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Pipeline assets and clinical trials appendix

Q4 2024

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Innovation: Pipeline growth

Overview of potential new vaccines and medicines

71 potential new vaccines and medicines in pipeline

RI&I
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Phase III / Registration

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camlipixant (GSK5464714)	P2X3 receptor antagonist	Refractory chronic cough
depemokimab (GSK3511294)	Long-acting anti-IL5 antibody*	Asthma^**
latozinemab (GSK4527223)	Anti-sortilin antibody*	Frontotemporal dementia[1]
linerixibat (GSK2330672)	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis
Low carbon version of MDI[2], *Ventolin* (salbutamol)	Beta 2 adrenergic receptor agonist	Asthma
Nucala (mepolizumab)	Anti-IL5 antibody	COPD[3]^
belrestotug (GSK4428859)	Anti-TIGIT antibody*	Non-small cell lung cancer**
Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma^
cobolimab (GSK4069889)	Anti-TIM-3 antibody*	Non-small cell lung cancer
Jemperli (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H colon cancer**
Zejula (niraparib)	PARP inhibitor*	Ovarian cancer**
Arexvy (RSV vaccine)	Recombinant protein, adjuvanted*	RSV adults (18-49 YoA[4] AIR[5])**
bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV[6] infection**
Bexsero (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
gepotidacin (GSK2140944)	BTI inhibitor*	Uncomplicated UTI[7]^**
ibrexafungerp (GSK5458448)	Antifungal glucan synthase inhibitor*	Invasive candidiasis
MenABCWY vaccine (GSK3536819)	Recombinant protein, OMV, conjugated vaccine	MenABCWY, 1st Gen^
tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI[7]
GSK4178116	Live, attenuated	Varicella new strain

* In-license or other alliance relationship with third party ** Additional indications or candidates also under investigation ^ In registration
1. Phase III trial in patients with progranulin gene mutation 2. Metered dose inhaler 3. Chronic obstructive pulmonary disorder 4. Years of age 5. At increased risk 6. Hepatitis B virus 7. Urinary tract infection

71 potential new vaccines and medicines in pipeline

RI&I
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Phase II

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Benlysta (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD[1,2]**
GSK1070806	Anti-IL18 antibody	Atopic dermatitis
GSK3915393	TG2 inhibitor*	Pulmonary fibrosis
GSK4527226 (AL-101)	Anti-sortilin antibody*	Alzheimer's disease
GSK4532990	HSD17B13 RNA interference*	NASH/MASH[3]**
GSK5784283	TSLP monoclonal antibody*	Asthma[4]
GSK4381562	Anti-PVRIG antibody*	Cancer
nelistotug (GSK6097608)	Anti-CD96 antibody*	Cancer
cabotegravir (GSK1265744)	Integrase inhibitor	HIV
VH3810109	Broadly neutralizing antibody*	HIV
VH3739937	Maturation inhibitor	HIV
VH4011499	Capsid protein inhibitor	HIV
VH4524184	Integrase inhibitor*	HIV
alpibectir (BVL-GSK3729098)	Ethionamide booster*	Tuberculosis
ganfeborole (GSK3036656)	Leucyl t-RNA synthetase inhibitor*	Tuberculosis
GSK3437949	Recombinant protein, adjuvanted*	Malaria fractional dose
GSK3536852	GMMA*	Shigella
GSK3993129	Recombinant subunit, adjuvanted	Cytomegalovirus[5]
GSK4023393	Recombinant protein, OMV, conjugated vaccine	MenABCWY, 2nd Gen[5]
GSK4077164	Bivalent GMMA*	Invasive non-typhoidal salmonella**
GSK4382276	mRNA*	Seasonal flu
GSK4396687	mRNA*	COVID-19
GSK4406371	Live, attenuated	MMRV[6] new strain
GSK5101955	*MAPS* Pneumococcal 24-valent paed*	Paediatric pneumococcal disease
GSK5536522	mRNA*	Flu H5N1 pre-pandemic[5]
GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV[7] infection
sanfetrinem cilexetil (GV118819)	Serine beta lactamase inhibitor*	Tuberculosis

* In-license or other alliance relationship with third party ** Additional indications or candidates also under investigation
1. Interstitial lung disease 2. In phase II/III study 3. Non-alcoholic steatohepatitis/metabolic dysfunction-associated steatohepatitis 4. Phase II study start expected in 2025 5. In phase I/II study 6. Measles, Mumps, Rubella, and Varicella 7. Hepatitis B virus

71 potential new vaccines and medicines in pipeline

RI&I
Oncology
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Infectious Diseases

Phase I

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GSK3862995	Anti-IL33 antibody	COPD[1]
GSK3888130	Anti-IL7 antibody*	Autoimmune disease
GSK4172239	DNMT1 inhibitor*	Sickle cell disease
GSK4347859	Interferon pathway modulator	Systemic lupus erythematosus
GSK4527363	B-cell modulator	Systemic lupus erythematosus
GSK4528287	Anti-IL23-IL18 bispecific antibody	Inflammatory bowel disease
GSK4771261	Monoclonal antibody against novel kidney target	Autosomal dominant PKD[2]
GSK5462688	RNA-editing oligonucleotide*	Alpha-1 antitrypsin deficiency
GSK5926371	Anti-CD19-CD20-CD3 trispecific antibody*	Autoimmune disease
belantamab (GSK2857914)	Anti-BCMA antibody	Multiple myeloma**
GSK4418959	Werner helicase inhibitor*	dMMR/MSI-H solid tumours[3]
GSK4524101	DNA polymerase theta inhibitor*	Cancer[3]
GSK5733584	ADC targeting B7-H4*	Gynaecologic malignancies
GSK5764227	ADC targeting B7-H3*	Solid tumours
XMT-2056[4] (wholly owned by Mersana Therapeutics)	STING agonist ADC*	Cancer
VH4527079	HIV entry inhibitor	HIV
GSK3536867	Bivalent conjugate*	Salmonella (*typhoid + paratyphoid*)
GSK3772701	*P. falciparum* whole cell inhibitor*	Malaria
GSK3882347	FimH antagonist*	Uncomplicated UTI[5]
GSK3923868	PI4K beta inhibitor	Rhinovirus disease
GSK3965193	PAPD5/PAPD7 inhibitor	Chronic HBV[6] infection[3]
GSK4024484	*P. falciparum* whole cell inhibitor*	Malaria
GSK5251738	TLR8 agonist*	Chronic HBV[6] infection
GSK5102188	Recombinant subunit, adjuvanted	UTI[5]
GSK5475152	mRNA*	Seasonal flu/COVID-19

* In-license or other alliance relationship with third party ** Additional indications or candidates also under investigation
1. Chronic obstructive pulmonary disorder 2. Polycystic kidney disease 3. In phase I/II study 4. GSK has an exclusive global license option to co-develop and commercialise the candidate 5. Urinary tract infection
6. Hepatitis B virus

Respiratory, Immunology and Inflammation pipeline

RI&I
Oncology
HIV
Infectious Diseases

Phase III / Registration

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camlipixant (GSK5464714)	P2X3 receptor antagonist	Refractory chronic cough
depemokimab (GSK3511294)	Long-acting anti-IL5 antibody*	Asthma^**
latozinemab (GSK4527223)	Anti-sortilin antibody*	Frontotemporal dementia[1]
linerixibat (GSK2330672)	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis
Low carbon version of MDI[2], *Ventolin* (salbutamol)	Beta 2 adrenergic receptor agonist	Asthma
Nucala (mepolizumab)	Anti-IL5 antibody	COPD[3]^

Phase II

6

Benlysta (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD[4,5]**
GSK1070806	Anti-IL18 antibody	Atopic dermatitis
GSK3915393	TG2 inhibitor*	Pulmonary fibrosis
GSK4527226 (AL-101)	Anti-sortilin antibody*	Alzheimer's disease
GSK4532990	HSD17B13 RNA interference*	NASH/MASH[6]**
GSK5784283	TSLP monoclonal antibody*	Asthma[7]

Phase I

9

GSK3862995	Anti-IL33 antibody	COPD[3]
GSK3888130	Anti-IL7 antibody*	Autoimmune disease
GSK4172239	DNMT1 inhibitor*	Sickle cell disease
GSK4347859	Interferon pathway modulator	Systemic lupus erythematosus
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GSK5926371	Anti-CD19-CD20-CD3 trispecific antibody*	Autoimmune disease

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1. Phase III trial in patients with progranulin gene mutation . 2. Metered dose inhaler 3. Chronic obstructive pulmonary disorder 4. Interstitial lung disease 5. In phase II/III study 6. Non-alcoholic steatohepatitis/metabolic dysfunction-associated steatohepatitis 7. Phase II study start expected in 2025 8. Polycystic kidney disease

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Oncology pipeline

Phase III / Registration

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belrestotug (GSK4428859)	Anti-TIGIT antibody*	Non-small cell lung cancer**
Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma^
cobolimab (GSK4069889)	Anti-TIM-3 antibody*	Non-small cell lung cancer
Jemperli (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H colon cancer**
Zejula (niraparib)	PARP inhibitor*	Ovarian cancer**

Phase II

2

GSK4381562	Anti-PVRIG antibody*	Cancer
nelistotug (GSK6097608)	Anti-CD96 antibody*	Cancer

Phase I

6

belantamab (GSK2857914)	Anti-BCMA antibody	Multiple myeloma**
GSK4418959	Werner helicase inhibitor*	dMMR/MSI-H solid tumour[1]
GSK4524101	DNA polymerase theta inhibitor*	Cancer[1]
GSK5733584	ADC targeting B7-H4*	Gynaecologic malignancies
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XMT-2056[2] (wholly owned by Mersana Therapeutics)	STING agonist ADC*	Cancer

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1. In phase I/II study 2. GSK has an exclusive global license option to co-develop and commercialise the candidate

HIV pipeline

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Phase II

5

cabotegravir (GSK1265744)	Integrase inhibitor	HIV
VH3810109	Broadly neutralizing antibody*	HIV
VH3739937	Maturation inhibitor	HIV
VH4011499	Capsid protein inhibitor	HIV
VH4524184	Integrase inhibitor*	HIV

Phase I

1

VH4527079	HIV entry inhibitor	HIV

* In-license or other alliance relationship with third party

Infectious Diseases pipeline

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Phase III / Registration 8

Arexvy (RSV vaccine)	Recombinant protein, adjuvanted*	RSV adults (18-49 YoA[1] AIR[2])**
bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV[3] infection**
Bexsero (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
gepotidacin (GSK2140944)	BTI inhibitor*	Uncomplicated UTI[4]^**
ibrexafungerp (GSK5458448)	Antifungal glucan synthase inhibitor*	Invasive candidiasis
MenABCWY vaccine (GSK3536819)	Recombinant protein, OMV, conjugated vaccine	MenABCWY, 1st Gen^
tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI[4]
GSK4178116	Live, attenuated	Varicella new strain

Phase II 14

alpibectir (BVL-GSK3729098)	Ethionamide booster*	Tuberculosis
ganfeborole (GSK3036656)	Leucyl t-RNA synthetase inhibitor*	Tuberculosis
GSK3437949	Recombinant protein, adjuvanted*	Malaria fractional dose
GSK3536852	GMMA*	Shigella
GSK3993129	Recombinant subunit, adjuvanted	Cytomegalovirus[5]
GSK4023393	Recombinant protein, OMV, conjugated vaccine	MenABCWY, 2nd Gen[5]
GSK4077164	Bivalent GMMA*	Invasive non-typhoidal salmonella**
GSK4382276	mRNA*	Seasonal flu
GSK4396687	mRNA*	COVID-19
GSK4406371	Live, attenuated	MMRV[6] new strain
GSK5101955	*MAPS* Pneumococcal 24-valent paed*	Paediatric pneumococcal disease
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GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV[3] infection
sanfetrinem cilexetil (GV118819)	Serine beta lactamase inhibitor*	Tuberculosis

Phase I 9

GSK3536867	Bivalent conjugate*	Salmonella (*typhoid + paratyphoid*)
GSK3772701	*P. falciparum* whole cell inhibitor*	Malaria
GSK3882347	FimH antagonist*	Uncomplicated UTI[4]
GSK3923868	PI4K beta inhibitor	Rhinovirus disease
GSK3965193	PAPD5/PAPD7 inhibitor	Chronic HBV[3] infection[5]
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GSK5251738	TLR8 agonist*	Chronic HBV[3] infection
GSK5102188	Recombinant subunit, adjuvanted	UTI[4]
GSK5475152	mRNA*	Seasonal flu/COVID-19

* In-license or other alliance relationship with third party ** Additional indications or candidates also under investigation ^ In registration
1. Years of age 2. At increased risk 3. Hepatitis B virus 4. Urinary tract infection 5. In phase II/III study 6. Measles, Mumps, Rubella, and Varicella 7. Hepatitis B virus

Changes since Q3 2024

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Infectious Diseases

Changes on pipeline

Progressed from Phase II to Phase III

- GSK4178116: Live, attenuated, Varicella new strain

Progressed from Phase I to Phase II

- cabotegravir (GSK1265744): Integrase inhibitor, HIV

New to Phase I

- GSK4528287: Anti-IL23-IL18 bispecific antibody, Inflammatory bowel disease
- GSK4771261: Monoclonal antibody against novel kidney target, ADPKD[1]
- GSK5926371: Anti-CD19-CD20-CD3 trispecific antibody, Autoimmune disease
- GSK4418959: Werner helicase inhibitor, dMMR/MSI-H solid tumours
- VH4527079: HIV entry inhibitor, HIV
- GSK5102188: Recombinant subunit, adjuvanted, UTI[2]
- GSK5475152: mRNA, Seasonal flu/COVID-19

