

Pipeline assets and clinical trials appendix Q3 2025

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Respiratory, Immunology and Inflammation (RI&I)

Oncology

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Innovation: Pipeline growth

Overview of potential new vaccines and medicines



Innovation: Pipeline growth Oncology Infectious Diseases Glossary

62 potential new vaccines and medicines in pipeline

RI&I Oncology Infectious Diseases

Phase III / Registration

depemokimab (GSK3511294)	Long-acting anti-IL5 antibody*	Asthma^**
linerixibat (GSK2330672)	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis^
Nucala (mepolizumab)	Anti-IL5 antibody	COPD ¹ ^
camlipixant (GSK5464714)	P2X3 receptor antagonist	Refractory chronic cough
latozinemab (GSK4527223)	Anti-sortilin antibody*	Frontotemporal dementia ²
Low carbon version of MDI ³ , Ventolin (salbutamol)	Beta 2 adrenergic receptor agonist	Asthma
Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma^
GSK5764227	ADC targeting B7-H3*	ES-SCLC ⁴ **
Jemperli (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H colon cancer**
Zejula (niraparib)	PARP inhibitor*	Newly diagnosed glioblastoma multiforme
Arexvy (RSV vaccine)	Recombinant protein, adjuvanted*	RSV adults (18-49 YoA 5 AIR 6) $^{\Lambda**}$
Blujepa (gepotidacin)	BTI inhibitor*	Uncomplicated UTI ^{7^} **
bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV ⁸ infection
Bexsero (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
GSK4178116	Live, attenuated	Varicella new seed
tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI ⁷



62 potential new vaccines and medicines in pipeline

RI&I Oncology HIV Infectious Diseases

Phase II

GSK5637608

Systemic sclerosis associated ILD^{1,2}** Benlysta (belimumab) Anti-BLys antibody MASH³ efimosfermin alfa (GSK6519754) FGF21 analog* GSK4527226 (AL-101) Alzheimer's disease Anti-sortilin antibody* MASH³** GSK4532990 HSD17B13 RNA interference* GSK5784283 TSLP monoclonal antibody* Asthma Ojjaara/Omjjara (momelotinib) JAK1, JAK2 and ACVR1 inhibitor* Myelodysplastic syndrome** cabotegravir (GSK1265744) Integrase inhibitor HIV VH3810109 Broadly neutralizing antibody* HIV Capsid protein inhibitor VH4011499 HIV VH4524184 Integrase inhibitor* HIV alpibectir (BVL-GSK3729098) Ethionamide booster* **Tuberculosis** ganfeborole (GSK3036656) Leucyl t-RNA synthetase inhibitor* **Tuberculosis** GSK4077164 Bivalent GMMA and TCV* Invasive non-typhoidal salmonella GSK4382276 mRNA* Seasonal flu GSK4396687 COVID-19 mRNA* MMRV⁴ new seed GSK4406371 Live, attenuated GSK5101955 MAPS Pneumococcal 24 valent paed* Paediatric pneumococcal disease GSK5102188 UTI^{5,6} Recombinant subunit, adjuvanted GSK5536522 mRNA* Flu H5N1 pre-pandemic⁶

Hepatitis B virus-targeted siRNA*

	* In-license or other alliand	e relationship with third	party ** Additional indications or candidates also un 3. Metabolic dysfunction-associated steatohepatitis	der investigation			
	1. Interstitial lung disease	2. In phase II/III study	3. Metabolic dysfunction-associated steatohepatitis	4. Measles, Mumps, Rubella, and Varicella	5. Urinary tract infection	6. In phase I/II study	7. Hepatitis B virus

