comparing the efficacy and safety of gepotidacin to ceftriaxone plus azithromycin
Timing start	Oct-19
Key end points	Number of participants with culture-confirmed bacterial eradication 4-8 days post treatment
Clinicaltrials.gov	Link

Infectious diseases

gepotidacin (uUTI)

NCT04020341 - EAGLE 2

Phase	III
Patient	Females with uUTI / acute cystitis
Subjects	1531
Treatment arms	**Arm A:** 1500mg BID gepotidiacin + placebo x 5days **Arm B:** 100mg BID nitrofurantoin + placebo x 5days
Description	A Phase III randomised, multicenter, parallel-group, double-blind, double-dummy study in adolescent and adult female participants comparing the efficacy and safety of gepotidacin to nitrofurantoin
Timing start	Oct-19 - Reported Nov-22
Key end points	Number of participants with therapeutic response (combined per participant clinical and microbiological response)
Clinicaltrials.gov	Link

NCT04187144 - EAGLE 3

Phase	III
Patient	Females with uUTI / acute cystitis
Subjects	1606
Treatment arms	**Arm A:** 1500mg BID gepotidiacin + placebo x 5days **Arm B:** 100mg BID nitrofurantoin + placebo x 5days
Description	A Phase III randomised, multicenter, parallel-group, double-blind, double-dummy study in adolescent and adult female participants comparing the efficacy and safety of gepotidacin to nitrofurantoin
Timing start	Apr-20 - Reported Nov-22
Key end points	Number of participants with therapeutic response (combined per participant clinical and microbiological response)
Clinicaltrials.gov	Link

Infectious diseases

bepirovirsen

NCT04676724 - B-TOGETHER

Phase	IIb
Patient	Patients with chronic hepatitis B virus
Subjects	100
Treatment arms	**Arm A:** bepirovirsen for 12 wks + PegIFN for =< 24 wks **Arm B:** bepirovirsen for 24 weeks + PegIFN =< 24 wks
Description	A Phase IIb multicenter, randomised, open label study to assess the efficacy and safety of sequential treatment with GSK3228836 followed by pegylated interferon alpha 2a
Timing start	Jan-21
Key end points	Sustained response for 24 weeks post treatment
Clinicaltrials.gov	Link

NCT05630807 - B-WELL 1

Phase	III
Patient	Nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	534
Treatment arms	**Arm A:** bepirovirsen for 24 weeks **Arm B:** placebo
Description	Phase III multicenter, randomised, double blind study to confirm the efficacy and safety of treatment with bepirovirsen
Timing start	Jan-23
Key end points	Number of participants achieving functional cure (FC) with baseline HBsAg≤ 3000IU/mL
Clinicaltrials.gov	Link

Infectious diseases

bepirovirsen

NCT05630820 - B-WELL 2

Phase	III
Patient	Nucleos(t)ide analogue treated patients with chronic hepatitis B Virus
Subjects	534
Treatment arms	**Arm A:** double-blind treatment of bepirovirsen for 24 weeks **Arm B:** placebo
Description	Phase III multicenter, randomised, double blind study to confirm the efficacy and safety of treatment with bepirovirsen
Timing start	Jan-23
Key end points	Number of participants achieving functional cure (FC) with baseline HBsAg ≤3000 IU/mL
Clinicaltrials.gov	Link

NCT04449029 - B-CLEAR

Phase	IIb
Patient	Patients with chronic hepatitis B virus
Subjects	457
Treatment arms: not on nucleos(t)ide treatment	**Arm A:** bepirovirsen 300 mg w/LD **Arm B:** bepirovirsen 300mg w/LD, bepi 150mg **Arm C:** bepirovirsen 300 mg, placebo **Arm D:** placebo, bepirovirsen 300 mg
Treatment arms: receiving stable nucleos(t)ide treatment	**Arm A:** bepirovirsen 300 mg **Arm B:** bepirovirsen 300mg, bepi 150 mg **Arm C:** bepirovirsen 300 mg, placebo **Arm D:** placebo, bepirovirsen 300 mg
Description	Phase IIb multicenter, randomised, partial-blind parallel cohort study to assess the efficacy and safety of treatment with GSK3228836
Timing start	Jul-20 - Reported Mar-22
Key end points	Sustained response for 24 weeks post treatment
Clinicaltrials.gov	Link

Infectious diseases

GSK3228836

NCT05276297

Phase	II
Patient	Nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	184
Treatment arms	**Arm A:** bepirovirsen for 24w, followed by targeted immunotherapy **Arm B:** bepirovirsen for 24w, followed by PBO **Arm C:** bepirovirsen for 12w, followed by targeted immunotherapy **Arm D:** bepirovirsen for 12w, followed by PBO
Description	A Phase II single-blinded, randomised, controlled multi-country study to evaluate the safety, reactogenicity, efficacy and immune response following sequential treatment with an ASO against chronic hepatitis B (CHB) followed by CHB targeted immunotherapy (CHB-TI)
Timing start	Mar-22
Key end points	Percentage of participants reporting any grade 3 AE, SVR
Clinicaltrials.gov	Link

Infectious diseases

RSV Older Adults

NCT04732871 - RSV OA-004

Phase	III
Patient	Adults ≥60 years of age
Subjects	1653
Treatment arms	**Arm A:** RSVPreF3 OA Day 1, 12 months & 24 months **Arm B:** RSVPreF3 OA Day 1 and 24 months **Arm C:** RSVPreF3 OA Day 1 then follow up
Description	A Phase III randomised, open-label, multi-country study to evaluate the immunogenicity, safety, reactogenicity and persistence of a single dose of the RSVPreF3 OA investigational vaccine and different revaccination schedules
Timing start	Feb-21
Key end points	Humoral immune response following a 1 dose primary schedule up to 12 months post dose 1
Clinicaltrials.gov	Link

NCT04886596 - RSV OA-006

Phase	III
Patient	Adults ≥60 years of age
Subjects	24,966
Treatment arms	**Arm A:** RSVPreF3 OA Lot 1 **Arm B:** RSVPreF3 OA Lot 2 **Arm C:** RSVPreF3 OA Lot 3 **Arm D:** RSVPreF3 OA Lot 4 **Arm E:** Placebo
Description	A Phase III randomised, placebo-controlled, observer-blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination doses of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above
Timing start	May-21 - Reported - Oct-22
Key end points	Efficacy of a single dose and annual revaccination doses of RSVPreF3 OA vaccine in the prevention of RSV-LRTD in adults ≥ 60
Clinicaltrials.gov	Link