Removed from Phase II

- VH4004280: Capsid protein inhibitor, HIV
- GSK3528869: Viral vector with recombinant protein, adjuvanted, Chronic HBV[3] infection

Removed from Phase I

- GSK2556286: Mtb cholesterol dependent inhibitor, Tuberculosis

Achieved pipeline catalysts

Regulatory decisions

Nucala: CRSwNP[4]	CN
Jemperli[5]: RUBY (Part 1)[6], 1L EC[7]	EU
Vocabria + Rekambys: HIV infection	EU
Arexvy: 50-59 YoA[8] AIR[9]	JP
Menveo liquid formulation, Men ACWY	EU

Regulatory submission acceptances

depemokimab: SWIFT-1/2, asthma	EU, CN, JP
depemokimab: ANCHOR-1/2, CRSwNP[4]	EU, CN, JP
Nucala: MATINEE, COPD[10]	US
Blenrep: DREAMM-7/8, 2L+ MM[11]	US
Blenrep: DREAMM-7, 2L+ MM[11] with priority review	CN
Shingrix liquid formulation	US, EU

Late-stage readouts

- linerixibat: GLISTEN, cholestatic pruritus in PBC[12] – Positive phase III data readout
- *Zejula*[5]: FIRST, 1L maintenance OC[13] – Positive phase III data readout

Other news

- *Jemperli*[5]: dMMR/MSI-H rectal cancer[14] – Breakthrough Therapy Designation (US)
- GSK5764227: ES-SCLC[15] – PRIME Designation (EU)
- GSK5764227: osteosarcoma[16] – Breakthrough Therapy Designation (US)

1. Autosomal dominant polycystic kidney disease 2. Urinary tract infection 3. Hepatitis B virus 4. Chronic rhinosinusitis with nasal polyps 5. Tesaro asset 6. Overall population 7. Endometrial cancer 8. Years of age 9. At increased risk 10. Chronic obstructive pulmonary disorder 11. Relapsed or refractory multiple myeloma 12. primary biliary cholangitis 13. Ovarian cancer 14. Locally advanced dMMR/MSI-H rectal cancer 15. Extensive-stage small-cell lung cancer with disease progression on or after platinum-based chemotherapy (relapsed or refractory) 16. Relapsed or refractory osteosarcoma

Upcoming pipeline catalysts: 2025 and 2026

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	H1 2025		H2 2025		2026	
Regulatory decision	*Nucala*: MATINEE, COPD[1]	US	depemokimab: SWIFT-1/2, asthma	US	depemokimab: SWIFT-1/2, asthma	EU. CN, JP
	Blenrep: DREAMM-7/8, 2L+ MM[2]	JP	depemokimab: ANCHOR-1/2, CRSwNP[6]	US	depemokimab: ANCHOR-1/2, CRSwNP[6]	EU. CN, JP
	gepotidacin: EAGLE-2/3, uUTI[3]	US	linerixibat: GLISTEN, cholestatic pruritus in PBC[7]	US	linerixibat: GLISTEN, cholestatic pruritus in PBC[7]	EU, CN, JP
	MenABCWY vaccine 1st Gen	US	*Blenrep*: DREAMM-7/8, 2L+ MM[2]	US, EU	*Nucala*: MATINEE, COPD[1]	EU, CN
	Shingrix: 18+ YoA[4] AIR[5]	CN	gepotidacin: EAGLE-1, GC[8]	US	*Ventolin* (low carbon MDI[11]): asthma	EU
	Shingrix liquid formulation	US			*Blenrep*: DREAMM-7/8, 2L+ MM[2]	CN
					cobolimab[9]: COSTAR, 2L NSCLC[10]	US, EU
					cabotegravir: Q4M PrEP[15], HIV prevention	US
					Arexvy: 18-49 YoA[4] AIR[5] and 18+ IC[12]	US, EU, JP
					bepirovirsen: B-WELL-1/2, chronic HBV[16] infection	US,JP
					Bexsero (infants US): Men B	US
					tebipenem pivoxil: PIVOT-PO, cUTI[13]	US
Regulatory submission acceptance	depemokimab: SWIFT-1/2, asthma	US	linerixibat: GLISTEN, cholestatic pruritus in PBC[7]	JP	camlipixant: CALM-1/2, RCC[14]	US, EU
	depemokimab: ANCHOR-1/2, CRSwNP[6]	US	*Ventolin* (low carbon MDI[11]): asthma	EU	depemokimab: OCEAN, EGPA[17]	US, EU, CN, JP
	linerixibat: GLISTEN, cholestatic pruritus in PBC[7]	US, EU, CN	*Blenrep*: DREAMM-8, 2L+ MM[2]	CN	latozinemab: INFRONT-3[18], FTD-GRN[19]	US, EU
	Nucala: MATINEE, COPD[1]	EU, CN	cobolimab[9]: COSTAR, 2L NSCLC[10]	US, EU	cabotegravir: Q4M PrEP[15], HIV prevention	US
	gepotidacin: EAGLE-1, GC[8]	US	*Arexvy*: 18-49 YoA[4] AIR[5] and 18+ IC[12]	US, EU, JP	bepirovirsen: B-WELL-1/2, chronic HBV[16] infection	US, EU, CN, JP
			Bexsero (infants US): Men B	US		
			tebipenem pivoxil: PIVOT-PO, cUTI[13]	US		
Late-stage Phase III readouts	depemokimab: AGILE, asthma		camlipixant: CALM-1, RCC[14]		camlipixant: CALM-2, RCC[14]	
	cobolimab[9]: COSTAR, 2L NSCLC[10]		depemokimab: NIMBLE, asthma		depemokimab: OCEAN, EGPA[17]	
	Zejula[9]: ZEAL, 1L maintenance NSCLC[10]		*Ventolin* (low carbon MDI[11]): asthma		latozinemab: INFRONT-3[18], FTD-GRN[19]	
			Bexsero (infants US): Men B		*Jemperli*[9]: AZUR-1, Rectal cancer[20, 21]	
			tebipenem pivoxil: PIVOT-PO, cUTI[13]		cabotegravir: Q4M PrEP[15], HIV prevention[21]	
					bepirovirsen: B-WELL-1/2, chronic HBV[16] infection	

1. Chronic obstructive pulmonary disorder 2. Multiple myeloma 3. Uncomplicated urinary tract infection 4. Years of age 5. At increased risk 6. Chronic rhinosinusitis with nasal polyps 7. Primary biliary cholangitis 8. Urogenital gonorrhoea 9. Tesaro asset 10. Non-small cell lung cancer 11. Metered dose inhaler 12. Immunocompromised 13. Complicated urinary tract infection 14. Refractory chronic cough 15. Pre-Exposure Prophylaxis 16. Hepatitis B virus 17. Eosinophilic granulomatosis with polyangiitis 18. INFRONT-3 study is sponsored by Alector Inc. 19. Frontotemporal dementia with progranulin gene mutation 20. Neoadjuvant locally advanced dMMR/MSI-H rectal cancer 21. Pivotal phase II study

Designations in our pipeline

RI&I
Oncology
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Infectious Diseases

Breakthrough Designation

latozinemab (GSK4527223)	Anti-sortilin antibody*	Frontotemporal dementia[1]	US
Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Relapsed or refractory multiple myeloma	CN
Jemperli[2] (dostarlimab)	Anti-PD-1 antibody*	Locally advanced dMMR/MSI-H rectal cancer	US
GSK5764227	ADC targeting B7-H3*	Relapsed or refractory extensive-stage SCLC[3]	US, EU
GSK5764227	ADC targeting B7-H3*	Relapsed or refractory osteosarcoma	US
bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV[4] infection	CN
GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV[4] infection	CN

Fast Track

latozinemab (GSK4527223)	Anti-sortilin antibody*	Frontotemporal dementia[1]	
GSK4172239	DNMT1 inhibitor*	Sickle cell disease	
Jemperli[2] (dostarlimab)	Anti-PD-1 antibody*	Neoadjuvant dMMR/MSI-H 1L rectal cancer	
alpibectir (BVL-GSK3729098)	Ethionamide booster*	Tuberculosis	
bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV[4] infection	
gepotidacin (GSK2140944)	BTI inhibitor*	Urogenital gonorrhoea	
ibrexafungerp (GSK5458448)	Antifungal glucan synthase inhibitor*	Invasive candidiasis	
tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI[5]	
GSK4382276	mRNA*	Seasonal flu	

Orphan Drug Designation

Benlysta (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD[6]	US
depemokimab (GSK3511294)	Long-acting anti-IL5 antibody*	Hypereosinophilic syndrome	JP
latozinemab (GSK4527223)	Anti-sortilin antibody*	Frontotemporal dementia[1]	US, EU
linerixibat (GSK2330672)	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis	US, EU
Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma	JP
ibrexafungerp (GSK5458448)	Antifungal glucan synthase inhibitor*	Invasive candidiasis	US, EU

Priority Review

Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Relapsed or refractory multiple myeloma	CN, JP
gepotidacin (GSK2140944)	BTI inhibitor*	Uncomplicated UTI[5]	US

Qualified Infectious Disease Product Designation

gepotidacin (GSK2140944)	BTI inhibitor*	Uncomplicated UTI[5] & urogenital gonorrhoea	
ibrexafungerp (GSK5458448)	Antifungal glucan synthase inhibitor*	Invasive candidiasis	
tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI[5]	

SENKU

bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV[4] infection	

8 ► BREAKTHROUGH DESIGNATION

US: Expedite development and review of drugs to treat serious conditions and may demonstrate substantial improvement over available therapy. Criteria includes preliminary clinical evidence that indicates substantial improvement on clinically significant endpoint over available therapies.

China: Enhance support for development of medicines to treat serious, life-threatening disease and target an unmet medical need

9 EU (PRIME): Enhance support for development of medicines that target an unmet medical need or a product expected to bring major therapeutic advantage.

► FAST TRACK (US) – Facilitate development and expedite review of drugs to treat serious conditions, including criteria that nonclinical or clinical data demonstrate potential to address unmet medical need

► OPHAN DRUG DESIGNATION – intended for treatment, diagnosis or prevention of rare diseases (US, EU, Japan)

► PRIORITY REVIEW

9 US: A process that directs resources to the evaluation of drugs that represent significant improvements in safety or effectiveness compared with standard applications, with a shorter User-Fee review time compared to standard review (6 months vs. 9 months)

China: Process to expedite products of major interest in terms of public health and therapeutic innovation

Japan: Faster access to new therapies responding to high medical needs, including orphan drugs and HIV medicines

3 ► Qualified Infectious Disease Product Designation (US) – an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections

4 ► SENKU (Japan) – Increase early patient access to innovative medicines through an expedited review process to treat serious conditions and fill an unmet medical need

* In-license or other alliance relationship with third party
1. In patients with progranulin gene mutation 2. Tesaro asset 3. Small-cell lung cancer
4. Hepatitis B virus 5. Urinary tract infection 6. Interstitial lung disease

1

Clinical Trials

Respiratory, Immunology and Inflammation

Respiratory, Immunology and Inflammation

camlipixant

NCT05599191 - CALM-1

Phase	III
Patient	Adult participants with refractory chronic cough, including unexplained chronic cough
Subjects	825
Treatment arms	Arm A: camlipixant 25 mg twice a day Arm B: camlipixant 50 mg twice a day Placebo twice a day
Description	A 52-week, randomised, double-blind, placebo-controlled, parallel-arm efficacy and safety study with open-label extension of camlipixant in adult participants with refractory chronic cough, including unexplained chronic cough
Timeline	Trial start: Q4 2022
Key end points	24-hour cough frequency
Clinicaltrials.gov	Link

NCT05600777 - CALM-2

Phase	III
Patient	Adult participants with refractory chronic cough, including unexplained chronic cough
Subjects	825
Treatment arms	Arm A: camlipixant 25 mg twice a day Arm B: camlipixant 50 mg twice a day Placebo twice a day
Description	A 24-week, randomised, double-blind, placebo-controlled, parallel-arm efficacy and safety study with open-label extension of camlipixant in adult participants with refractory chronic cough, including unexplained chronic cough
Timeline	Trial start: Q1 2023
Key end points	24-hour cough frequency
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

depemokimab

NCT04719832 - SWIFT-1

Phase	III
Patient	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype
Subjects	395
Treatment arms	Arm A: depemokimab plus SoC Arm B: placebo plus SoC
Description	A 52-week, randomised, double-blind, placebo-controlled, parallel-group, multi-centre trial of the efficacy and safety of depemokimab adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
Timeline	Trial start: Q1 2021 Data reported: Q2 2024
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	397
Treatment arms	Arm A: depemokimab plus SoC Arm B: placebo plus SoC
Description	A 52-week, randomised, double-blind, placebo-controlled, parallel-group, multi-centre trial of the efficacy and safety of depemokimab adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
Timeline	Trial start: Q1 2021 Data reported: Q2 2024
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

depemokimab

NCT05243680 - AGILE

Phase	III
Patient	Adult and adolescents with severe asthma with an eosinophilic phenotype from studies SWIFT-1 and SWIFT-2
Subjects	641
Treatment arms	Participants diagnosed with asthma receiving depemokimab
Description	A 52-week, open label extension phase of SWIFT-1 and SWIFT-2 to assess the long-term safety and efficacy of depemokimab adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
Timeline	Trial start: Q1 2022
Key end points	Number of participants with AEs and SAEs and incidence of immunogenicity over 52 weeks
Clinicaltrials.gov	Link