Chronic HBV⁷ infection

62 potential new vaccines and medicines in pipeline

RI&I
Oncology
HIV
Infectious Diseases

Glossary

Phase I

COPD¹** GSK3862995 Anti-IL33 antibody GSK3888130 Anti-IL7 antibody* Autoimmune 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 PKD² Alpha-1 antitrypsin deficiency GSK5462688 RNA-editing oligonucleotide* GSK5926371 Anti-CD19-CD20-CD3 trispecific antibody* Autoimmune disease GSK6582701 $COPD^{1}$ PDF3/4 inhibitor* belantamab (GSK2857914) Anti-BCMA antibody Multiple myeloma GSK4418959 dMMR/MSI-H solid tumours³ Werner helicase inhibitor* GSK4524101 DNA polymerase theta inhibitor* Cancer³ GSK5458514 PSMAxCD3 T cell engaging bispecific antibody* Prostate cancer³ GSK5733584 ADC targeting B7-H4* Gynaecologic malignancies** GSK6042981 (IDRX-42) KIT inhibitor* Gastrointestinal stromal tumours XMT-2056⁴ STING agonist ADC* Cancer (wholly owned by Mersana Therapeutics) VH4527079 HIV entry inhibitor HIV GSK3772701 P. falciparum whole cell inhibitor* Malaria GSK3882347 Uncomplicated UTI⁵ FimH antagonist* GSK3923868 PI4K beta inhibitor Rhinovirus disease Chronic HBV⁶ infection³ GSK3965193 PAPD5/PAPD7 inhibitor GSK4024484 P. falciparum whole cell inhibitor* GSK4424989 Recombinant/glycoconjugate vaccine* Group A streptococcal infections Chronic HBV⁶ infection GSK5251738 TLR8 agonist* GSK5459248 MAPS Pneumococcal 30+ valent adults* Pneumococcal disease GSK5475152 Seasonal flu/COVID-19³ mRNA*

^{1.} Chronic obstructive pulmonary disease 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

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

Phase II

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Benlysta (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD ^{4,5} **
efimosfermin alfa (GSK6519754)	FGF21 analog*	MASH ⁶
GSK4527226 (AL-101)	Anti-sortilin antibody*	Alzheimer's disease
GSK4532990	HSD17B13 RNA interference*	MASH ^{6**}
GSK5784283	TSLP monoclonal antibody*	Asthma

Phase I

GSK3862995	Anti-IL33 antibody	COPD ¹ **
GSK3888130	Anti-IL7 antibody*	Autoimmune 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 ⁷
GSK5462688	RNA-editing oligonucleotide*	Alpha-1 antitrypsin deficiency
GSK5926371	Anti-CD19-CD20-CD3 trispecific antibody*	Autoimmune disease
GSK6582701	PDE3/4 inhibitor*	COPD ¹



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

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

Innovation: Pipeline growth Oncology Infectious Diseases Glossary

Oncology pipeline

RI&I Oncology Infectious Diseases

Phase III / Registration

Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma^
GSK5764227	ADC targeting B7-H3*	ES-SCLC ¹ **
Jemperli (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H colon cancer**
Zejula (niraparib)	PARP inhibitor*	Newly diagnosed glioblastoma multiforme

Phase II

	_	
Ojjaara/Omjjara (momelotinib)	JAK1, JAK2 and ACVR1 inhibitor*	Myelodysplastic syndrome**

Phase I

belantamab (GSK2857914)	Anti-BCMA antibody	Multiple myeloma
GSK4418959	Werner helicase inhibitor*	dMMR/MSI-H solid tumours ²
GSK4524101	DNA polymerase theta inhibitor*	Cancer ²
GSK5458514	PSMAxCD3 T cell engaging bispecific antibody*	Prostate cancer ²
GSK5733584	ADC targeting B7-H4*	Gynaecologic malignancies**
GSK6042981 (IDRX-42)	KIT inhibitor*	Gastrointestinal stromal tumours
XMT-2056 ³ (wholly owned by Mersana Therapeutic	STING agonist ADC*	Cancer



^{*} In-license or other alliance relationship with third party ^ In registration ** Additional indications or candidates also under investigation 1. Extensive-stage small-cell lung cancer 2. In phase I/II study 3. GSK has an exclusive global license option to co-develop and commercialise the candidate