Infectious diseases

RSV Older Adults

NCT04841577 - RSV OA-007

Phase	III
Patient	Adults ≥60 years of age
Subjects	885
Treatment arms	**Arm A: 1 dose of** RSVPreF3 OA + 1 dose of FLU-QIV on Day 1 **Arm B: 1 dose of** FLU-QIV on Day 1, 1 dose of RSVPreF3 OA on Day 31
Description	A Phase III open-label, randomised, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU-QIV vaccine
Timing start	Apr-21
Key end points	Humoral immune response 1 month post vaccination upon co-administration compared to the immune response when vaccine is administered alone
Clinicaltrials.gov	Link

NCT05559476 - RSV OA-008

Phase	III
Patient	Adults aged 65 years and above
Subjects	1028
Treatment arms	**Arm A: 1 dose of** RSVPreF3 OA + 1 dose of Flu-HD on day 1 **Arm B: 1 dose of** Flu HD on Day 1 ,1 dose of RSVPreF3 OA on Day 31
Description	A Phase III open-label, randomised, controlled, multicountry study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU HD vaccine
Timing start	Oct-22
Key end points	Humoral immune response 1 month post vaccination upon co-administration compared to the immune response when vaccine is administered alone
Clinicaltrials.gov	Link

Infectious diseases

RSV Older Adults

NCT05059301 - RSV OA-009

Phase	III
Patient	Adults aged 60 years and above
Subjects	770
Treatment arms	**Arm A:** 1 dose of a combination of the RSVPreF3 antigen Lot 1 and AS01E adjuvant Lot A at day 1 **Arm B:** 1 dose of a combination of the RSVPreF3 antigen Lot 2 and AS01E adjuvant Lot B at day 1 **Arm C:** 1 dose of a combination of the RSVPreF3 antigen Lot 3 and AS01E adjuvant Lot C at Day 1
Description	A Phase III randomised, double-blind, multi-country study to evaluate consistency, safety and reactogenicity of 3 lots of RSVPreF3 OA investigational vaccine administrated as a single dose in adults 60 years and older
Timing start	Oct-21
Key end points	RSVPreF3 Specific Immunoglobin (Ig)G antibody concentrations at 1 month post vaccination for three lots of RSVPreF3 OA investigational vaccine
Clinicaltrials.gov	Link

NCT05568797 - RSV OA-017

Phase	III
Patient	Adults aged 60 years and above
Subjects	880
Treatment arms	**Arm A: 1 dose** RSVPreF3 OA investigational vaccine and 1 dose of FLU aQIV vaccine on Day 1 **Arm B:** one dose of Flu aQIV on day 1 and 1 dose of RSVPreF3 OA on day 31
Description	A Phase III open-label, randomised, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of an RSVPreF3 OA investigational vaccine when co-administered with FLU aQIV (inactivated influenza vaccine - adjuvanted)
Timing start	Oct-22
Key end points	Humoral immune response 1 month post vaccination upon co-administration compared to the immune response when vaccine is administered alone
Clinicaltrials.gov	Link

Infectious diseases

RSV Older Adults

NCT05590403 - RSV OA-018

Phase	III
Patient	Adults 50-59 years of age, including adults at increased risk of respiratory syncytial virus lower respiratory tract disease, and older adults ≥60 years of age
Subjects	1520
Treatment arms	**Arm A:** adults HA-RSVPreF3 OA Group **Arm B:** adults HA-Placebo Group **Arm C:** adults AIR-RSVPReF3 OA Group **Arm D:** adults AIR-Placebo Group **Arm E:** OA-RSVPReF3 OA Group ≥60 years of age
Description	A Phase III observer-blind, randomised, placebo-controlled study to evaluate the non-inferiority of the immune response and safety of the RSVPreF3 OA investigational vaccine
Timing start	Oct-22
Key end points	Humoral immune response in healthy participants 50-59 yoa and in participants 50-59 YOA at increased risk of RSV-LRTD compared to OA (≥ 60 yoa)
Clinicaltrials.gov	Link

Infectious diseases

MenABCWY

NCT04707391 - MenABCWY-019

Phase	III
Patient	Aged 15-25 years
Subjects	1206
Treatment arms	**Arm A:** 2 doses of MenABCWY days 1, 181 + placebo day 211 **Arm B:** 1 dose MenABCWY day 1; 2 doses of MenB on Day 181 and Day 211
Description	A Phase IIIb randomised, controlled, observer-blind study to evaluate safety and immunogenicity of GSK's Meningococcal ABCWY vaccine when administered in healthy adolescents and adults previously primed with meningococcal ACWY vaccine
Timing start	Jan-21
Key end points	hSBA titres
Clinicaltrials.gov	Link

NCT04502693 - MenABCWY V72 72

Phase	III
Patient	Aged 10-25 years
Subjects	3657
Treatment arms	**Arm A:** rMenB+OMV NZ (2/3 dose schedule) plus MenACWY **Arm B:** rMenB+OMV NZ (2 dose schedule) plus MenACWY plus placebo **Arm C:** placebo + MenABCWY lot 1 **Arm D:** placebo + MenABCWY lot 2 **Arm E:** placebo + MenABCWY lot 3 **Arm F:** rMenB+OMV NZ + MenACWY + placebo
Description	Effectiveness of GlaxoSmithKline Biologicals S.A.'s Meningococcal Group B and combined ABCWY vaccines in healthy adolescents and young adults
Timing start	Aug-20 - Reported - Mar-23
Key end points	Bactericidal activity
Clinicaltrials.gov	Link

Infectious diseases

MenABCWY

NCT05087056 - MenABCWY-020

Phase	II
Patient	Healthy adolescents
Subjects	300
Treatment arms	**Arm A:** ABCWY-24 Group **Arm B:** ABCWY-48 Group
Description	A Phase IIb randomised, observer-blind study to describe the safety, tolerability and immunogenicity of MenABCWY administered on different dosing schedules
Timing start	Dec-21
Key end points	hSBA titers ≥ LLOQ of each *N.meningitidis* serogroup B indicator strains
Clinicaltrials.gov	Link

Infectious diseases

Varicella New Strain

NCT05084508 - Varicella NS

Phase	II
Patient	Healthy children between 12 - 15 months
Subjects	800
Treatment arms	**Arm A:** low potency varicella NS vaccine, plus routine schedule **Arm B:** medium potency varicella NS vaccine, plus routine schedule **Arm C:** high potency varicella NS vaccine, plus routine schedule **Arm D:** marketed varicella vaccine lot 1, plus routine schedule **Arm E:** marketed varicella vaccine lot 2, plus routine schedule
Description	A Phase II observer-blind, randomised, controlled study to evaluate the immunogenicity and safety of a varicella vaccine at various potencies compared with Varivax as a first dose, administered in healthy children in their second year of life
Timing start	Oct-21
Key end points	Anti-glycoprotein-E antibodies at day 43
Clinicaltrials.gov	Link