NCT04718389 - NIMBLE

Phase	III
Patient	Adult and adolescent severe asthmatic participants with an eosinophilic phenotype treated with depemokimab compared with mepolizumab or benralizumab
Subjects	1667
Treatment arms	Arm A: participants receiving depemokimab plus placebo matching prior anti-IL-5/5R treatment Arm B: participants receiving prior anti-IL-5/5R treatment plus placebo matching depemokimab
Description	A 52-week, randomised, double-blind, double-dummy, parallel group, multi-centre, non-inferiority trial assessing exacerbation rate, additional measures of asthma control and safety in adult and adolescent severe asthmatic participants with an eosinophilic phenotype treated with depemokimab compared with mepolizumab or benralizumab
Timeline	Trial start: Q1 2021
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

depemokimab

NCT05274750 - ANCHOR-1

Phase	III
Patient	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
Subjects	276
Treatment arms	Arm A: depemokimab Arm B: placebo
Description	A randomized, double-blind, parallel group trial to assess the efficacy and safety of 100 mg subcutaneous depemokimab in patients with CRSwNP
Timeline	Trial start: Q2 2022 Data reported: Q3 2024
Key end points	Change from baseline in total endoscopic nasal polyps (NP) score at week 52 Change from baseline in mean nasal obstruction verbal response scale (VRS) score from Week 49 through to Week 52
Clinicaltrials.gov	Link

NCT05281523 - ANCHOR-2

Phase	III
Patient	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
Subjects	264
Treatment arms	Arm A: depemokimab Arm B: placebo
Description	A randomized, double-blind, parallel group trial to assess the efficacy and safety of 100 mg subcutaneous depemokimab in patients with CRSwNP
Timeline	Trial start: Q2 2022 Data reported: Q3 2024
Key end points	Change from baseline in total endoscopic nasal polyps (NP) score at week 52 Change from baseline in mean nasal obstruction verbal response scale (VRS) score from Week 49 through to Week 52
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

depemokimab

NCT05263934 - OCEAN

Phase	III
Patient	Adults with relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) receiving standard of care 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 trial to investigate the efficacy and safety of depemokimab compared with mepolizumab in adults with relapsing or refractory EGPA receiving standard of care therapy
Timeline	Trial start: Q3 2022
Key end points	Number of participants with remission
Clinicaltrials.gov	Link

NCT05334368 - DESTINY

Phase	III
Patient	Adults with hypereosinophilic syndrome (HES) receiving standard of care therapy
Subjects	120
Treatment arms	Arm A: depemokimab Arm B: placebo
Description	A randomised, double-blind, placebo-controlled trial to investigate the efficacy and safety of depemokimab in adults with HES
Timeline	Trial start: Q3 2022
Key end points	Frequency of HES flares
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

linerixibat

NCT04950127 - GLISTEN

Phase	III
Patient	Participants with primary biliary cholangitis (PBC)
Subjects	238
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, multicentre trial to evaluate the efficacy and safety of linerixibat for the treatment of cholestatic pruritus in participants with primary biliary cholangitis
Timeline	Trial start: Q3 2021 Data reported: Q4 2024
Key end points	Change from baseline in monthly itch scores over 24 weeks using Numerical Rating Scale (NRS)
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

Ventolin (low carbon version of MDI)

NCT06261957

Phase	III
Patient	Participants aged 12 years and above with asthma
Subjects	412
Treatment arms	Arm A: Salbutamol HFA-134a Arm B: Salbutamol HFA-152a
Description	A randomized, double-blind, parallel group, multi-centre study to evaluate the long-term safety of salbutamol rescue medication when administered via metered dose inhalers containing the propellant HFA-152a or reference HFA-134a
Timeline	Trial start: Q2 2024
Key end points	AEs
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

Nucala (mepolizumab)

NCT04133909 - MATINEE

Phase	III
Patient	Participants with chronic obstructive pulmonary disease (COPD) experiencing frequent exacerbations and characterised by eosinophil levels
Subjects	806
Treatment arms	Arm A: placebo Arm B: mepolizumab
Description	A multicentre randomised, double-blind, parallel-group, placebo-controlled trial of mepolizumab 100 mg subcutaneously as add-on treatment in participants with COPD experiencing frequent exacerbations and characterised by eosinophil levels
Timeline	Trial start: Q4 2019 Primary data reported: Q3 2024
Key end points	Annualised rate of moderate or severe exacerbations
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

Benlysta (belimumab)

NCT05878717 - BLISSc-ILD

Phase	II/III
Patient	Adults with systemic sclerosis associated interstitial lung disease (SSc-ILD)
Subjects	300
Treatment arms	**Arm A**: belimumab + standard therapy **Arm B**: placebo + standard therapy
Description	A randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy and safety of belimumab administered subcutaneously in adults with SSc-ILD
Timeline	Trial start: Q4 2023
Key end points	Absolute change from baseline in Forced Vital Capacity (FVC) millilitre (mL) at week 52
Clinicaltrials.gov	Link

NCT06572384 - BEconneCTD-ILD

Phase	III
Patient	Adults with Interstitial Lung Disease (ILD) associated with Connective Tissue Disease (CTD)
Subjects	440
Treatment arms	**Arm A**: belimumab + standard therapy **Arm B**: placebo + standard therapy
Description	A randomized, double-blind, placebo controlled, parallel group study to evaluate the efficacy and safety of belimumab administered subcutaneously in adults with Interstitial Lung Disease (ILD) associated with Connective Tissue Disease (CTD)
Timeline	Trial start: Q3 2024
Key end points	Absolute change from baseline in Forced Vital Capacity (FVC) millilitre (mL) at week 52
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK1070806 (Atopic dermatitis)

NCT05999799 - AtDventure

Phase	IIb
Patient	Patients with moderate to severe atopic dermatitis
Subjects	175
Treatment arms	Arm A: GSK1070806 dose 1 Arm B: GSK1070806 dose 2 Arm C: GSK1070806 dose 3 Arm D: GSK1070806 dose 4 placebo
Description	A randomized, double-blind, parallel group, placebo-controlled dose finding study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of GSK1070806 SC injection
Timeline	Trial start: Q4 2023
Key end points	Percent change from baseline in eczema area and severity index (EASI) at Week 16
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK3915393 (Pulmonary fibrosis)

NCT06317285

Phase	II
Patient	Participants with Idiopathic Pulmonary Fibrosis (IPF)
Subjects	150
Treatment arms	Arm A: GSK3915393 Arm B: placebo
Description	A randomized, double-blind, placebo controlled, parallel group study (TRANSFORM) to evaluate the efficacy and safety of GSK3915393 in participants With Idiopathic Pulmonary Fibrosis (IPF)
Timeline	Trial start: Q2 2024
Key end points	Absolute change from baseline in Forced Vital Capacity (FVC) in millilitres (mL) at Week 26
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK4527226 (Alzheimer's disease)

NCT06079190 - PROGRESS-AD

Phase	II
Patient	Participant must be in the Alzheimer's continuum as defined by the 2018 National Institute on Aging and Alzheimer's Association (NIAAA) Research Framework corresponding to the clinical categories of MCI due to AD and mild AD dementia.
Subjects	282
Treatment arms	Arm 1: GSK4527226 Dose 1 Arm 2 GSK4527226 Dose 2 Arm 3: Placebo
Description	A parallel group, randomized, double-blind, placebo-controlled, 3-arm, multicentre treatment study to evaluate the efficacy and safety of GSK4527226 (AL101) intravenous infusion compared with placebo in patients with early Alzheimer's Disease
Timeline	Trial start: Q4 2023
Key end points	CDR-SB, iADRS, ADAS-Cog14, ADCS-ADL-MCI, ADCS-iADL, ADCOMS
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK4532990 (NASH/MASH)

NCT05583344 - HORIZON

Phase	IIb
Patient	Adults with non-alcoholic steatohepatitis (NASH) and advanced fibrosis
Subjects	284
Treatment arms	Arm 1: high dose GSK4532990 Arm 2: low dose GSK4532990 Arm 3: placebo
Description	A placebo-controlled trial to evaluate the efficacy and safety of GSK4532990 in adults with advanced non-alcoholic steatohepatitis (NASH)
Timeline	Trial start: Q1 2023
Key end points	Part 1: Percentage of participants achieving ≥ 1 stage improvement in histological fibrosis with no worsening of NASH (at week 52) Part 2: Percentage of participants achieving NASH resolution with no worsening of fibrosis (at week 52)
Clinicaltrials.gov	Link

NCT06104319 - SKYLINE

Phase	IIa
Patient	Adult participants with NASH or suspected NASH
Subjects	56
Treatment arms	Arm 1: GSK4532990 Dose 1 Arm 2: GSK4532990 Dose 2 Arm 3: GSK4532990 Dose 3 Arm 4: GSK4532990 Dose 4
Description	A single dose, open-label, dose exploration study to assess the PK-PD activity, safety, and tolerability of GSK4532990 in adult participants with NASH or suspected NASH
Timeline	Trial start: Q1 2024
Key end points	Predicted percent change from baseline in liver biopsy-derived HSD17B13 protein expression levels and mRNA expression levels
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK4532990 (ALD)

NCT06613698 - STARLIGHT

Phase	II
Patient	Adults with alcohol-related liver disease (ALD)
Subjects	393
Treatment arms	Arm 1: GSK4532990 Dose 1 Arm 2: GSK4532990 Dose 2 Arm 3: GSK4532990 Dose 3 Arm 4: GSK4532990 Dose 4 Arm 5: Placebo
Description	A dose-finding, double-blind, placebo-controlled study to evaluate the efficacy and safety of GSK4532990 for steatohepatitis in adults with ALD
Timeline	Trial start: Q4 2024
Key end points	AEs, SAEs Change from baseline in Liver Stiffness measurement (LSM) reduction using FibroScan® at Week 28 (kiloPascal) Liver stiffness will be measured by vibration-controlled transient elastography (VCTE) using the FibroScan® device. Change from baseline in model for end-stage liver disease (MELD) score reduction at Week 28
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK3862995 (COPD)

NCT06154837

Phase	I
Patient	Part A: Healthy participants Part B: Participants with Chronic Obstructive Pulmonary Disorder
Subjects	120
Treatment arms	Part A: Single ascending dose (SAD) of GSK3862995B Part B, arm A: Repeat doses GSK3862995B Part B, arm B: Placebo
Description	A two-part randomized, double-blind, placebo-controlled study to investigate safety, tolerability, immunogenicity, pharmacokinetics and pharmacodynamics of GSK3862995B following single ascending doses in healthy participants and repeat doses in participants with Chronic Obstructive Pulmonary Disease (COPD)
Timeline	Trial start: Q4 2023
Key end points	AEs and SAEs
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK4172239 (Sickle cell disease)

NCT05660265

Phase	I
Patient	Participants with sickle cell disease
Subjects	40
Treatment arms	Cohort 1: GSK4172239D (Dose 1) or placebo Cohort 2: GSK4172239D (Dose 2) or placebo Cohort 3: GSK4172239D (Dose 3) or placebo Cohort 4: GSK4172239D (Dose 4) or placebo Cohort 5: GSK4172239D (Dose 5) or placebo Food effect cohort
Description	A randomised, placebo-controlled, double-blind (sponsor unblind), parallel group, single dose, dose escalation to evaluate the safety, tolerability and pharmacokinetics of GSK4172239D
Timeline	Trial start: Q3 2023
Key end points	Area under curve zero to time infinity (AUC 0-inf) for GSK4106401 after a single oral dose of GSK4172239D
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK4347859 (Systemic lupus erythematosus)

NCT06188507

Phase	I
Patient	Healthy participants
Subjects	44
Treatment arms	Part 1, cohort 1: GSK4347859 or placebo Part 1, cohort 2: GSK4347859 or placebo Part 2, cohort 3: GSK4347859 (dose level A) or placebo Part 2, cohort 4: GSK4347859 (dose level B) or placebo Part 2, cohort 5: GSK4347859 (dose level C) or placebo
Description	A randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of GSK3996401 following single and multiple ascending doses of GSK4347859 in healthy participants
Timeline	Trial start: Q1 2024
Key end points	AEs and SAEs Maximum observed plasma concentration (Cmax) of GSK3996401 following administration of GSK4347859
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK4527363 (Systemic lupus erythematosus)

NCT06576271

Phase	I
Patient	Part A: healthy participants Part B: participants with active systemic lupus erythematosus Part C: healthy participants of Chinese and Japanese descent
Subjects	112
Treatment arms	Part A: Healthy participants receiving GSK4527363, placebo matching GSK4527363, or belimumab Part B: Participants with SLE receiving GSK4527363 or belimumab Part C: Healthy Japanese and Chinese participants receiving GSK4527363 or placebo matching GSK4527363
Description	A first-time-in-human, three-part study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of GSK4527363
Timeline	Trial start Q4 2024
Key end points	AEs and SAEs Clinically significant changes in physical examination, laboratory parameters, vital signs, and 12 lead electrocardiogram (ECG) findings Number of participants with clinically significant changes in Columbia-Suicide Severity Rating Scale (C-SSRS)
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK4528287 (IBD)