HIV pipeline

RI&I Oncology Infectious Diseases

Phase II

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

Phase I

HIV entry inhibitor VH4527079 HIV



Innovation: Pipeline growth RI&I Oncology HIV Infectious Diseases Glossary

Infectious Diseases pipeline

RI&I Oncology Infectious Diseases

Phase III / Registration

Arexvy (RSV vaccine)	Recombinant protein, adjuvanted*	RSV adults $(18-49 \text{ YoA}^1 \text{ AIR}^2)^{^*}$
Blujepa (gepotidacin)	BTI inhibitor*	Uncomplicated UTI ³ ^**
bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV ⁴ infection
Bexsero (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
GSK4178116	Live, attenuated	Varicella new seed
tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI ³

Phase II

alpibectir (BVL-GSK3729098)	Ethionamide booster*	Tuberculosis	
ganfeborole (GSK3036656)	Leucyl t-RNA synthetase inhibitor*	Tuberculosis	
GSK4077164	Bivalent GMMA and TCV*	Invasive non-typhoidal salmonella	
GSK4382276	mRNA*	Seasonal flu	
GSK4396687	mRNA*	COVID-19	
GSK4406371	Live, attenuated	MMRV ⁴ new seed	
GSK5101955	MAPS Pneumococcal 24 valent paed*	Paediatric pneumococcal disease	
GSK5102188	Recombinant subunit, adjuvanted	UTI ^{3,5}	
GSK5536522	mRNA*	Flu H5N1 pre-pandemic ⁵	
GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV ⁷ infection	

Phase I

GSK3772701	P. falciparum whole cell inhibitor*	Malaria
GSK3882347	FimH antagonist*	Uncomplicated UTI ³
GSK3923868	PI4K beta inhibitor	Rhinovirus disease
GSK3965193	PAPD5/PAPD7 inhibitor	Chronic HBV ⁴ infection ⁵
GSK4024484	P. falciparum whole cell inhibitor*	Malaria
GSK4424989	Recombinant/glycoconjugate vaccine*	Group A streptococcal infections
GSK5251738	TLR8 agonist*	Chronic HBV ⁶ infection
GSK5459248	MAPS Pneumococcal 30+ valent adults*	Pneumococcal disease
GSK5475152	mRNA*	Seasonal flu/COVID-19 ⁵

cated UTI³ us disease infection⁵ Malaria l infections /⁶ infection cal disease

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

Innovation: Pipeline growth RI&I Oncology HIV Infectious Diseases Glossary

Changes since Q2 2025

RI&I Oncology HIV Infectious Diseases

US

CN

Changes on pipeline

Progressed to Phase III

GSK5764227: ADC targeting B7-H3, ES-SCLC¹

New to Phase I

GSK6582701: PDE3/4 inhibitor, COPD²

GSK4424989: Recombinant/glycoconjugate vaccine, Group A streptococcal infections

GSK5459248: MAPS Pneumococcal 30+ valent adults, Pneumococcal disease

Removed from Phase III

cobolimab (GSK4069889): Anti-TIM-3 antibody, Non-small cell lung cancer

Removed from Phase II

GSK3915393: TG2 inhibitor, Pulmonary fibrosis

GSK4381562: Anti-PVRIG antibody, Cancer

nelistotug (GSK6097608): Anti-CD96 antibody, Cancer

GSK3993129: Recombinant subunit, adjuvanted, Cytomegalovirus

GSK4023393: Recombinant protein, OMV, conjugated vaccine, MenABCWY 2nd Gen

Removed from Phase I

GSK4172239: DNMT1 inhibitor, Sickle cell disease

Achieved pipeline catalysts

Regulatory decisions

Blenrep: 3L+ MM³
Shingrix: 18+ YoA⁴ AIR⁵

Regulatory submission acceptances

gepotidacin: GC⁶ with Priority Review US

Late-stage readouts

latozinemab: INFRONT-3⁷, FTD-GRN⁸ - Phase III data readout

Ventolin (low carbon MDI⁹): asthma - Positive phase III data readout

Bexsero: Men B (infants) - Positive phase III data readout

Other news

Zejula¹⁰: malignant glioma - Orphan Drug Designation (US)