Infectious diseases

AFX3772

NCT05412030

Phase	II
Patient	Healthy infants
Subjects	121
Treatment arms	**Arm A:** 1 mcg AFX3772 administered intramuscularly 4 times within 12 months **Arm B:** 2 mcg AFX3772 administered intramuscularly 4 times within 12 months **Arm C:** 5 mcg AFX3772 administered intramuscularly 4 times within 12 months **Arm D:** PCV13 administered intramuscularly 4 times within 12 months
Description	A Phase II randomised, double-blind, multi-dose, dose finding study to evaluate the safety, tolerability and immunogenicity of AFX3772 compared with PCV13
Timing start	Jun-22
Key end points	Safety, tolerability profiles of 3 different dose levels of AFX3772 compared with PCV13 with respect to the proportion of participants with Aes
Clinicaltrials.gov	Link

Infectious diseases

Bexsero

NCT04415424

Phase	III
Patient	Gay and bisexual men
Subjects	730
Treatment arms	**Arm A:** 4CMenB vaccine **Arm B:** placebo
Description	A multicentre randomised controlled trial evaluating the efficacy of the four-component Meningococcal B vaccine 4CMenB (Bexsero®) in the prevention of *N. gonorrhoeae* infection
Timing start	Jul-21
Key end points	Whether the 4CMenB vaccine, when administered in a 2-dose regimen at 0 and 3 months, changes the incidence of the first episode of *N. gonorrhoeae*
Clinicaltrials.gov	Link

NCT04350138

Phase	II
Patient	Men and women 18-50 years of age who are disproportionately vulnerable to N. gonorrhoeae infection
Subjects	2200
Treatment arms	**Arm A:** 4CMenB vaccine **Arm B:** placebo
Description	A Phase II randomised, observer-blind, placebo-controlled study to assess the efficacy of Meningococcal Group B Vaccine rMenB+OMV NZ (Bexsero) in preventing gonococcal infection
Timing start	Dec-20
Key end points	Number of participants diagnosed with urogenital or anorectal gonococcal infection post second vaccination
Clinicaltrials.gov	Link

Infectious diseases

Bexsero

NCT03621670 - V72_57

Phase	III
Patient	North American infants 6 weeks through 12 weeks of age
Subjects	1200
Treatment arms	**Arm A:** MenB+PCV Group **Arm B:** Placebo+PCV Group
Description	Safety and immunogenicity of GSK Meningococcal Group B Vaccine and 13-valent pneumococcal vaccine administered concomitantly with routine infant vaccines to healthy infants
Timing start	Dec-20
Key end points	% subjects with solicited local and systemic AEs and % subjects with hSBA antibody titers ≥ LLOQ for each of the M14459, 96217, NZ98/254 and M13520 test strains
Clinicaltrials.gov	Link

NCT04318548 - V72_79

Phase	III
Patient	Healthy adolescents and young adults 16-18 years of age
Subjects	945
Treatment arms	**Arm A:** MenB+MenACWY Group **Arm B:** MenB Group **Arm C:** MenACWY Group
Description	A Phase IIIb randomised, observer-blind, multicenter study to assess the safety and immunogenicity of GSK's Meningococcal Group B Vaccine when administered concomitantly with GSK's Meningococcal MenACWY conjugate vaccine
Timing start	Aug-20
Key end points	Subjects with solicited local AEs, solicited systemic AEs and unsolicited AEs, SAEs
Clinicaltrials.gov	Link

Infectious diseases

Bexsero

NCT04502693 - V72_72

Phase	III
Patient	Healthy adolescents and young adults 16-18 years of age
Subjects	3657
Treatment arms	**Arm A:** MenB_0_2_6 Group **Arm B:** MenB_0_6 Group **Arm C:** ABCWY lot 1 Group **Arm D:** ABCWY lot 2 Group **Arm E:** ABCWY lot 3 Group **Arm F:** ACWY Group (comparator)
Description	A Phase III randomised, controlled, observer-blind study to demonstrate effectiveness, immunogenicity and safety of GSK's Meningococcal Group B and combined ABCWY vaccines when administered to healthy adolescents and young adults MenACWY conjugate vaccine
Timing start	Aug-20
Key end points	Effectiveness of 2 or 3 doses of GSK's licenced meningococcal group B Bexsero (rMenB+OMV NZ) vaccine and of 2 doses of GSK's investigational combined meningococcal (MenABCWY) vaccine (GSK3536819A), immunogenicity, safety
Clinicaltrials.gov	Link

HIV

HIV

Cabotegravir - PrEP

NCT02720094 - HPTN 083

Phase	III
Patient	Pre-exposure prophylaxis in HIV-uninfected cisgender men & transgender women who have sex with men
Subjects	4570
Treatment arms	**Arm A** **Step 1:** cabotegravir + TDF/FTC daily for 5 weeks **Step 2:** CAB LA + placebo daily to week 153 **Step 3:** oral TDF/FTC daily from week 153 for 48weeks **Arm B** **Step 1:** oral TDF/FTC + oral CAB placebo for 5 weeks **Step 2:** oral TDF/FTC + CAB LA placebo to week 153 **Step 3:** oral TDF/FTC
Description	A Phase IIb/III double blind safety and efficacy study of injectable cabotegravir compared to daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC)
Timing start	Dec-16 - Reported - May 20
Key end points	HIV infections
Clinicaltrials.gov	Link

NCT03164564 - HPTN 084

Phase	III
Patient	HIV uninfected women who are at high risk of acquiring HIV
Subjects	3224
Treatment arms	**Arm A** **Step 1:** oral cabotegravir + oral TDF/FTC for 5 weeks **Step 2:** two CAB injections four weeks apart and every 8 weeks and oral placebo from week 5 **Step 3:** daily TDF/FTC for up to 48 weeks, starting within 8 weeks of the last injection **Arm B** **Step 1:** daily TDF/FTC and oral placebo for 5 weeks **Step 2:** daily TDF/FTC + placebo injections four weeks apart and every 8 weeks **Step 3:** daily TDF/FTC up to 48 weeks starting within 8 weeks of the last injection
Description	A Phase III double blind safety and efficacy study of long-acting injectable cabotegravir compared to daily oral TDF/FTC for pre-exposure prophylaxis in HIV-uninfected women
Timing start	Nov-17 - Reported - May 20
Key end points	HIV infections
Clinicaltrials.gov	Link