NCT06681181

Phase	I
Patient	Healthy participants
Subjects	48
Treatment arms	Part A: Dose 1 of GSK4528287 Part B: Dose 2 of GSK4528287 Part C: Dose 3 of GSK4528287 Part D: Dose 4 of GSK4528287 Part E: Dose 5 of GSK4528287 Part F: Dose 6 of GSK4528287 Part G: Placebo comparator
Description	A randomized, double blind, placebo controlled, single dose escalation study to evaluate the safety, tolerability, pharmacokinetics, and target engagement of GSK4528287 in healthy participants
Timeline	Trial start: Q4 2024
Key end points	AEs and SAEs
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

GSK4771261 (Autosomal dominant polycystic kidney disease)

NCT06734234

Phase	I
Patient	Part A: Healthy participants Part B: Participants with autosomal dominant polycystic kidney disease (ADPKD)
Subjects	84
Treatment arms	Part A: Health participants receiving different doses of GSK4771261, or placebo Part B: Participants with ADPKD receiving different doses of GSK4771261, or placebo
Description	A two-part randomized, double-blind, placebo-controlled, multi-centre study to evaluate safety, tolerability, and effects on blood and urine markers of single ascending doses of GSK4771261
Timeline	Trial start: Q4 2024
Key end points	AEs and SAEs
Clinicaltrials.gov	Link

Respiratory, Immunology and Inflammation

belantamab

NCT06413511

Phase	Ib
Patient	Participants with moderate to severe Systemic Lupus Erythematosus (SLE)
Subjects	16
Treatment arms	belantamab
Description	A dose escalation, open label study to evaluate the safety, tolerability, pharmacokinetics and pharmacological effect of a single intravenous infusion of belantamab in participants with moderate to severe SLE
Timeline	Trial start: Q2 2024
Key end points	AEs, SAEs
Clinicaltrials.gov	Link

Oncology

Oncology

belrestotug & CD226 assets

NCT05565378 - GALAXIES LUNG-201

Phase	II
Patient	Participants with previously untreated, locally advanced/metastatic, Programmed Death Ligand 1-selected non small cell lung cancer (NSCLC)
Subjects	340
Treatment arms	Comparator Arm: pembrolizumab monotherapy Intervention Arm: dostarlimab monotherapy Substudy 1A: dostarlimab + belrestotug (Dose A) Substudy 1B: dostarlimab + belrestotug (Dose B) Substudy 1C: dostarlimab + belrestotug (Dose C) Substudy 2: dostarlimab + belrestotug + nelistotug
Description	A randomized, open-label, platform trial utilizing a master protocol to evaluate novel immunotherapy combinations in participants with previously untreated, locally advanced/metastatic, Programmed Death Ligand 1-selected NSCLC
Timeline	Trial start: Q4 2022
Key end points	ORR
Clinicaltrials.gov	Link

NCT06472076 - GALAXIES LUNG-301

Phase	III
Patient	Participants with previously untreated, unresectable, locally advanced or metastatic PD-L1 selected non-small cell lung cancer
Subjects	1000
Treatment arms	Experimental: dostarlimab plus belrestotug Comparator: pembrolizumab plus placebo
Description	A randomized, multicentre, double-blind trial to investigate the safety and efficacy of belrestotug in combination with dostarlimab compared with placebo in combination with pembrolizumab in participants with previously untreated, unresectable, locally advanced or metastatic PD-L1 selected non-small cell lung cancer
Timeline	Trial start: Q3 2024
Key end points	PFS, OS
Clinicaltrials.gov	Link

Oncology

belrestotug & CD226 assets

NCT03739710 – ENTRÉE Lung

Phase	II
Patient	Participants with non-small cell lung cancer (NSCLC)
Subjects	185
Treatment arms	Arm B: dostarlimab + belrestotug Arm C: dostarlimab + belrestotug + nelistotug
Description	A randomized, open-label platform trial utilizing a master protocol to trial novel regimens versus standard of care treatment in NSCLC participants
Timeline	Trial start: Q1 2019
Key end points	Part 1: Number of participants with AEs, SAEs, DLT, clinically significant changes in vital signs, physical examination and laboratory parameters. Number of participants requiring dose modifications. Part 2: Overall survival
Clinicaltrials.gov	Link

NCT06062420 - GALAXIES H&N-202

Phase	II
Patient	Participants with recurrent/metastatic PD-L1 positive squamous cell carcinoma of the head and neck
Subjects	360
Treatment arms	dostarlimab monotherapy Sub study 1: dostarlimab and belrestotug Sub study 2: dostarlimab and nelistotug Sub study 3: dostarlimab and belrestotug and nelistotug Sub study 4: dostarlimab and GSK4381562
Description	A randomized, open-label, platform study using a master protocol to evaluate novel immunotherapy combinations as first-line treatment in participants with recurrent/metastatic PD-L1 positive squamous cell carcinoma of the head and neck
Timeline	Trial start: Q4 2023
Key end points	ORR
Clinicaltrials.gov	Link

Oncology

belrestotug & CD226 assets

NCT04446351 - nelistotug FTIH

Phase	I
Patient	Participants with advanced solid tumours
Subjects	244
Treatment arms	Arm A: nelistotug Arm B: nelistotug + dostarlimab Arm C: dostarlimab Arm D: dostarlimab + belrestotug Arm E: dostarlimab + belrestotug + nelistotug Arm G: dostarlimab + cobolimab
Description	A first time in human, open-label trial of nelistotug (GSK6097608) administered as monotherapy and in combination with anticancer agents
Timeline	Trial start: Q1 2020
Key end points	DLT, AEs and SAEs
Clinicaltrials.gov	Link

NCT05277051 - PVRIG FTIH

Phase	I
Patient	Participants with selected advanced solid tumours
Subjects	141
Treatment arms	Arm A: GSK4381562 monotherapy Arm B: GSK4381562 plus dostarlimab Arm C: GSK4381562 plus dostarlimab plus belrestotug Arm D: dostarlimab plus belrestotug Arm E: dostarlimab plus belrestotug plus GSK4381562 Arm F: dostarlimab plus belrestotug plus nelistotug Arm G: China Cohort: Participants receiving dostarlimab Arm H: China Cohort: Participants receiving dostarlimab plus belrestotug Arm I: GSK5764227 plus dostarlimab
Description	An open-label study of GSK4381562 administered as monotherapy and in combination with anticancer agents
Timeline	Trial start: Q1 2022
Key end points	DLT, Safety and PK
Clinicaltrials.gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT04246047 - DREAMM-7

Phase	III
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	571
Treatment arms	Arm A: belantamab mafodotin + bortezomib + dexamethasone (UnitedVd) Arm B: daratumumab, bortezomib + dexamethasone (D-Vd)
Description	A multicentre, open-label, randomised trial 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)
Timeline	Trial start: Q2 2020 Primary data reported: Q4 2023
Key end points	PFS, CRR, ORR, DoR, TTR, OS, PFS2, MRD negativity rate, safety
Clinicaltrials.gov	Link

NCT04484623 - DREAMM-8

Phase	III
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	357
Treatment arms	Arm A: belantamab mafodotin+ pomalidomide + dexamethasone (B-Pd) Arm B: Pomalidomide, bortezomib + dexamethasone (P-Vd)
Description	A multicentre, open-label, randomised trial to evaluate the efficacy and safety of belantamab mafodotin in combination with pomalidomide and dexamethasone (B-Pd) versus pomalidomide plus bortezomib and dexamethasone (PVd)
Timeline	Trial start: Q4 2020 Primary data reported: Q1 2024
Key end points	PFS, MRD negativity rate, ORR, CRR, VGPR or better rate, DoR, TTBR, TTR, TTP, OS, PFS2, safety
Clinicaltrials.gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT04126200 - DREAMM-5

Phase	I/II
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	464
Treatment arms	Substudy 1: belantamab mafodotin + OX40 (GSK3174998) Substudy 2: belantamab mafodotin + feladilimab Substudy 3: belantamab mafodotin + nirogacestat (GSI) Substudy 4: belantamab mafodotin + dostarlimab Substudy 5: belantamab mafodotin + isatuximab Substudy 6: belantamab mafodotin + nirogacestat + lenalidomide + dexamethasone Substudy 7: belantamab mafodotin + nirogacestat + pomalidomide + dexamethasone
Description	A randomised, open-label platform trial utilizing a master protocol to trial belantamab mafodotin as monotherapy and in combination with anti-cancer treatments
Timeline	Trial start: Q4 2019
Key end points	Dose escalation phase: DLT, safety, ORR Cohort expansion phase: ORR, CBR, safety
Clinicaltrials.gov	Link

NCT04091126 - DREAMM-9

Phase	I
Patient	Patients with newly diagnosed multiple myeloma (MM)
Subjects	144
Treatment arms	Belantamab mafodotin, selected doses Bortezomib, administered subcutaneously or intravenously approximately 1 hour after the belantamab mafodotin infusion until Cycle 8 Lenalidomide, administered as 25 or 10 mg orally, depending upon renal function. Dexamethasone, administered orally as 20 mg in cycles 1-8 and 40 mg in Cycle 9 onwards
Description	A randomised, dose and schedule evaluation trial to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of belantamab mafodotin administered in combination with standard of care
Timeline	Trial start: Q4 2019
Key end points	DLT, safety, RDI of lenalidomide and bortezomib, PK, PD, ORR, CRR, VGPR or better
Clinicaltrials.gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT06679101 - DREAMM-10

Phase	III
Patient	Newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation (TI-NDMM)
Subjects	520
Treatment arms	Arm A: belantamab mafodotin + lenalidomide + dexamethasone Arm B: daratumumab + lenalidomide + dexamethasone
Description	Open label trial of belantamab mafodotin in combination with lenalidomide and dexamethasone (BRd) to evaluate if this prolongs progression free survival and /or improves minimal residual disease negative status compared with daratumumab, lenalidomide, and dexamethasone (DRd) in participants with TI-NDMM
Timeline	Trial start: Q4 2024
Key end points	PFS, MRD negativity rate
Clinicaltrials.gov	Link

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	belantamab mafodotin monotherapy
Description	A trial to evaluate the pharmacokinetics and safety of belantamab mafodotin monotherapy
Timeline	Trial start: Q4 2020
Key end points	PK, change in vital signs, safety
Clinicaltrials.gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT04398680 - DREAMM-13

Phase	I
Patient	Relapsed/refractory multiple myeloma (RRMM) who have normal and impaired hepatic function
Subjects	28
Treatment arms	belantamab mafodotin monotherapy
Description	A trial to evaluate the pharmacokinetics and safety of belantamab mafodotin monotherapy in participants who have normal and impaired hepatic function
Timeline	Trial start: Q2 2021
Key end points	PK, change in vital signs, safety
Clinicaltrials.gov	Link

NCT05064358 - DREAMM-14

Phase	II
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	177
Treatment arms	belantamab mafodotin
Description	A randomised, parallel, open-label study to investigate the safety, efficacy and pharmacokinetics of various dosing regimens of single-agent belantamab mafodotin (GSK2857916)
Timeline	Study start: Q1 2022
Key end points	% of patients with >= Gr 2 ocular events, safety, ORR, TTR, DoR, TTP, PFS, OS
Clinicaltrials.gov	Link

Oncology

cobolimab

NCT04655976 - COSTAR LUNG

Phase	II/III
Patient	Patients with advanced non-small cell lung cancer (NSCLC) who have progressed on prior anti-PD-(L)1 therapy and chemotherapy
Subjects	758
Treatment arms	Arm A: cobolimab + dostarlimab + docetaxel Arm B: dostarlimab + docetaxel Arm C: docetaxel
Description	A randomised, open label trial comparing cobolimab + dostarlimab + docetaxel to dostarlimab + docetaxel to docetaxel alone
Timeline	Trial start: Q4 2020
Key end points	OS(primary), ORR, PFS, DoR, TTD
Clinicaltrials.gov	Link

Oncology

Jemperli (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 (+SoC) followed by placebo
Description	A randomised, double-blind, multi-centre trial of dostarlimab plus carboplatin-paclitaxel with and without niraparib maintenance versus placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced endometrial cancer
Timeline	Trial start: Q3 2019 Part 1 data reported: Q4 2022; Part 2 data reported: Q4 2023
Key end points	Part 1: Co-primary PFS by IA (dMMR/MSI-H and ITT) and OS (ITT) Part 2: Primary PFS (ITT) and key secondary OS (ITT)
Clinicaltrials.gov	Link

NCT04581824 - PERLA

Phase	II
Patient	Participants with metastatic non-squamous non-small cell lung cancer (NSCLC)
Subjects	244
Treatment arms	Arm A: dostarlimab + chemotherapy Arm B: pembrolizumab + chemotherapy
Description	A randomised, double-blind trial to evaluate the efficacy of dostarlimab plus chemotherapy versus pembrolizumab plus chemotherapy in metastatic non-squamous NSCLC
Timeline	Trial start: Q4 2020 Primary data reported: Q4 2022
Key end points	ORR, OS, PFS
Clinicaltrials.gov	Link

Oncology

Jemperli (dostarlimab)

NCT02715284 - GARNET

Phase	I/II
Patient	Participants with 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 multi-centre, open-label, first-in-human trial evaluating dostarlimab in participants with advanced solid tumours who have limited available treatment options
Timeline	Trial start: Q1 2016 Primary data reported: Q1 2019
Key end points	ORR, DoR, safety
Clinicaltrials.gov	Link