Shingrix liquid formulation - Positive CHMP opinion (EU)



H2 2025 H₁ 2026 H₂ 2026 US EU. CN. JP linerixibat: cholestatic pruritus in PBC³ EU depemokimab: asthma depemokimab: asthma Regulatory decision depemokimab: CRSwNP1 US depemokimab: CRSwNP1 EU. CN, JP Ventolin (low carbon MDI⁴): asthma EU Blujepa (gepotidacin): GC² Arexvv: 18+ IC5 US linerixibat: cholestatic pruritus in PBC³ US US. EU. JP bepirovirsen: chronic HBV¹³ infection Shingrix liquid formulation Nucala: COPD⁹ EU EU. CN US. JP Blenrep: DREAMM-7, 2L+ MM10 Bexsero: Men B (infants) CN US Arexvy: 18-49 YoA¹¹ AIR¹² tebipenem pivoxil: cUTI6 US US, JP Arexvv: 18+ YoA¹¹ EU linerixibat: cholestatic pruritus in PBC³ CN linerixibat: cholestatic pruritus in PBC³ JΡ camlipixant: RCC7 US. EU. JP Regulatory submission Ventolin (low carbon MDI⁴): asthma EU Arexvy: Older adults 60+ YoA¹¹(China) Blenrep: DREAMM-8, 2L+ MM10 CN CN acceptance Arexvy: 18+ IC⁵ US, EU, JP bepirovirsen: chronic HBV¹³ infection US. EU. CN. JP cabotegravir: Q4M PrEP¹⁴, HIV prevention US US Bexsero: Men B (infants) US tebipenem pivoxil: cUTI⁶ camlipixant: CALM-1, RCC^{7,8} Arexvy: Older adults 60+ YoA¹¹ (China) camlipixant: CALM-2, RCC⁷ Late-stage Phase III bepirovirsen: B-WELL-1/2, chronic HBV¹³ infection depemokimab: NIMBLE, asthma depemokimab: OCEAN, EGPA¹⁵ readouts Jemperli¹⁶: AZUR-1, Rectal cancer^{17, 18} cabotegravir: Q4M PrEP¹⁴, HIV prevention¹⁸



Innovation: Pipeline growth RI&I HIV Oncology Infectious Diseases Glossary RI&I Oncology Designations in our pipeline Infectious Diseases **Breakthrough Designation** ► BREAKTHROUGH DESIGNATION latozinemab (GSK4527223) Frontotemporal dementia¹ US Anti-sortilin antibody* CN Anti-BCMA ADC* Relapsed or refractory multiple myeloma Locally advanced dMMR/MSI-H rectal cancer Anti-PD-1 antibody* US ADC targeting B7-H3* Relapsed or refractory extensive-stage SCLC³ US. EU significant endpoint over available therapies. ADC targeting B7-H3* Relapsed or refractory osteosarcoma US Chronic HBV⁴ infection bepirovirsen (GSK3228836) Antisense oligonucleotide* CN China: Enhance support for development of medicines to treat serious, life-threatening GSK5637608 Chronic HBV⁴ infection Hepatitis B virus-targeted siRNA* CN disease and target an unmet medical need Fast Track 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

latozinemab (GSK4527223)	Anti-sortilin antibody*	Frontotemporal dementia ¹
GSK6042981 (IDRX-42)	KIT inhibitor*	Gastrointestinal stromal tumours
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
Blujepa (gepotidacin)	BTI inhibitor*	Uncomplicated urogenital gonorrhoea
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 PBC ⁷	US, EU, JP
GSK4771261	Monoclonal antibody against novel kidney target	Autosomal dominant PKD ⁸	US
GSK6042981 (IDRX-42)	KIT inhibitor*	Gastrointestinal stromal tumours	US, EU
Zejula (niraparib)	PARP inhibitor*	Glioblastoma multiforme	US
D: " D :			

Priority Review

Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Relapsed or refractory multiple myeloma	CN
Blujepa (gepotidacin)	BTI inhibitor*	Uncomplicated urogenital gonorrhoea	US