HIV

Cabotegravir - treatment

NCT02951052 - ATLAS

Phase	III
Patient	HIV-1-infected adults who are virologically suppressed
Subjects	618
Treatment arms	**Arm A:** CAB LA + RPV LA every 4 weeks **Arm B**: current antiretroviral regimen
Description	A Phase III randomised, multicenter, parallel-group, non-inferiority, open-label study 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
Timing start	Oct-16 - Reported - Aug 18
Key end points	Virologic failure endpoint (HIV-1 RNA>=50 c/mL) as per FDA snapshot algorithm at week 48
Clinicaltrials.gov	Link

NCT03299049 - ATLAS-2M

Phase	III
Patient	HIV-1-infected adults who are virologically suppressed
Subjects	1049
Treatment arms	**Arm A:** group 1 receiving study treatment once in 4 weeks **Arm B:** group 1 receiving study treatment once in 8 weeks **Arm C:** group 2 receiving study treatment once in 4 weeks **Arm D:** group 2 receiving study treatment once in 8 weeks
Description	A Phase III randomised, multicenter, parallel-group, non-inferiority, open-label study evaluating the efficacy, safety and tolerability of long-acting cabotegravir plus long-acting rilpivirine administered every 8 weeks or every 4 weeks
Timing start	Oct-17 - Reported - Aug 18
Key end points	Plasma HIV-RNA >=50 Copies Per Milliliter (c/mL) as per FDA snapshot algorithm at week 48
Clinicaltrials.gov	Link

HIV

Cabotegravir

NCT02938520 - FLAIR

Phase	III
Patient	HIV-1 infected antiretroviral therapy naive adult participants
Subjects	631
Treatment arms	**Arm A:** CAB LA + RPV LA every 4 weeks **Arm B:** ABC / DTG / 3TC (600 mg/50mg/300mg) once daily
Description	A Phase III randomised, multicenter, parallel-group, open-label study evaluating the efficacy, safety and tolerability of LA intramuscular cabotegravir and rilpivirine for maintenance of virologic suppression following switch from an integrase inhibitor single tablet regimen
Timing start	Oct-16 - Reported - Oct-18
Key end points	Virologic failure using snapshot algorithm at week 48
Clinicaltrials.gov	Link

NCT04542070 - SOLAR

Phase	IIIb
Patient	HIV-1 infected adults who are virologically suppressed
Subjects	688
Treatment arms	**Arm A:** Participants will receive long-acting cabotegravir (CAB LA) + long-acting rilpivirine (RPV LA) regimen **Arm B:** Participants will receive BIK, that is a combination of bictegravir (BIC) + emtricitabine (FTC) + tenofovir alafenamide (TAF)
Description	A Phase IIIb randomised, multicenter, active-controlled, parallel-group, non-inferiority, open-label study evaluating the efficacy, safety and tolerability of switching to long-acting cabotegravir plus long-acting rilpivirine administered every two months from a bictegravir/emtricitabine/tenofovir alafenamide single tablet regimen
Timing start	Nov-20 - Reported - Feb-23
Key end points	Participants with plasma HIV-1 ribonucleic acid (RNA) >= 50 c/mL - OLI at month 12
Clinicaltrials.gov	Link

HIV

GSK3810109

NCT04871113 - B-NAB

Phase	II
Patient	Anti-retroviral naiive HIV-1 infected adults
Subjects	62
Treatment arms	**Part 1** **Cohort 1:** '109A infusion (40mg/kg) **Cohort 2:** '109A infusion (280 mg/kg) **Part 2** **Cohort 3:** '109A IV or SC – dosing determined from part 1 **Cohort 4:** '109A IV or SC – dosing determined from part 1 **Cohort 5:** '109A IV or SC – dosing determined from part 1
Description	A Phase IIa multicentre, randomised, open-label, two part adaptive design study to evaluate the antiviral effect, safety and tolerability of GSK3810109A, an HIV-1 specific broadly neutralizing human monoclonal antibody in antiretroviral-naïve HIV-1-infected adults
Timing start	Jun-21
Key end points	Safety, plasma HIV-1 levels
Clinicaltrials.gov	Link

Immunology/Respiratory

Immunology/Respiratory

depemokimab

NCT04719832 - SWIFT-1

Phase	III
Patient	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype
Subjects	375
Treatment arms	**Arm A:** depemokimab plus SoC **Arm B:** placebo plus SoC
Description	A 52-week, randomised, double-blind, placebo-controlled, parallel-group, multicentre study of the efficacy and safety of GSK3511294 (depemokimab) adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
Timing start	Mar-21
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials.gov	Link

NCT04718103 - SWIFT-2

Phase	III
Patient	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype
Subjects	375
Treatment arms	**Arm A:** depemokimab plus SoC **Arm B:** placebo plus SoC
Description	A 52-week, randomised, double-blind, placebo-controlled, parallel-group, multicentre study of the efficacy and safety of GSK3511294 (depemokimab) adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
Timing start	Mar-21
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials.gov	Link

Immunology/Respiratory

depemokimab

NCT05243680 - AGILE

Phase	III
Patient	Adult and adolescents with severe asthma with an eosinophilic phenotype from studies SWIFT-1 and SWIFT-2
Subjects	637
Treatment arms	**Arm A:** participants diagnosed with asthma receiving GSK3511294 (depemokimab)
Description	A multicentre, single arm, open-label extension study to evaluate the long-term safety of GSK3511294 (depemokimab)
Timing start	Mar-22
Key end points	No. of participants with adverse events (AEs) and serious adverse events (SAEs) and incidence of immunogenicity over 52 weeks
Clinicaltrials.gov	Link

NCT04718389 - NIMBLE

Phase	III
Patient	Adult and adolescent severe asthmatics with an Eosinophilic Phenotype treated with GSK3511294 compared with mepolizumab or benralizumab
Subjects	1700
Treatment arms	**Arm A:** participants receiving GSK3511294 (depemokimab) plus placebo matching prior anti-IL-5/5R treatment **Arm B:** participants receiving prior anti-IL-5/5R treatment plus placebo matching GSK3511294 (depemokimab)
Description	A 52-week randomised, double-blind, double-dummy, parallel group, multicentre, non-inferiority study assessing exacerbation rate, additional measures of asthma control and safety
Timing start	Jan-21
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials.gov	Link