NCT05723562 - AZUR-1

Phase	II
Patient	Patients with untreated stage II/III mismatch repair deficient/high microsatellite instability (dMMR/MSI-H) locally advanced rectal cancer
Subjects	154
Treatment arms	dostarlimab monotherapy
Description	A single-arm, open-label trial with dostarlimab monotherapy in participants with untreated stage II/III dMMR/MSI-H locally advanced rectal cancer
Timeline	Trial start: Q1 2023
Key end points	Sustained cCR for 12, 24 and 36 months, EFS at 3 years
Clinicaltrials.gov	Link

Oncology

Jemperli (dostarlimab)

NCT05855200 - AZUR-2

Phase	III
Patient	Participants with untreated T4N0 or Stage III (resectable), mismatch repair deficient/high microsatellite instability (dMMR/MSI-H) colon cancer
Subjects	711
Treatment arms	Arm A: dostarlimab Arm B: Standard of care (FOLFOX/CAPEOX) or expectant observation post surgery.
Description	An open-label, randomized trial of perioperative dostarlimab monotherapy versus standard of care in participants with untreated T4N0 or Stage III dMMR/MSI-H resectable colon cancer
Timeline	Trial start: Q3 2023
Key end points	EFS assessed by Blinded Independent Central Review (BICR)
Clinicaltrials.gov	Link

NCT06567782 - AZUR-4

Phase	II
Patient	Participants with previously untreated T4N0 or stage III MMRp/MSS colon cancer
Subjects	120
Treatment arms	Arm A: dostarlimab plus CAPEOX (chemotherapy) Arm B: CAPEOX (chemotherapy)
Description	An open label, randomized study of neoadjuvant dostarlimab plus CAPEOX versus CAPEOX in participants with previously untreated T4N0 or stage III MMRp/MSS colon cancer
Timeline	Trial start: Q4 2024
Key end points	Major pathological response (mPR) rate, AEs, SAEs, immune-mediated AEs, and AEs leading to death or discontinuation of study intervention and by severity
Clinicaltrials.gov	Link

Oncology

Jemperli (dostarlimab)

NCT06256588 - JADE

Phase	III
Patient	Participants have newly diagnosed unresected locally advanced histologically confirmed HNSCC of the oral cavity, oropharynx, hypopharynx or larynx and completed cisplatin plus radiotherapy (termed "CRT" in this protocol) with curative intent and has no evidence of distant metastatic disease.
Subjects	864
Treatment arms	Arm A: dostarlimab Arm B: Placebo
Description	A randomized, double-blind, placebo-controlled study to evaluate dostarlimab as sequential therapy after chemoradiation in participants with locally advanced unresected head and neck squamous cell carcinoma
Timeline	Trial start: Q1 2024
Key end points	EFS assessed by Blinded Independent Central Review (BICR)
Clinicaltrials.gov	Link

Oncology

Zejula (niraparib)

NCT03602859 - FIRST

Phase	III
Patient	Participants with Stage III or IV nonmucinous epithelial ovarian cancer
Subjects	1402
Treatment arms	Arm A: SOC (carboplatin + paclitaxel ± bevacizumab) +placebo Arm B: SOC + niraparib Arm C: SOC + dostarlimab + niraparib
Description	A randomised, double-blind 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
Timeline	Study start: Q4 2018 Data reported: Q4 2024
Key end points	PFS and OS for ITT participants. Primary analysis is ARM B vs ARM C.
Clinicaltrials.gov	Link

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 randomised, double-blind, placebo-controlled, multicentre study comparing niraparib plus pembrolizumab versus placebo plus pembrolizumab as maintenance therapy
Timeline	Study start: Q4 2020
Key end points	Primary: PFS in CR/PR population assessed by BICR using Response Evaluation Criteria in Solid tumours (RECIST) ; key secondary: PFS in ITT, OS in CR/PR, OS ITT, TPP CNS
Clinicaltrials.gov	Link

Oncology

belantamab

NCT05714839 - DREAMM-20

Phase	I/II
Patient	Relapsed/refractory multiple myeloma (RRMM)
Subjects	48
Treatment arms	Part 1: belantamab Part 2: belantamab and Belamaf For both parts, may switch to belantamab mafodotin in case of PD
Description	An open-lab multicentre, dose escalation and expansion trial to investigate the safety, tolerability and clinical activity of belantamab as monotherapy and in combination with other treatments in participants with multiple myeloma
Timeline	Trial start: Q2 2023
Key end points	Part 1: Safety and tolerability (including DLTs), PK and recommended Part 2 dose Part 2: Safety and tolerability, PK, efficacy, and recommended phase II dose
Clinicaltrials.gov	Link

Oncology

GSK4418959

NCT06710847 - SYLVER

Phase	I/II
Patient	Adult Participants With Mismatch Repair-deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid tumours
Subjects	73
Treatment arms	Arm A: GSK4418959 dose escalation Arm B: GSK4418959 dose escalation Arm C: GSK4418959 dose escalation plus PD-1 inhibitor
Description	An open-label, multicentre, dose escalation and expansion study of the oral DNA Helicase Werner Inhibitor (WRNi) GSK4418959 alone or in combination with other anti-cancer agents
Timeline	Trial start: Q4 2024
Key end points	Number of participants with dose limiting toxicities (DLRs), treatment emer gent adverse events (TEAEs), and dosage interruptions, dose reductions, drug discontinuation up to 21 days
Clinicaltrials.gov	Link

Oncology

GSK4524101

NCT06077877

Phase	I/II
Patient	Adult participants with solid tumours
Subjects	135
Treatment arms	Arm A, Part 1: GSK4524101 monotherapy Arm B, Part 1: GSK4524101 plus niraparib Arm C, Part 1: GSK4524101 food effect cohort Arm D, Part 2: GSK4524101 plus niraparib Arm E, Part 2: Niraparib
Description	A first-time-in-human, open-label, multicentre, dose escalation and expansion study of the oral DNA Polymerase Theta inhibitor (POLQi) GSK4524101 and the PARP inhibitor (PARPi) niraparib in adult participants with solid tumours
Timeline	Trial start: Q4 2023
Key end points	DLTs, AEs, SAEs, ORR
Clinicaltrials.gov	Link

Oncology

GSK5733584

NCT06431594

Phase	I
Patient	Adult participants with solid tumours
Subjects	240
Treatment arms	Part 1: Dose escalation with GSK5733584 Part 2: Dose expansion with GSK5733584
Description	A trial to evaluate the safety, tolerability, pharmacokinetics and clinical activity of GSK5733584 for injection in subjects with advanced solid tumours
Timeline	Trial start: Q3 2024
Key end points	Part 1: DLT Part 2: ORR
Clinicaltrials.gov	Link

Oncology

GSK5764227

NCT06551142

Phase	I
Patient	Adult participants with advanced solid tumours
Subjects	240
Treatment arms	Phase 1a: GSK5764227 Phase 1b: GSK5764227 Phase 1b active comparator: topotecan
Description	A clinical study to evaluate the safety, tolerability, pharmacokinetics, and clinical activity of GSK5764227 in participants with advanced solid tumours
Timeline	Trial start: Q3 2024
Key end points	Phase 1a: AEs, SAEs, DLTs Phase 1b: PFS, ORR
Clinicaltrials.gov	Link

HIV

HIV

VH3739937

NCT06061081

Phase	IIa
Patient	Treatment-naïve adults living with HIV-1
Subjects	28
Treatment arms	Arm A: VH3739937 Arm B: placebo
Description	A randomized, double-blind (sponsor-unblinded), placebo-controlled, adaptive study to investigate the antiviral effect, safety, tolerability and pharmacokinetics of VH3739937 in treatment-naïve adults living with HIV-1
Timeline	Trial start: Q4 2023 Trial on temporary halt
Key end points	AEs and SAEs, concentrations of VH3739937
Clinicaltrials.gov	Link

HIV

VH3810109

NCT05996471 - EMBRACE

Phase	IIb
Patient	Antiretroviral therapy (ART)-experienced adults living with HIV
Subjects	128
Treatment arms	Group 1: VH3810109 + cabotegravir Group 2 VH3810109 + rHuPH20 + cabotegravir Group 3: Active comparator - Participants receiving standard of care (SOC) antiretroviral therapy (ART)
Description	A multicentre, randomised, open-label, trial comparing the efficacy, safety, PK, and tolerability of VH3810109, administered either intravenously or as a subcutaneous infusion with rHuPH20, in combination with cabotegravir given intramuscularly, to standard of care in virologically suppressed, antiretroviral therapy (ART)-experienced adults living with HIV
Timeline	Trial start: Q3 2023
Key end points	Safety, plasma HIV-1 levels
Clinicaltrials.gov	Link

HIV

VH4011499

NCT06012136

Phase	I
Patient	Healthy adults
Subjects	160
Treatment arms	Arm A: VH4004280 Arm B: Placebo Arm C: VH4011499
Description	A double-blind (sponsor-unblinded), placebo-controlled, randomized, single dose escalation study to evaluate the safety, tolerability, and pharmacokinetics of a parenterally administered suspension of investigational capsid inhibitors in healthy adults
Timeline	Trial start: Q3 2023
Key end points	AEs, PK
Clinicaltrials.gov	Link

NCT06039579 - CINNAMON

Phase	II
Patient	HIV-1 infected treatment-naïve adults
Subjects	42
Treatment arms	Arm A: VH4004280 Arm B: VH4011499 Arm C: VH4004280-matching placebo Arm D: VH4011499-matching placebo
Description	A randomized, double-blind (sponsor-unblinded), placebo-controlled trial to investigate the antiviral effect, safety, tolerability and pharmacokinetics of orally administered investigational capsid inhibitor monotherapy in HIV-1 infected treatment-naïve adults
Timeline	Trial start: H2 2023 Trial end: Q2 2024
Key end points	Maximum change from baseline (Day 1) in plasma HIV-1 RNA
Clinicaltrials.gov	Link

HIV

VH4011499

NCT06724640

Phase	I
Patient	Adults without HIV
Subjects	168
Treatment arms	VH4011499 Active Group VH4011499 Placebo Group
Description	A double-blind (sponsor-unblinded), placebo-controlled, randomized, single dose escalation study to investigate the safety, tolerability, and pharmacokinetics of parenterally administered long-acting formulations of VH4011499 in adults without HIV
Timeline	Trial start: Q4 2024
Key end points	AEs, PK
Clinicaltrials.gov	Link

HIV

VH4524184

NCT06214052

Phase	IIa
Patient	HIV-1 infected treatment naïve adults
Subjects	28
Treatment arms	Arm A: VH4524184 Arm B: Placebo
Description	A randomized, double-blind (sponsor unblinded), placebo-controlled study to investigate the antiviral effect, safety, tolerability and pharmacokinetics of VH4524184 in HIV-1 infected treatment naïve adults
Timeline	Trial start: Q1 2024 Trial end: Q2 2024
Key end points	Maximum change from baseline in log10 plasma HIV-1 RNA
Clinicaltrials.gov	Link

HIV

cabotegravir

NCT05418868

Phase	I
Patient	Healthy adult volunteers
Subjects	180
Treatment arms	Part A: Participants receiving CAB 200 mg/mL with rHuPH20 Part C: Participants receiving CAB 400 mg/mL Part D: Participants receiving CAB 400 mg/mL with rHuPH20 Part E: Participants receiving rilpivirine (RPV) formulation
Description	A multi-centre, open-label, single dose escalation trial to evaluate the pharmacokinetics, safety and tolerability of long-acting cabotegravir co-administered with recombinant human hyaluronidase PH20 (rHuPH20) in healthy adult volunteers
Timeline	Trial start: Q2 2022
Key end points	Plasma concentrations of cabotegravir and rilpivirine
Clinicaltrials.gov	Link

NCT06033547

Phase	I
Patient	Healthy adult volunteers
Subjects	56
Treatment arms	Part A: Participants receiving cabotegravir Formulation F Part B: Participants receiving cabotegravir Formulation G
Description	An open-label, single dose escalation study to evaluate the pharmacokinetics, safety and tolerability of two different formulations of long-acting cabotegravir administered to healthy adult participants
Timeline	Trial start: Q3 2023
Key end points	Plasma concentrations of cabotegravir
Clinicaltrials.gov	Link

HIV

cabotegravir ultra long-acting (ULA) for HIV Prevention

NCT06741397

Phase	IIb
Patient	Healthy adolescent and adult participants
Subjects	200
Treatment arms	Participants receive lead-in injections comprising cabotegravir LA during month one and injections of a new formulation of CAB LA at Month 3, Month 5 and every 4 months thereafter to Month 29
Description	A single arm, repeat dose study to evaluate the pharmacokinetic profile, safety, and tolerability of a new formulation of cabotegravir LA injected intramuscularly Q4M in adolescent and adult participants at risk of HIV acquisition
Timeline	Trial start: Q4 2024
Key end points	CAB trough concentrations
Clinicaltrials.gov	Link

NCT06786520

Phase	I
Patient	Healthy adult volunteers
Subjects	60
Treatment arms	Participants will receive the CAB LA Q2M regimen up to Month 9 then will receive the CAB ULA Q4M regimen up to Month 23.
Description	A single arm, repeat dose study to evaluate the pharmacokinetics, safety, and tolerability of switching to cabotegravir ultra long-acting (CAB ULA) from cabotegravir long-acting (CAB LA) in healthy adult volunteers
Timeline	Trial start: Q1 2025
Key end points	Plasma concentration of CAB at the end of the CAB LA phase compared to plasma concentration of CAB at the end of the CAB ULA phase
Clinicaltrials.gov	Link

HIV

VH4527079

NCT06652958

Phase	I
Patient	Healthy adults and persons with HIV
Subjects	86
Treatment arms	Arm A, Cohort 1: VH4527079 Dose 1 (lowest dose) by IV infusion. Arm A, Cohort 2: VH4527079 Dose 2 (low dose) by IV infusion. Arm A, Cohort 3: VH4527079 Dose 3 (mid-low dose) by IV infusion. Arm A, Cohort 4: VH4527079 Dose 4 (mid-high dose) by IV infusion. Arm A, Cohort 5: VH4527079 Dose 5 (high dose) by IV infusion. Arm A, Cohort 6: VH4527079 Dose 6 (max dose) by IV infusion. Arm A, Cohort 7: VH4527079 Dose 1 (lowest dose) by SC injection Arm B, Cohort 8: three doses of VH4527079 dose that is selected in Arm A, by IV infusion, separated by a time interval. Arm B, Cohort 9: Participants with HIV receive three doses of VH4527079 dose that is selected in Arm A, by IV infusion, separated by a time interval.
Description	An open-label study of the safety and pharmacokinetics of a human monoclonal antibody, VH4527079, administered either intravenously or subcutaneously to healthy adults and persons with HIV
Timeline	Trial start: Q4 2024
Key end points	Safety
Clinicaltrials.gov	Link

Infectious diseases

Infectious diseases

Arexvy (RSV Adults)

NCT04732871 - RSV OA=ADJ-004

Phase	III
Patient	Adults ≥60 years of age
Subjects	1720
Treatment arms	Arm A: RSVPreF3 OA Day 1, 12 months & 24 months Arm B: RSVPreF3 OA Day 1 , 24 and 48 months Arm C: RSVPreF3 OA Day 1 then follow up, at month 36, re-randomization in 2 groups
Description	A randomised, open-label, multi-country trial to evaluate the immunogenicity, safety, reactogenicity and persistence of a single dose of the RSVPreF3 OA investigational vaccine and different revaccination schedules in adults aged 60 years and above
Timeline	Trial start: Q1 2021 Primary data reported: Q2 2022
Key end points	Humoral immune response
Clinicaltrials.gov	Link

NCT04886596 - RSV OA=ADJ-006

Phase	III
Patient	Adults ≥60 years of age
Subjects	26,668
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 randomised, placebo-controlled, observer-blind, multi-country trial to demonstrate the efficacy of a single dose and revaccination prior to Season 2 of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above
Timeline	Trial start: Q2 2021 Primary data reported: Q2 2022; season two data reported: Q2 2023; season three data reported: Q4 2024
Key end points	Efficacy of a single dose and revaccination prior to Season 2 of RSVPreF3 OA vaccine in the prevention of RSV-LRTD in adults ≥ 60 YoA
Clinicaltrials.gov	Link

Infectious diseases

Arexvy (RSV Adults)

NCT04841577 - RSV OA=ADJ-007

Phase	III
Patient	Adults ≥60 years of age
Subjects	976
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	An open-label, randomised, controlled, multi-country trial to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU-QIV vaccine in adults aged 60 years and above
Timeline	Trial start: Q2 2021 Primary data reported: Q4 2022
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=ADJ-008

Phase	III
Patient	Adults aged 65 years and above
Subjects	1029
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	An open-label, randomised, controlled, multi-country trial to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU HD vaccine in adults aged 65 years and above
Timeline	Trial start: Q4 2022 Primary data reported: Q2 2023
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

Arexvy (RSV Adults)

NCT05059301 - RSV OA=ADJ-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 randomised, double-blind, multi-country trial to evaluate consistency, safety and reactogenicity of 3 lots of RSVPreF3 OA investigational vaccine administrated as a single dose in adults aged 60 years and above
Timeline	Trial start: Q4 2021 Trial end: Q2 2022
Key end points	RSVPreF3-binding IgG concentrations at 1 month post vaccination for three lots of RSVPreF3 OA investigational vaccine
Clinicaltrials.gov	Link

NCT05568797 - RSV OA=ADJ-017

Phase	III
Patient	Adults aged 65 years and above
Subjects	1045
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	An open-label, randomised, controlled, multi-country trial to evaluate the immune response, safety and reactogenicity of an RSVPreF3 OA investigational vaccine when co-administered with FLU aQIV (inactivated influenza vaccine – adjuvanted) in adults aged 65 years and above
Timeline	Trial start: Q4 2022 Primary data reported: Q2 2023
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

Arexvy (RSV 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	1576
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	An observer-blind, randomised, placebo-controlled trial to evaluate the non-inferiority of the immune response and safety of the RSVPreF3 OA investigational vaccine in adults 50 59 years of age, including adults at increased risk of respiratory syncytial virus lower respiratory tract disease, compared to older adults ≥60 years of age
Timeline	Trial start: Q4 2022 Primary data reported: Q4 2023
Key end points	Humoral immune response in healthy participants 50-59 years of age and in participants 50-59 years of age at increased risk of RSV-LRTD compared to OA (≥ 60 YoA)
Clinicaltrials.gov	Link

NCT05879107 - RSV OA=ADJ-019

Phase	III
Patient	Adults ≥60 years of age
Subjects	1113
Treatment arms	Arm A (co-ad group): RSVPreF3 OA investigational vaccine co-administered with PCV20 vaccine Arm B (control group): PCV20 vaccine on Day 1 and the RSVPreF3 OA investigational vaccine on Day 31.
Description	An open-label, randomised, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with PCV20 in adults aged 60 years and older
Timeline	Trial start: Q2 2023
Key end points	Opsonophagocytic antibody titers for each of the pneumococcal vaccine serotypes and RSV-A & RSV-B serum neutralizing titers
Clinicaltrials.gov	Link

Infectious diseases

Arexvy (RSV Adults)

NCT05966090 - RSV OA=ADJ-020

Phase	III
Patient	Adults aged 50 years and older
Subjects	530
Treatment arms	Arm A: Participants will be administered first dose of HZ/su vaccine and the RSVPreF3 OA investigational vaccine together on Day 1. A second dose of the HZ/su vaccine will be administered at Day 61. Arm B: Participants will be administered first dose HZ/su vaccine on Day 1, followed by the RSVPreF3 OA investigational vaccine on Day 31, and then second dose of HZ/su vaccine on Day 61.
Description	An open-label, randomised, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with Herpes Zoster recombinant subunit (HZ/su) vaccine in adults aged 50 years and older
Timeline	Trial start: Q3 2023 Primary data reported: Q3 2024
Key end points	Anti-gE antibody concentrations expressed as group geometric mean concentration ratio RSV-A & -B serum neutralizing titers expressed as group geometric mean titer
Clinicaltrials.gov	Link

NCT05921903 - RSV OA=ADJ-023

Phase	IIb
Patient	Immunocompromised (IC) adults 50 years of age and above
Subjects	375
Treatment arms	Arm A: RSV_IC_1 group, IC patients receiving 1 dose of RSVPreF3 OA investigational vaccine at Visit 1 (Day 1). Arm B: RSV_IC_2 group, IC patients receiving 2 doses of RSVPreF3 OA investigational vaccine at Visit 1 (Day 1) and Visit 3 (Visit 1 + 30-60 days) Arm C: RSV_HA group, healthy participants receiving 1 dose of RSVPreF3 OA investigational vaccine at Visit 1 (Day 1).
Description	A randomised, controlled, open-label trial to evaluate the immune response and safety of the RSVPreF3 OA investigational vaccine in adults (≥50 years of age) when administered to lung and renal transplant recipients comparing one versus two doses and compared to healthy controls (≥50 years of age) receiving one dose
Timeline	Trial start: Q3 2023 Primary data reported: Q4 2024
Key end points	RSV-A & -B serum neutralizing titers expressed as mean geometric increase post Dose 2 over post Dose 1
Clinicaltrials.gov	Link

Infectious diseases

Arexvy (RSV Adults)

NCT06374394 - RSV OA=ADJ-013

Phase	III
Patient	Adults aged 50 years and above
Subjects	850
Treatment arms	RSVPreF3 OA investigational vaccine COVID-19 mRNA vaccine
Description	An open-label, randomized, controlled study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with a COVID-19 mRNA vaccine (Omicron XBB.1.5)
Timeline	Trial start: Q2 2024
Key end points	RSV-A, RSV-B neutralization titers SARS-CoV-2 Omicron XBB.1.5 neutralization titers
Clinicaltrials.gov	Link

NCT06389487 - RSV OA=ADJ-025

Phase	IIIb
Patient	Adult participants, 18-49 YOA, at increased risk (AIR) for RSV disease and older adults (OA) participants, >=60 YOA
Subjects	1450
Treatment arms	Part A: RSV-A-AIR Group, RSVPreF3 OA investigational vaccine Part A: RSV-OA Group, RSVPreF3 OA investigational vaccine Part B: RSV-A-AIR Group, RSVPreF3 OA investigational vaccine
Description	An open-label study to evaluate the non-inferiority of the immune response and to evaluate the safety of the RSVPreF3 OA investigational vaccine in adults 18-49 years of age at increased risk for Respiratory Syncytial Virus disease, compared to older adults >=60 years of age
Timeline	Trial start: Q2 2024 Primary data reported: Q3 2024
Key end points	RSV-A, RSV-B neutralizing titers Seroresponse rate (SRR) in RSV-A and RSV-B neutralizing titers
Clinicaltrials.gov	Link

Infectious diseases

Arexvy (RSV Adults)

NCT06551181 - RSV OA=ADJ-021

Phase	III
Patient	Adults aged 60 years and above
Subjects	2600
Treatment arms	Overseas: RSVPreF3 OA investigational vaccine China: RSVPreF3 OA investigational vaccine China: Placebo
Description	A study on the immune response, safety and the occurrence of Respiratory Syncytial Virus (RSV)-associated respiratory tract illness after administration of RSV OA vaccine in adults 60 years and older
Timeline	Trial start: Q3 2024
Key end points	RSV-A, RSV-B neutralization titers Seroresponse rate (SRR) in RSV-A and RSV-B neutralizing titers
Clinicaltrials.gov	Link

NCT06534892 - OA+ADJ-012

Phase	IIIb
Patient	Adults aged 60 years and above
Subjects	12000
Treatment arms	RSV_PreS4: Participants in this group will receive 1 dose of RSVPreF3 OA vaccine before RSV Season 4. RSV_PreS5: Participants in this group will receive 1 dose of RSVPreF3 OA vaccine before RSV Season 5. RSV_1Dose: Participants in this group will not receive any additional dose of RSV PreF3 OA vaccine.
Description	A randomized, open label, multicountry, multi-center, extension and crossover vaccination study to evaluate the immunogenicity and safety of different revaccination schedules and persistence of a single dose of the RSVPreF3 OA vaccine in adults aged 60 years and above who participated in the RSV OA=ADJ-006 study
Timeline	Trial start: Q3 2024
Key end points	RSV-A, RSV-B neutralization titers
Clinicaltrials.gov	Link

Infectious diseases

bepirovirsen

NCT05630807 - B-WELL 1

Phase	III
Patient	Non-cirrhotic nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	981
Treatment arms	Arm A: bepirovirsen for 24 weeks Arm B: placebo
Description	A multicentre, randomised, double blind trial to confirm the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus
Timeline	Trial start: Q1 2023
Key end points	Number of participants with baseline HBsAg≤ 3000IU/mL achieving functional cure (FC)
Clinicaltrials.gov	Link

NCT05630820 - B-WELL 2

Phase	III
Patient	Non-cirrhotic nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	857
Treatment arms	Arm A: bepirovirsen for 24 weeks Arm B: placebo
Description	A multicentre, randomised, double blind trial to confirm the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus
Timeline	Trial start: Q1 2023
Key end points	Number of participants with baseline HBsAg≤ 3000IU/mL achieving functional cure (FC)
Clinicaltrials.gov	Link

Infectious diseases

gepotidacin

NCT04020341 - EAGLE 2

Phase	III
Patient	Females with uUTI / acute cystitis
Subjects	1531
Treatment arms	Arm A: 1500 mg BID gepotidacin + placebo x 5 days Arm B: 100 mg BID nitrofurantoin + placebo x 5 days
Description	A randomised, multicentre, parallel-group, double-blind, double-dummy trial in adolescent and adult female participants comparing the efficacy and safety of gepotidacin to nitrofurantoin in the treatment of uncomplicated urinary tract infection (acute cystitis)
Timeline	Trial start: Q4 2019 Data reported: Q2 2023
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: 1500 mg BID gepotidacin + placebo x 5 days Arm B: 100 mg BID nitrofurantoin + placebo x 5 days
Description	A randomised, multicentre, parallel-group, double-blind, double-dummy trial in adolescent and adult female participants comparing the efficacy and safety of gepotidacin to nitrofurantoin in the treatment of uncomplicated urinary tract infection (acute cystitis)
Timeline	Trial start: Q2 2020 Data reported: Q2 2023
Key end points	Number of participants with therapeutic response (combined per participant clinical and microbiological response)
Clinicaltrials.gov	Link