Immunology/Respiratory

depemokimab

NCT05274750 - ANCHOR-1

Phase	III
Patient	Chronic Rhinosinusitis With Nasal Polyps (CRSwNP) - ANCHOR-1
Subjects	250
Treatment arms	**Arm A:** depemokimab (GSK3511294) **Arm B:** placebo
Description	Randomised double-blind, parallel group Phase III study to assess the efficacy and safety of 100 mg SC depemokimab
Timing start	Apr-22
Key end points	Change from baseline in total endoscopic nasal polyps (NP) score at week 52 Change from Baseline in mean nasal obstruction visual analogue scale (VAS) score (scores on a scale)
Clinicaltrials.gov	Link

NCT05281523 - ANCHOR-2

Phase	III
Patient	Chronic Rhinosinusitis With Nasal Polyps (CRSwNP) - ANCHOR-2
Subjects	250
Treatment arms	**Arm A:** depemokimab (GSK3511294) **Arm B:** placebo
Description	Randomised double-blind, parallel group Phase III study to assess the efficacy and safety of 100 mg SC depemokimab
Timing start	Apr-22
Key end points	Change from baseline in total endoscopic nasal polyps (NP) score at week 52 Change from Baseline in mean nasal obstruction visual analogue scale (VAS) score (scores on a scale)
Clinicaltrials.gov	Link

Immunology/Respiratory

depemokimab

NCT05263934 - OCEAN

Phase	III
Patient	Adults with relapsing or refractory EGPA receiving SoC therapy
Subjects	160
Treatment arms	**Arm A:** depemokimab+placebo matching mepolizumab **Arm B:** mepolizumab+placebo matching depemokimab
Description	A 52-week randomised, double-blind, double-dummy, parallel-group, multicentre, non-inferiority study to investigate the efficacy and safety of depemokimab compared with mepolizumab
Timing start	Jul-22
Key end points	No. of participants with remission
Clinicaltrials.gov	Link

NCT05334368 - DESTINY

Phase	III
Patient	Adults with Hypereosinophilic Syndrome (HES) receiving standard of care (SoC) therapy
Subjects	120
Treatment arms	**Arm A:** depemokimab **Arm B:** placebo
Description	A Phase III randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of depemokimab
Timing start	Sep-22
Key end points	Frequency of HES flares
Clinicaltrials.gov	Link

Immunology/Respiratory

mepolizumab (Nucala)

NCT04133909 - MATINEE

Phase	III
Patient	Participants with COPD experiencing frequent exacerbations and characterised by eosinophil levels (Study 208657)
Subjects	800
Treatment arms	**Arm A:** placebo **Arm B:** mepolizumab
Description	A multicenter randomised, double-blind, parallel-group, placebo-controlled study of mepolizumab 100 mg SC as add-on treatment
Timing start	Oct-19
Key end points	Annualised rate of moderate or severe exacerbations
Clinicaltrials.gov	Link

NCT04607005 - MERIT

Phase	III
Patient	Adults with CRSwNP / Eosinophilic Chronic Rhinosinusitis (ECRS) MERIT
Subjects	160
Treatment arms	**Arm A:** mepolizumab + Standard of care (SoC) **Arm B:** placebo + SoC
Description	A randomised double-blind, placebo controlled, parallel group Phase III study to assess the clinical efficacy and safety of 100 mg SC mepolizumab
Timing start	Feb-21
Key end points	Change from baseline in total endoscopic NP score at week 52 Change from Baseline in mean nasal obstruction visual analogue scale (VAS) score (scores on a scale)
Clinicaltrials.gov	Link

Immunology/Respiratory

latozinemab

NCT03987295 - INFRONT-2

Phase	II
Patient	Heterozygous carriers of granulin or C9orf72 mutations causative of frontotemporal dementia
Subjects	40
Treatment arms	**Arm A:** FTD-GRN AL001; 60 mg/kg, every 4 weeks **Arm B:** FTD-C9orf72 AL001; 60 mg/kg, every 4 weeks
Description	A Phase II multicenter, open-label study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of AL001
Timing start	Sep-19
Key end points	Safety and efficacy of AL001 as measured by the CDR® plus NACC FTLD-SB in 96 weeks
Clinicaltrials.gov	Link

NCT04374136 - INFRONT-3

Phase	III
Patient	Individuals at risk for or with frontotemporal dementia due to heterozygous mutations in the progranulin gene
Subjects	180
Treatment arms	**Arm A:** AL001 every 4 weeks **Arm B:** placebo every 4 weeks **Arm C:** open label - AL001 every 4 weeks
Description	A Phase III multicenter, randomised, double blind, placebo controlled study to evaluate the efficacy and safety of AL001
Timing start	Jul-20
Key end points	Evaluation of efficacy of AL001 as measured by the CDR® plus NACC FTLD-SB up to 96 weeks
Clinicaltrials.gov	Link

Oncology

Oncology

belantamab mafodotin

NCT04126200 - DREAMM-5

Phase	I/II
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	464
Treatment arms	**Sub-study 1:** belantamab mafodotin + OX40 (GSK3174998) **Sub-study 2:** belanatamab mafodotin+ feladilimab **Sub-study 3:** belantamab mafodotin + nirogacestat (GSI) **Sub-study 4:** belantamab mafodotin + dostarlimab **Sub-study 5:** belantamab mafodotin+ isatuximab **Sub-study 6:** belantamab mafodotin+ nirogacestat + lenalidomide + dexamethasone **Sub-study 7:** belantamab mafodotin + nirogacestat + pomalidomide + dexamethasone
Description	A Phase I/II randomised, open-label platform study utilizing a master protocol to study Belantamab Mafodotin (GSK2857916) as monotherapy and in combination with anti-cancer treatments, DREAMM-5
Timing start	Oct-19
Key end points	Dose escalation phase: DLT, safety, ORR Cohort expansion phase: ORR, CBR, safety
Clinicaltrials.gov	Link

NCT03544281 - DREAMM-6

Phase	I/II
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	152
Treatment arms	**Arm A:** belantamab mafodotin+ lenalidomide + dexamethasone **Arm B:** belantamab mafodotin+ bortezomib + dexamethasone
Description	A Phase I/II open-label, dose escalation and expansion study to evaluate safety, tolerability and clinical activity of the antibody-drug conjugate GSK2857916 administered in combination with lenalidomide plus dexamethasone (Arm A), or bortezomib plus dexamethasone (Arm B), DREAMM-6
Timing start	Sep-18
Key end points	DLT, safety, ORR, PK
Clinicaltrials.gov	Link

Oncology

belantamab mafodotin

NCT04246047 - DREAMM-7

Phase	III
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	575
Treatment arms	**Arm A:** belantamab mafodotin + bortezomib + dexamethasone (B-Vd) **Arm B:** daratumumab, bortezomib + dexamethasone (D-Vd)
Description	A multicenter, open-label, randomised Phase III study to evaluate the efficacy and safety of the combination of Belantamab Mafodotin, bortezomib and dexamethasone (B-Vd) compared with the combination of daratumumab, bortezomib and dexamethasone (D-Vd) DREAMM-7
Timing start	May-20
Key end points	PFS, CRR, ORR, DoR, TTR, TTP, OS, PFS2, MRD negativity rate, safety
Clinicaltrials.gov	Link

NCT04484623 - DREAMM-8

Phase	III
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	300
Treatment arms	**Arm A:** belantamab mafodotin+ pomalidomide + dexamethasone (B-Pd) **Arm B:** Pomalidomide, bortezomib + dexamethasone (P-Vd)
Description	A Phase III multicenter, open-label, randomised study to evaluate the efficacy and safety of Belantamab Mafodotin in combination with pomalidomide and dexamethasone (B-Pd) versus pomalidomide plus bortezomib and dexamethasone (PVd) DREAMM-8
Timing start	Oct-20
Key end points	PFS, MRD negativity rate, ORR, CRR, VGPR or better rate, DoR, TTBR, TTR, TTP, OS, PFS2, safety
Clinicaltrials.gov	Link

Oncology

belantamab mafodotin

NCT04091126 - DREAMM-9

Phase	I
Patient	Patients with newly diagnosed multiple myeloma (MM)
Subjects	144
Treatment arms	**Cohort 1:** belantamab mafodotin 1.9 mg/kg Q3/4W + VRd/Rd **Cohort 2:** belantamab mafodotin 1.4 mg/kg Q6/8W + VRd/Rd **Cohort 3:** belantamab mafodotin 1.9 mg/kg Q6/8W + VRd/Rd **Cohort 4:** belantamab mafodotin 1.0 mg/kg Q3/4W + VRd/Rd **Cohort 5:** belantamab mafodotin 1.4 mg/kg Q3/4W + VRd/Rd **Cohort 6:** belantamab mafodotin 1.4mg/kg cycle 1, 1.0 mg/kg Q9/12W Cycle 4+VRd/Rd **Cohort 7:** belantamab mafodotin 1.9 mg/kg Cycle 1, 1.4 mg/kg Q9/12W Cycle 4+VRd/Rd **Cohort 8a:** belantamab mafodotin 1.9 mg/kg Cycle 1,4; 1.4 mg/kg Q9/12W from Cycle 7 +VRd/Rd **Cohort 8b:** belantamab mafodotin 1.4 mg/kg Cycle 1,3; 1.0 mg/kg Q9/12W from Cycle 6 +VRd/Rd **Cohort 8c:** belantamab mafodotin 1.0 mg/kg Cycle 1,5;1.0 mg/kg Q9/12W from Cycle 9 +VRd/Rd
Description	A Phase 1 randomised, dose and schedule evaluation study to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of Belantamab Mafodotin administered in combination with standard of care, DREAMM-9
Timing start	Dec-19
Key end points	DLT, safety, RDI of lenalidomide and bortezomib, PK, PD, ORR, CRR, VGPR or better,
Clinicaltrials.gov	Link

Oncology

belantamab mafodotin

NCT04398745 - DREAMM-12

Phase	I
Patient	Relapsed/refractory multiple myeloma (RRMM) who have normal and varying degrees of impaired renal function
Subjects	36
Treatment arms	**Arm A:** belantamab mafodotin monotherapy
Description	A Phase I study to evaluate the pharmacokinetics and safety of Belantamab Mafodotin monotherapy, DREAMM-12
Timing start	Oct-20
Key end points	PK, change in vital signs, safety
Clinicaltrials.gov	Link

NCT04398680 - DREAMM-13

Phase	I
Patient	Relapsed/refractory multiple myeloma (RRMM) who have normal and impaired hepatic function
Subjects	28
Treatment arms	**Arm A:** belantamab mafodotin monotherapy
Description	A Phase I study to evaluate the pharmacokinetics and safety of Belantamab Mafodotin monotherapy in participants who have normal and impaired hepatic function (DREAMM-13)
Timing start	44287
Key end points	PK, change in vital signs, safety
Clinicaltrials.gov	Link

Oncology

belantamab mafodotin

NCT05064358 - DREAMM-14

Phase	II
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	180
Treatment arms	**Cohort 1**: belantamab mafodotin at DL1 **Cohort 2**: belantamab mafodotin at DL2 **Cohort 3**: belantamab mafodotin at DL3 **Cohort 4**: belantamab mafodotin at DL4 **Cohort 5**: belantamab mafodotin at DL4 with alt dose modification
Description	A Phase II randomised, parallel, open-label study to investigate the safety, efficacy and pharmacokinetics of various dosing regimens of single-agent Belantamab Mafodotin (GSK2857916) DREAMM-14
Timing start	Mar-22
Key end points	% of patients with >= Gr 2 ocular events, safety, ORR, TTR, DoR, TTP, PFS, OS
Clinicaltrials.gov	Link

Oncology

belantamab mafodotin

NCT05714839 - DREAMM-20

Phase	I/II
Patient	Relapsed/refractory multiple myeloma (RRMM) [Parts 1 and 2] Transplant-Ineligible Newly Diagnosed Multiple Myeloma (TI NDMM) [Part 3]
Subjects	124
Treatment arms	**Part 1**: belantamab (may switch to belantamab mafodotin in case of PD) **Part 2**: Bela-xRd and Belamaf-xRd. The combination treatment xRd includes lenalidomide (R) and dexamethasone (d). x will be either a standard of care (SoC) or an emerging treatment. **Part 3**: Participants with TI-NDMM will receive Bela-xRd and Belamaf-xRd. The combination treatment xRd includes lenalidomide (R) and dexamethasone (d). x will be either a standard of care (SoC) or an emerging
Description	A Phase I/II open-lab multicentre, dose escalation and expansion study to investigate the safety, tolerability and clinical activity of belantamab as monotherapy and in combination with other treatments in participants with MM (DREAMM-20)
Timing start	Feb-23
Key end points	**Part 1:** Safety and tolerability (including DLTs), PK and recommended Part 2 Dose **Part 2:** Safety and tolerability, PK and Recommended Phase 2 Dose **Part 3:** Safety and tolerability, PK and Efficacy
Clinicaltrials.gov	Link