Infectious diseases

gepotidacin

NCT04010539 - EAGLE 1

Phase	III
Patient	Uncomplicated urogenital gonorrhoea caused by *Neisseria gonorrhoeae*
Subjects	628
Treatment arms	Arm A: 2 x 3000 mg gepotidacin for one day Arm B: ceftriaxone (500mg IM), 1 g azithromycin
Description	A randomised, multicentre, open-label trial in adolescent and adult participants comparing the efficacy and safety of gepotidacin to ceftriaxone plus azithromycin in the treatment of uncomplicated urogenital gonorrhoea caused by *Neisseria gonorrhoeae*
Timeline	Trial start: Q4 2019 Data reported: Q1 2024
Key end points	Number of participants with culture-confirmed bacterial eradication 4-8 days post treatment
Clinicaltrials.gov	Link

Infectious diseases

MenABCWY

NCT04707391 - MenABCWY-019

Phase	IIIb
Patient	Healthy adolescents and adults aged 15-25 years
Subjects	1247
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 randomised, controlled, observer-blind trial to evaluate safety and immunogenicity of GSK's meningococcal ABCWY vaccine when administered in healthy adolescents and adults previously primed with meningococcal ACWY vaccine
Timeline	Trial start: Q1 2021 Data reported: Q1 2024
Key end points	hSBA titers
Clinicaltrials.gov	Link

NCT04502693 - MenABCWY V72 72

Phase	III
Patient	Healthy adolescents and adults ages 10-25 years
Subjects	3638
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 GSK Biologicals S.A.'s Meningococcal Group B and combined ABCWY vaccines in healthy adolescents and young adults
Timeline	Trial start: Q3 2020 Data reported: Q1 2023
Key end points	hSBA titers
Clinicaltrials.gov	Link

Infectious diseases

MenABCWY

NCT05087056 - MenABCWY-020

Phase	IIb
Patient	Healthy adolescents ≥11 to <15 years of age
Subjects	300
Treatment arms	Arm A: ABCWY-24 Group Arm B: ABCWY-48 Group
Description	A randomised, observer-blind trial to describe the safety, tolerability and immunogenicity of MenABCWY administered on different dosing schedules in healthy adolescents
Timeline	Trial start: Q4 2021
Key end points	hSBA titers ≥ LLOQ of each *N. meningitidis* serogroup B indicator strain
Clinicaltrials.gov	Link

Infectious diseases

GSK4178116 (Varicella new strain)

NCT06693895

Phase	III
Patient	Healthy children aged 12 to 15 months
Subjects	750
Treatment arms	Participants receive 1 dose of a VNS vaccine, 1 dose of measles, mumps, and rubella (MMR) vaccine, 1 dose of hepatitis A (HAV) vaccine, and 1 dose of PCV (either PCV 13 or Vaxneuvance or PCV 20) on Day 1. Participants receive 1 dose of a marketed VV, 1 dose of MMR vaccine, 1 dose of HAV vaccine, and 1 dose of PCV (either PCV 13 or Vaxneuvance or PCV 20) on Day 1.
Description	A Phase 3a, observer-blind, randomized, controlled study to evaluate the safety of an investigational varicella vaccine compared with Varivax, administered as a first dose to healthy children 12 to 15 months of age
Timeline	Trial start: Q4 2024
Key end points	AEs, SAEs
Clinicaltrials.gov	Link

NCT06740630

Phase	III
Patient	Healthy children 12 to 15 months of age
Subjects	1840
Treatment arms	Participants receive 1 dose of the investigational VNS vaccine of Lot 1 or Lot 2 or Lot 3, 1 dose of measles, mumps, and rubella (MMR) vaccine, 1 dose of hepatitis A vaccine (HAV), and 1 dose of PCV (either PCV 13 or Vaxneuvance or PCV 20) on Day 1. Participants receive 1 dose of a marketed varicella vaccine (VV) of Lot 1 or Lot 2, 1 dose of MMR vaccine, 1 dose of HAV vaccine, and 1 dose of PCV (either PCV 13 or Vaxneuvance or PCV 20) on Day 1.
Description	A Phase 3a, observer-blind, randomized, controlled study to demonstrate lot-to-lot consistency and evaluate the immunogenicity and safety of an investigational varicella vaccine compared with Varivax, administered as a first dose to healthy children 12 to 15 months of age
Timeline	Trial start: Q1 2025
Key end points	Anti-glycoprotein-E antibodies at day 43
Clinicaltrials.gov	Link

Infectious diseases

ganfeborole

NCT05382312

Phase	IIa
Patient	Males and females aged 18 to 65 years inclusive with drug-sensitive (rifampicin-susceptible) pulmonary tuberculosis
Subjects	128
Treatment arms	Arm A: Participants receiving GSK3036656+bedaquiline Arm B: Participants receiving GSK3036656+delamanid Arm C: Participants receiving bedaquiline+delamanid Arm D: Participants receiving RIFAFOUR e-275
Description	A parallel group, randomised, open-label, 4 treatment arm trial to assess the early bactericidal activity, safety and tolerability of oral GSK3036656 in combination with either oral delamanid or oral bedaquiline, oral delamanid in combination with oral bedaquiline, or standard of care in males and females aged 18 to 65 years inclusive with drug-sensitive (rifampicin-susceptible) pulmonary tuberculosis
Timeline	Trial start: Q3 2022
Key end points	Change from baseline in log10 CFU of *Mycobacterium tuberculosis*
Clinicaltrials.gov	Link

Infectious diseases

GSK3536852 (Shigella)

NCT05073003

Phase	I/II
Patient	Adults in Europe (Stage 1) followed by age de-escalation from adults to children and infants and dose finding in infants in Africa (Stage 2)
Subjects	550
Treatment arms	Drug: altSonflex Placebo (adults stage 1 in Europe) Biological: altSonflex1-2-3 High Dose C (adults stage 1 in Europe, adults, children and infants stage 2 in Africa) Biological: altSonflex1-2-3 Medium Dose B (children and infants stage 2 in Africa) Biological: altSonflex1-2-3 Low Dose A (infants stage 2 in Africa) Comparators: Menveo and Boostrix (adults stage 2 in Africa) Comparators: Menveo and Typhim Vi (children stage 2 in Africa) Comparators: Menveo and Infanrix (infants stage 2 in Africa)
Description	A staged observer-blind, randomised, controlled, multi-country trial to evaluate the safety, reactogenicity, and immune responses to the GVGH altSonflex1-2-3 vaccine against *S. sonnei* and *S. flexneri* serotypes 1b, 2a, and 3a, in adults in Europe (Stage 1) followed by age de-escalation from adults to children and infants, and dose-finding in infants in Africa (Stage 2)
Timeline	Trial start: Q4 2021
Key end points	Immune response to identify the preferred dose of each component of the altSonflex1-2-3 vaccine (low, medium, or high) for infants 9 months of age in Africa (Stage 2). To evaluate the safety and reactogenicity of the altSonflex1-2-3 vaccine in all participants in Europe and Africa (Stage 1 and Stage 2)
Clinicaltrials.gov	Link

Infectious diseases

GSK3993129 (Cytomegalovirus)

NCT05089630

Phase	I/II
Patient	Healthy adults 18 to 50 years of age
Subjects	329
Treatment arms	Arm A: pentamer (low)/gB(low)/adjuvant vaccine Arm B: pentamer (med)/gB(low)/adjuvant vaccine Arm C: pentamer (med)/gB(med)/adjuvant vaccine Arm D: pentamer (high)/gB(med)/adjuvant vaccine Arm F: placebo (saline)
Description	A randomised, observer-blind, placebo-controlled, dose escalation trial to assess safety, reactogenicity and immunogenicity of a candidate CMV vaccine comprising recombinant protein and adjuvant
Timeline	Trial start: Q4 2021
Key end points	Safety, reactogenicity and immunogenicity
Clinicaltrials.gov	Link

Infectious diseases

GSK4023393 (MenABCWY, 2nd Gen)

NCT05082285

Phase	II
Patient	Healthy infants
Subjects	724
Treatment arms	Combination Product: MenABCWY-2Gen low dose vaccine Combination Product: MenABCWY-2Gen high dose vaccine Combination Product: MenABCWY Combination Product: MenB + MenACWY-TT
Description	A randomised, partially blinded trial to assess the safety, tolerability and immunogenicity of meningococcal combined ABCWY vaccine when administered to healthy infants
Timeline	Trial start: Q4 2021
Key end points	AEs, including all SAEs, AEs leading to withdrawal and AEs of special interest (AESIs), medical attended events (MAE) Immunogenicity by hSBA to indicator strains
Clinicaltrials.gov	Link

Infectious diseases

GSK4077164 (iNTS Typhimurium + Enteritidis)

NCT05480800

Phase	I/IIa	
Patient	Healthy European and African adults	
Subjects	155	
Treatment arms	Arm A: iNTS-TCV low dose group - Europe	Arm F: Step 2 group (placebo) - Europe
	Arm B: iNTS-GMMA and TCV low doses group - Europe	Arm G: iNTS-TCV full dose_2 group - Africa
	Arm C: Step 1 group (placebo) - Europe	Arm H: iNTS-GMMA and TCV full doses_2 group - Africa
	Arm D: iNTS-TCV full dose_1 group - Europe	Arm I: Stage 2 group (control) - Africa
	Arm E: iNTS-GMMA and TCV full doses_1 group - Europe	
Description	An observer-blind, randomised, controlled, two-stage, multi-country trial to evaluate the safety, reactogenicity and immune response of the trivalent vaccine against iNTS and Typhoid fever	
Timeline	Trial start: Q3 2022	
Key end points	To evaluate the safety, reactogenicity and immunogenicity profile of iNTS-TCV vaccine in healthy European/African adults	
Clinicaltrials.gov	Link	

Infectious diseases

GSK4382276 (mRNA Seasonal Flu)

NCT05823974

Phase	I/II
Patient	Healthy younger and older adults
Subjects	1256
Treatment arms	Biological: Flu mRNA Combination Product: Control 1 Combination Product: Control 2
Description	A randomized, dose-finding/dose-confirmation study to evaluate the reactogenicity, safety and immunogenicity of mRNA-based multivalent seasonal influenza vaccine candidates administered in healthy younger and older adults
Timeline	Trial start: Q2 2023
Key end points	Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events Serum anti-influenza antigen seroconversion rates and geometric mean titers
Clinicaltrials.gov	Link

NCT06431607

Phase	IIa
Patient	Adults 18 years of age and older
Subjects	838
Treatment arms	Flu mRNA_YA_Groups: Formulations 1, 2, 3, 4 YA_Active Comparator Group 1: Active Comparator 1 Flu mRNA_OA_Groups: Formulation 5, 6, 7, 8 OA_Active Comparator Group 2: Active Comparator 2 Flu mRNA_YA_Group: Formulation 9 YA_Active Comparator Group 3: Active Comparator 3 Flu mRNA_OA_Group 5: Formulation 10 OA_Active Comparator Group 4: Comparator 4
Description	A randomized, observer-blind, dose-finding study to evaluate the immunogenicity and safety of mRNA-based multivalent seasonal influenza vaccine candidates in adults 18 years of age and older
Timeline	Trial start: Q2 2024
Key end points	Antigen 1 antibody titres
Clinicaltrials.gov	Link

Infectious diseases

GSK4406371 (MMRV new strain vaccine)

NCT05630846

Phase	II
Patient	Healthy children 4-6 years of age
Subjects	801
Treatment arms	Investigational MMRV(H)NS vaccine Investigational MM(H)RVNS vaccine Investigational M(L)M(L)R(L)V(L)NS vaccine Marketed MMRV_Lot 1 and Lot 2 vaccine
Description	A single-blind, randomized, controlled trial to evaluate the immunogenicity and safety of a measles, mumps, rubella, varicella vaccine compared with ProQuad, administered in healthy children 4-6 years of age
Timeline	Trial start: Q4 2022
Key end points	Anti-measles, anti-mumps, anti-rubella, and anti-glycoprotein H antibodies geometric mean concentrations
Clinicaltrials.gov	Link

Infectious diseases

GSK5101955 (Paediatric Pneumococcal disease)

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 and PCV20 administered intramuscularly 4 times within 12 months
Description	A randomised, double-blind, multi-dose, dose finding trial to evaluate the safety, tolerability and immunogenicity of AFX3772 compared with PCV13 and PCV20 in healthy infants
Timeline	Trial start: Q2 2022
Key end points	Safety, tolerability profiles of 3 different dose levels of AFX3772 compared with PCV13 and PCV20 with respect to the proportion of participants with AEs
Clinicaltrials.gov	Link

Infectious diseases

GSK5536522 (mRNA Flu H5N1 pre-pandemic)

NCT06382311

Phase	I/II
Patient	Healthy younger and older adults
Subjects	1080
Treatment arms	Phase 1 cohort 1: Flu Pandemic mRNA (5 dose levels) and placebo Phase 1 cohort 2: Flu Pandemic mRNA (5 dose levels) and placebo Phase 2 Part A cohort 3: Flu Pandemic mRNA (5 dose levels) or placebo Phase 2 Part A cohort 4: Flu Pandemic mRNA (5 dose levels) or placebo Phase 2 Part B cohort 5: Flu Pandemic mRNA (7 dose levels) or placebo Phase 2 Part B cohort 6: Flu Pandemic mRNA (7 dose levels) or placebo
Description	A randomized, observer-blind, dose-finding/dose-confirmation study to evaluate the safety, reactogenicity and immunogenicity of the mRNA-based investigational pandemic H5 influenza vaccine candidate administered in healthy younger and older adults
Timeline	Trial start: Q2 2024
Key end points	Percentage of participants with AEs, MAAEs, SAEs, and AESIs.
Clinicaltrials.gov	Link