Oncology

cobolimab

NCT04655976 - COSTAR LUNG

Phase	III
Patient	(NSCLC) who have progressed on prior anti-PD-(L)1
Subjects	750
Treatment arms	**Arm A:** cobolimab+dostarlimab+docetaxel **Arm B:** dostarlimab+docetaxel **Arm C:** docetaxel
Description	A randomised, open label Phase II/III study comparing Cobolimab + Dostarlimab + Docetaxel to Dostarlimab + Docetaxel to Docetaxel alone
Timing start	Dec-20
Key end points	OS, ORR, PFS, DoR, TTD
Clinicaltrials.gov	Link

Oncology

dostarlimab

NCT04581824 - PERLA

Phase	II
Patient	Metastatic NSCLC
Subjects	243
Treatment arms	**Arm A:** dostarlimab+chemo **Arm B:** pembrolizumab+chemo
Description	Phase II randomised, double-blind study to evaluate the efficacy of Dostarlimab plus chemotherapy versus Pembrolizumab plus chemotherapy in metastatic non-squamous non-small cell lung cancer
Timing start	Nov-20 - Reported - Oct-22
Key end points	ORR, OS, PFS
Clinicaltrials.gov	Link

NCT02715284 - GARNET

Phase	I
Patient	Late-stage NSCLC, endometiral (MSS and MSI-high(MSI-H solid tumours and advanced solid tumours
Subjects	740
Treatment arms	**Part 1:** dostarlimab at ascending weight doses **Part 2A:** dostarlimab fixed dose of 500mg Q3W or 1000mg administered Q6W dose **Part 2B:** Cohort A1 dMMR/MSI-H endometrial **Part 2B:** Cohort A2 MMR proficient/MSS endometrial **Part 2B:** Cohort E: NSCLC **Part 2B:** Cohort F non-endometrial dMMR/MSI-H & POLE-mutation **Part 2B:** Cohort G PROC without known BRCA
Description	A Phase 1 dose escalation and cohort expansion study of TSR-042, an Anti-PD-1 Monoclonal Antibody
Timing start	Mar-16 - Reported - Mar-19
Key end points	ORR, DoR, safety
Clinicaltrials.gov	Link

Oncology

dostarlimab

NCT03981796 - RUBY ENGOT-EN6 GOG-3031

Phase	III
Patient	Patients with recurrent or primary advanced endometrial cancer
Subjects	785
Treatment arms	**Arm A:** dostarlimab + SoC followed by dostarlimab **Arm B:** placebo + SoC followed by placebo **Arm C:** dostarlimab + SoC followed by dostarlimab+niraparib **Arm D:** placebo (+chemo) followed by PBO
Description	A Phase III randomised, double-blind, multicenter study of Dostarlimab (TSR-042) plus Carboplatin-paclitaxel versus placebo plus Carboplatin-paclitaxel
Timing start	Jul-19 - reported - Dec-22
Key end points	Part 1: PFS by IA (dmmr/msi-h and ITT) and OS (ITT) Part 2: PFS (ITT)
Clinicaltrials.gov	Link

SoC = carboplatin-paclitaxel

NCT05723562 - AZUR-1

Phase	II
Patient	Patients with untreated stage II/III dMMR/MSI-H locally advanced rectal cancer
Subjects	100
Treatment arms	**Arm A:** dostarlimab monotherapy
Description	A Phase II single-arm, open-label study with dostarlimab monotherapy
Timing start	Mar-23
Key end points	Sustained cCR for 12, 24 and 36 months, EFS3
Clinicaltrials.gov	Link

Oncology

Zejula

NCT04475939 - ZEAL-1L

Phase	III
Patient	Participants whose disease has remained stable or responded to 1L platinum based chemo with pembrolizumab for stage IIIB/IIIC or IV NSCLC
Subjects	666
Treatment arms	**Arm A:** niraparib plus pembrolizumab **Arm B:** placebo plus pembrolizumab
Description	A Phase III randomised, double-blind, placebo-controlled, multicenter study comparing Niraparib plus Pembrolizumab versus placebo plus Pembrolizumab as maintenance therapy
Timing start	Oct-20
Key end points	OS, PFS assessed by BICR using Response Evaluation Criteria in Solid Tumors (RECIST)
Clinicaltrials.gov	Link

NCT03602859 - FIRST

Phase	III
Patient	Participants with Stage III or IV Nonmucinous Epithelial Ovarian Cancer
Subjects	1332 (with N=1138 in ARM B and C)
Treatment arms*	**Arm A:** SOC+placebo **Arm B:** SOC+niraparib **Arm C:** SOC+dostarlimab+niraparib
Description	A randomised, double-blind, phase III comparison of platinum-based therapy with TSR-042 and Niraparib versus standard of care platinum-based therapy as first-line treatment of Stage III or IV Nonmucinous Epithelial Ovarian Cancer
Timing start	Oct-18
Key end points	PFS for PD-L1 positive participants
Clinicaltrials.gov	Link

SOC = Carboplatin + Paclitaxel + Bevacizumab

* the primary analysis is ARM B vs ARM C. This is an adaptive study with ARM A closed post topline

Oncology

Zejula

NCT02655016 - PRIMA

Phase	III
Patient	733
Subjects	Patients with advanced ovarian cancer following response on front line platinum-based chemo
Treatment arms	**Arm A:** niraparib **Arm B:** placebo
Description	A Phase III randomised, double-blind, placebo-controlled, multicenter study of niraparib maintenance treatment
Timing start	Jul-16
Key end points	PFS, OS
Clinicaltrials.gov	Link

NCT04915755 - ZEST

Phase	III
Patient	800
Subjects	Participants with either HER2-Negative BRCA-mutated or triple-negative breast cancer with molecular disease based on presence of circulating tumor DNA after definitive therapy
Treatment arms	**Arm A:** niraparib **Arm B:** placebo
Description	A Phase III randomised, double-blind study comparing the efficacy and safety of niraparib to placebo
Timing start	Jun-21
Key end points	DFS, OS, TTP
Clinicaltrials.gov	Link

Oncology

momelotinib

NCT03441113 - MOMENTUM

Phase	II
Patient	Participants with PMF or post-polycythemia vera or Post-PV/ET MF)
Subjects	400
Treatment arms	**Arm A:** Study GS-US-352-0101 **Arm B:** Study GS-US-352-1214 **Arm C:** Study GS-US-352-1154 **Arm D:** Study SRA-MMB-301
Description	Extended access of momelotinib
Timing start	May-18
Key end points	No. of patients who had access to and received the intervention
Clinicaltrials.gov	Link

Opportunity driven

Opportunity driven

daprodustat

NCT02879305 - ASCEND-D

Phase	III
Patient	Dialysis subjects with anemia associated with CKD
Subjects	2964
Treatment arms	**Arm A:** daprodustat **Arm B:** darbepoetin alfa
Description	Phase III randomised, open-label (sponsor-blind) active-controlled, parallel-group, multi-center, event driven study
Timing start	Sep-16 - Reported Nov-20
Key end points	Time to first occurrence of MACE during CV evaluation period and mean change from baseline Hgb during the evaluation period (week 28 to 52)
Clinicaltrials.gov	Link

NCT03029208 - ASCEND-ID

Phase	III
Patient	Incident dialysis subjects with anemia of CKD
Subjects	312
Treatment arms	**Arm A:** daprodustat treated anemic subjects **Arm B:** darbepoetin alfa treated anemic subjects
Description	A 52-week open-label (Sponsor-blind) randomised, active-controlled, parallel-group, multi-center study to evaluate the efficacy and safety of daprodustat compared to recombinant human erythropoietin
Timing start	May-17 - Reported Sep-20
Key end points	Mean change from baseline in Hemoglobin (Hgb) during evaluation period (week 28 to week 52)
Clinicaltrials.gov	Link

Opportunity driven

daprodustat

NCT03400033 - ASCEND-TD

Phase	III
Patient	Dialysis subjects with anemia of CKD
Subjects	407
Treatment arms	**Arm A:** daprodustat TIW **Arm B:** epoetin alfa
Description	A Phase III randomised, double-blind, active-controlled, parallel-group, multi-center study 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 analogs
Timing start	Sep-18 - Reported Jun-20
Key end points	Mean change from baseline in hemoglobin levels over the evaluation period (week 28 to week 52)
Clinicaltrials.gov	Link

NCT02876835 - ASCEND-ND

Phase	III
Patient	Non-dialysis subjects with anemia associated with CKD
Subjects	3872
Treatment arms	**Arm A:** daprodustat **Arm B:** darbepoetin alfa
Description	A Phase III randomised, open-label (sponsor-blind) active-controlled, parallel-group, multi-center, event driven study to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa
Timing start	Sep-16 - Reported - Apr-21
Key end points	Time to first occurrence of MACE during CV evaluation period and mean change from baseline Hgb during the evaluation period (week 28 to 52)
Clinicaltrials.gov	Link

Opportunity driven

daprodustat

NCT03409107 - ASCEND-NHQ

Phase	III
Patient	ESA naïve non-dialysis subjects with anemia of CKD
Subjects	614
Treatment arms	**Arm A:** daprodustat **Arm B:** placebo
Description	A 28-week randomised, double-blind, placebo-controlled, parallel-group, multi-center study to evaluate the efficacy, safety and effects on quality of life of daprodustat compared to placebo
Timing start	Mar-18 - Reported - Oct-20
Key end points	Mean change from baseline in Hgb levels over the evaluation period (week 24 to 28) and mean change from baseline to week 28 in the SF-36 vitality score
Clinicaltrials.gov	Link

Opportunity driven

linerixibat

NCT04950127 - GLISTEN

Phase	III
Patient	Participants with Primary Biliary Cholangitis (PBC)
Subjects	230
Treatment arms	**Arm A:** linerixibat **Arm B:** linerixibat followed by placebo **Arm C:** placebo **Arm D:** placebo followed by linerixibat
Description	A two-part randomised, placebo controlled, double blind, multicenter Phase III study to evaluate the efficacy and safety of linerixibat for the treatment of Cholestatic Pruritus
Timing start	Aug-21
Key end points	Change from baseline in monthly Itch Scores over 24 weeks using Numerical Rating Scale (NRS)
Clinicaltrials.gov	Link

Opportunity driven

GSK4532990

NCT05583344

Phase	II
Patient	Adults with Non-alcoholic Steatohepatitis (NASH) and advanced (F3) fibrosis
Subjects	246
Treatment arms	**Arm 1:** high dose GSK4532990 **Arm 2:** low dose GSK4532990 **Arm 3:** placebo
Description	Placebo-controlled phase 2b study to evaluate the efficacy and safety of **GSK4532990** in adults with pre-cirrhotic Non-Alcoholic Steatohepatitis (NASH)
Timing start	Jan-23
Key end points	**Part 1:** Percentage of participants achieving ≥ 1 stage improvement in histological fibrosis with no worsening **Part 2:** Percentage of participants achieving NASH Resolution with no worsening of fibrosis (at week 52)
Clinicaltrials.gov	Link

Glossary

Glossary

ADC	Antibody drug conjugate
AE	Adverse event
AIR	At increased risk
BIC	Bictegravir
BRCA	Breast Cancer
BRCAm	Breast Cancer gene-mutated
CA	Canada
CAE	Corneal Adverse Events
CBR	Clinical benefit rate
cCR	Complete clinical response
CKD	Chronic Kidney Disease
CN	China
COPD	Chronic obstructive pulmonary disease
CRR	Complete response rate
cUTI	Complicated urinary tract infection
CV	Cardiovascular
DFS	Disease-free survival
DLT	Dose-limiting toxicity
dMMR	Deficient mismatch repair
DoR	Duration of response
FTC	Emtricitabine
GC	Uncomplicated Urogenital Gonorrhea
GMMA	Generalised Modules for Membrane Antigens
GSI	Gamma secretase inhibitor
HA	Healthy adults
HBV	Hepatitis B virus
HES	Hypereosinophilic syndrome
Hgb	Hemoglobin
hSBA	Human serum bactericidal assay
HZ	Herpes Zoster
ICR	Independent central review
LLOQ	Lower limit of quantitation
MAPS	Mulitple Antigen Presenting System
MM	Multiple myeloma
MMR	Measles, mumps and rubella
MMRV	Measles, mumps, rubella and varicella
MRD	Multiple rising dose
MSI-H	Microsatellite instability high
NSCLC	Non-small cell lung cancer
OMV	Outer membrane vesicle
ORR	Overall response rate
OS	Overall surival
PBC	Primary Biliry Cholangitis
PFS	Progression-free survival
PFS2	Time to second disease progression or death
PK	Pharmacokinetic
PMF	Primary Myelofibrosis
Post-PV/ET MF	Post-essential Thrombocythemia Myelofibrosis
RPV LA	Long-acting rilpivirine regimen
RRMM	Relapsed/refractory multiple myeloma
RSV	Respiratory syncytial virus
SAE	Serious adverse event
siRNA	Small interfering RNA
SoC	Standard of care
TDF	Tenofovir disoproxil fumarate
TTBR	Time to best response
TTD	Time to treatment discontinuation
TTP	Time to tumour progression
TTR	Time to treatment response
UTI	Urinary tract infection
uUTI	Uncomplicated urinary tract infection
VGPR	Very good partial remission
VSP	Vital sign parameters
YoA	Years of Age