Infectious diseases

GSK5637608 (Chronic HBV infection)

NCT06537414 - B-UNITED

Phase	IIb
Patient	Participants with chronic hepatitis B virus on background nucleos(t)ide analogue therapy
Subjects	280
Treatment arms	Arms 1A & 2A: daplusiran/tomligisiran dose level 1 + bepirovirsen Arms 1B & 2B: daplusiran/tomligisiran dose level 2 + bepirovirsen Arm 2C: placebo + bepirovirsen
Description	A multi-centre, randomized, partially placebo-controlled, double-blind study to investigate the safety and efficacy of sequential therapy with daplusiran/tomligisiran followed by bepirovirsen in participants with chronic hepatitis B virus on background nucleos(t)ide analogue therapy
Timeline	Trial start: Q4 2024
Key end points	Number of participants achieving functional cure
Clinicaltrials.gov	Link

Infectious diseases

GSK4077164 (iNTS S. typhimurium + S. enteritidis + S. Typhi)

NCT06213506

Phase	IIa
Patient	Adults, children and infants, including dose-finding in infants in Africa (Ghana)
Subjects	20 adults/40 children/60 infants 9 months/ 396 infants 6 weeks
Treatment arms	Stage 1: Age-de-escalation Adults (dose C or control) Children (dose B or C or control) Infants, 9 months (dose A, B, C or control) Infants, 6 months (dose A, B, C, or control) Stage 2: Dose finding in infants 6 weeks of age
Description	An observer-blind, randomized, controlled, age-de-escalation, single centre interventional study to evaluate the safety, reactogenicity, and immune response of the GVGH iNTS vaccine against *S. typhimurium* and *S. enteritidis*, in adults, children and infants, including dose-finding in infants, in Africa (Ghana)
Timeline	Trial start: Q1 2024
Key end points	To evaluate the safety, reactogenicity and immunogenicity profile of iNTS-GMMA vaccine in adults, children and infants (Ghana)
Clinicaltrials.gov	Link

Infectious diseases

GSK3536867 (Salmonella typhoid + paratyphoid A)

NCT05613205

Phase	I
Patient	Healthy adults aged 18-50 years in Europe
Subjects	96
Treatment arms	Arm A: Step 1a low dose without adjuvant group Arm B: Step 1a control group Arm C: Step 1b low dose with adjuvant group Arm D: Step 1b control group Arm E: Step 2 full dose without adjuvant group Arm F: Step 2 full dose with adjuvant group Arm G: Step 2 control group
Description	An observer-blind, randomised, controlled, single-centre trial to evaluate the safety, reactogenicity and immune responses to an adjuvanted and non-adjuvanted conjugate vaccine against Salmonella Typhi and Salmonella Paratyphi A
Timeline	Trial start: Q4 2022
Key end points	Percentage of participants with solicited administration-site events, systemic events, unsolicited adverse event and any serious adverse events after the first vaccination
Clinicaltrials.gov	Link

Infectious diseases

GSK3882347 (Uncomplicated UTI)

NCT05138822

Phase	Ib
Patient	Female participants with acute uncomplicated urinary tract infection
Subjects	141
Treatment arms	GSK3882347 Nitrofurantoin
Description	A double-blind, double dummy, randomised, nitrofurantoin controlled, repeat oral dose trial to investigate the safety, tolerability, pharmacokinetics and microbiological response of GSK3882347 in female participants with acute uncomplicated urinary tract infection
Timeline	Trial start: Q4 2022
Key end points	Numbers of participants with microbiological response (responder/non-responder of GSK3882347) at the TOC visit
Clinicaltrials.gov	Link

Infectious diseases

GSK3923868 (Rhinovirus disease)

NCT06597500

Phase	I
Patient	Healthy Participants
Subjects	20
Treatment arms	Cohort 1: GSK3923868 Cohort 2: GSK3923868 + itraconazole
Description	A single-centre, open-label, single sequence study to evaluate the effect of itraconazole on the pharmacokinetics of single inhaled doses of GSK3923868 in healthy participants
Timeline	Trial start: Q4 2024
Key end points	Area under curve and Cmax after a single inhaled dose of GSK3923868 with or without itraconazole co-administration; AEs and SAEs
Clinicaltrials.gov	Link

Infectious diseases

GSK3965193 (Chronic HBV infection)

NCT05330455

Phase	I/II
Patient	Healthy participants and those living with chronic hepatitis B infection
Subjects	132
Treatment arms	Part 1 cohort 1: GSK3965193 and placebo Part 1 cohort 2: GSK3965193 and placebo Part 2A cohort 3: GSK3965193 or placebo Part 2A cohort 4: GSK3965193 or placebo Part 2A cohort 5: GSK3965193 or placebo Part 2B cohort 6: GSK3965193 Part 3 cohort 7: GSK3965193 or placebo Part 4 cohort 8: GSK3965193 and bepirovirsen or placebo and bepirovirsen
Description	Four-part, randomised, double-blind (Parts 1, 2A, 3 and 4), multi-centre, placebo-controlled trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of GSK3965193 monotherapy in healthy participants and in participants living with chronic hepatitis B infection; and GSK3965193 in combination with bepirovirsen
Timeline	Trial start: Q2 2022
Key end points	Number of participants with AEs, SAEs, and withdrawals due to AEs Part 3: Change from Baseline in HBsAg levels Part 4 : Number of participants achieving sustained virologic response
Clinicaltrials.gov	Link

Infectious diseases

GSK4024484 (Malaria)

NCT06171113

Phase	I
Patient	Healthy adults aged 18-60 years
Subjects	144
Treatment arms	Group/Arm 1: 6mg SAD GSK'484 or placebo (fasted state) Group/Arm 2: 12mg SAD GSK'484 or placebo (fasted state) Group/Arm 3: 24mg SAD GSK'484 or placebo (fasted state) Group/Arm 4: 40mg SAD GSK'484 or placebo (fasted state) Group/Arm 5: 60mg SAD GSK'484 or placebo (fasted state) Group/Arm 6: 80mg SAD GSK'484 or placebo (fasted state) Group/Arm 7: Food Effect (GSK'484 or placebo in fed state) Group/Arm 8: 100 mg SAD GSK'484 or matching placebo Group/Arm 9: Optional Group (dose escalation or dose level modification flexibility) Group/Arm 10: 10mg MAD GSK'484 or matching placebo Group/Arm 11: 20mg MAD GSK'484 or matching placebo Group/Arm 12: 30mg MAD GSK'484 or matching placebo
Description	A randomised, double-blind placebo-controlled, First Time in Human Study to evaluate the safety and pharmacokinetics of single and multiple oral doses and food effect of GSK4024484
Timeline	Trial start: Q4 2023
Key end points	Number of participants with AEs and SAEs
Clinicaltrials.gov	Link

Infectious diseases

GSK5102188 (UTI)

NCT06702449

Phase	I/II
Patient	Adults 18 through 64 years of age
Subjects	448
Treatment arms	Part 1 Group A1/A2: candidate UTI vaccine low dose formulation 1 or placebo Part 1 Group B1/B2: candidate UTI vaccine low dose formulation 2 or placebo Part 1 Group C1/C2: candidate UTI vaccine medium dose formulation 1 or placebo Part 1 Group D1/D2: candidate UTI vaccine medium dose formulation 2 or placebo Part 1 Group E1/E2: candidate UTI vaccine high dose formulation 1 or placebo Part 1 Group F1/F2: candidate UTI vaccine high dose formulation 2 or placebo Part 2 Group 1: candidate UTI vaccine HTD formulation 2 Part 2 Group 1: placebo
Description	A seamless observer-blind, randomized, placebo-controlled, multicenter study to assess the safety and immunogenicity of a UTI vaccine when administered to adults 18 through 64 years of age and clinical efficacy when administered to females 18 through 64 years of age
Timeline	Trial start: Q4 2024
Key end points	Part 1: Safety and immunogenicity Part 2: Safety and immunogenicity; Efficacy- Incidence rate (IR) of the first occurrence of a urine culture confirmed uUTI due to E. coli in the investigational group compared to the IR in placebo group over 12 months
Clinicaltrials.gov	Link

Infectious diseases

GSK5475152 (mRNA Seasonal Flu/COVID-19 combo)

NCT06680375

Phase	I/II	
Patient	Healthy younger and older adults	
Subjects	780	
Treatment arms	mRNA Flu/COVID-19 Dose 1 Group	Flu+COVID-19 _YA Group
	mRNA Flu/COVID-19 Dose 2 Group	mRNA Flu _YA Group
	Flu+COVID-19 Group	mRNA COVID-19 _YA Group
	mRNA Flu Group	mRNA Flu/COVID-19 _Older Adult (OA) Group
	mRNA COVID-19 Dose 1 Group	Flu+COVID-19 _OA Group
	mRNA COVID-19 Dose 2 Group	mRNA Flu _OA Group
	mRNA Flu/COVID-19 _Young Adult (YA) Group	mRNA COVID-19 _OA Group
Description	A randomised, controlled study to assess safety, and immunogenicity of an investigational FLU Seasonal/SARS-CoV-2 combination mRNA vaccine in adults	
Timeline	Trial start: Q4 2024	
Key end points	Safety, reactogenicity and immunogenicity	
Clinicaltrials.gov	Link	

Glossary

Glossary

ADC	Antibody drug conjugate
ADPKD	Autosomal dominant polycystic kidney disease
AE	Adverse event
AESI	Adverse event of special interest
AIR	At increased risk
ALD	Alcohol-related liver disease
ART	Antiretroviral therapy
AUC	Area under curve
BCMA	B-cell maturation antigen
BICR	Blinded Independent Central Review
BRCA	Breast cancer
CAE	Corneal adverse events
CBR	Clinical benefit rate
cCR	Complete clinical response
CFU	Colony forming units
CKD	Chronic kidney disease
CfB	Change from baseline
Cmax	Maximum observed plasma concentration
CMV	Cytomegalovirus
CN	China
COPD	Chronic obstructive pulmonary disease
CP	Cholestatic pruritus
CRR	Complete response rate
CRSwNP	Chronic rhinosinusitis with nasal polyps
CRT	Cisplatin plus radiotherapy
CTD-ILD	Connective tissue disorder interstitial lung disease
cUTI	Complicated urinary tract infection
CV	Cardiovascular
DDI	Drug-drug interaction
DL	Dose level
DLT	Dose-limiting toxicity
dMMR	Deficient mismatch repair
DNMT1	DNA methyltransferase 1
DoR	Duration of response
EASI	Eczema Area and Severity Index
EC	Endometrial cancer
ECG	Electrocardiogram
EFS	Event free survival
EGPA	Eosinophilic granulomatosis with polyangiitis
ES-SCLC	Extensive-stage small-cell lung cancer
FC	Functional cure
FTD-GRN	Frontotemporal dementia with progranulin gene mutation
FVC	Forced vital capacity
FC	Urogenital gonorrhea
GMMA	Generalised Modules for Membrane Antigens
GSI	Gamma secretase inhibitor
HA	Healthy adults
HBV	Hepatitis B virus
HES	Hypereosinophilic syndrome
Hgb	Hemoglobin
HNSCC	Head and neck squamous cell carcinoma
hSBA	Human serum bactericidal assay
HZ	Herpes zoster
IBAT	Ileal bile acid transporter
IC	Immunocompromised
ICR	Independent central review
iNTS	Invasive non-typhoidal salmonella
IPF	Idiopathic Pulmonary Fibrosis
ITT	Intention-to-treat
JP	Japan
LLOQ	Lower limit of quantitation
MAD	Multiple ascending dose
MAE	Medical attended events
MAPS	Multiple Antigen Presenting System
MASH	Metabolic dysfunction-associated steatohepatitis
MCI	Mild cognitive impairment

Glossary

MDI	Metered dose inhaler
MM	Multiple myeloma
MMR	Measles, mumps and rubella
MMRV	Measles, mumps, rubella and varicella
MRD	Multiple rising dose
MSI-H	Microsatellite instability high
NASH	Non-alcoholic steatohepatitis
NRS	Numeric Rating Scale
NSCLC	Non-small cell lung cancer
OA	Older adult
OC	Ovarian cancer
OMV	Outer membrane vesicle
ORR	Overall response rate
OS	Overall survival
PARP	Poly (ADP-ribose) polymerase
PBC	Primary biliary cholangitis
PD	Pharmacodynamic

MDI	Metered dose inhaler
PD-L1	Programmed death ligand
PFS	Progression-free survival
PFS2	Time to second disease progression or death
PK	Pharmacokinetic
PMF	Primary myelofibrosis
POLQ	DNA polymerase theta
RCC	Refractory chronic cough
RL	Repeat dose level
RRMM	Relapsed/refractory multiple myeloma
RSV	Respiratory syncytial virus
SAD	Single ascending dose
SAE	Serious adverse event
sAg	Surface antigen
siRNA	Small interfering RNA
SLE	Systemic lupus erythematosus
SoC	Standard of care

SRR	Seroresponse rate
SSc-ILD	Systemic sclerosis associated interstitial lung disease
STING	Stimulator of interferon genes
TG2	Transglutaminase 2
TIM-3	T-cell immunoglobulin and mucin domain 3
TLR	Toll-like receptor
TOC	Test of cure
TSLP	thymic stromal lymphopoietin
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
YoA	Years of age