Qualified Infectious Disease Product Designation

Blujepa (gepotidacin)	BTI inhibitor*	Uncomplicated urogenital gonorrhoea
tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI ⁵

SENKU

bepirovirsen (GSK3228836) Antisense oligonucleotide* Chronic HBV⁴ infection

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

- rare diseases (US, EU, Japan)

► PRIORITY REVIEW

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

- Qualified Infectious Disease Product Designation (US) an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections
- ► 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 7. Primary biliary cholangitis 8. Polycystic kidney disease

Clinical Trials





NCT04719832 - SWIFT-1 NCT04718103 - SWIFT-2

Phase	III	Phase	III
Patient	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype	Patient	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype
Subjects	395	Subjects	397
T	Arm A: depemokimab + SoC	Treatment arms	Arm A: depemokimab + SoC
Treatment arms	Arm B: placebo + SoC		Arm B: placebo + 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	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
Time aline	Trial start: Q1 2021	Timeline	Trial start: Q1 2021
Timeline	Data reported: Q2 2024	Ilmeline	Data reported: Q2 2024
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks	Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials.gov	<u>Link</u>	Clinicaltrials.gov	<u>Link</u>



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
- Imeline	Data reported: Q2 2025
Key end points	Number of participants with AEs and SAEs and incidence of immunogenicity over 52 weeks
Clinicaltrials.gov	<u>Link</u>

NCT04718389 - NIMBLE

Adult and adolescent severe asthmatic participants with an eosinophilic obenotype treated with depemokimab compared with mepolizumab or penralizumab
719
Arm A: participants receiving depemokimab plus placebo matching prior anti- L-5/5R treatment
Arm B: participants receiving prior anti-IL-5/5R treatment plus placebo matching depemokimab
A 52-week, randomised, double-blind, double-dummy, parallel group, multicentre, 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
Trial start: Q1 2021
Annualised rate of clinically significant exacerbations over 52 weeks
<u>_ink</u>



NCT05274750 - ANCHOR-1 NCT05281523 - ANCHOR-2

Phase	III	Phase	III
Patient	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)	Patient	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
Subjects	276	Subjects	264
T	Arm A: depemokimab + SoC	Treatment arms	Arm A: depemokimab + SoC
Treatment arms	Arm B: placebo + SoC		Arm B: placebo + SoC
Description	A randomized, double-blind, parallel group trial to assess the efficacy and safety of 100 mg subcutaneous depemokimab in patients with CRSwNP	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	Timeline	Trial start: Q2 2022
Imeline	Data reported: Q3 2024		Data reported: Q3 2024
	Change from baseline in total endoscopic nasal polyps (NP) score at week 52		Change from baseline in total endoscopic nasal polyps (NP) score at week 52
Key end points	Change from baseline in mean nasal obstruction verbal response scale (VRS) score from Week 49 through to Week 52	Key end points	Change from baseline in mean nasal obstruction verbal response scale (VRS) score from Week 49 through to Week 52
Clinicaltrials.gov	<u>Link</u>	Clinicaltrials.gov	<u>Link</u>
· ·	<u> </u>		



NCT05263934 - OCEAN

Phase	III
Patient	Adults with relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) receiving standard of care therapy
Subjects	160
T	Arm A: depemokimab + placebo matching mepolizumab + SoC
Treatment arms	Arm B: mepolizumab + placebo matching depemokimab + SoC
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 up to 52 weeks
Clinicaltrials.gov	<u>Link</u>

NCT05334368 - DESTINY

Phase	III
Patient	Adults with uncontrolled hypereosinophilic syndrome (HES) receiving standard of care therapy
Subjects	123
Treatment arms	Arm A: depemokimab + SoC
	Arm B: placebo + SoC
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 up to 52 weeks
Clinicaltrials.gov	<u>Link</u>



NCT06959095 - ENDURA-1 NCT06961214 - ENDURA-2

Phase	III	Phase	III
Patient	Adults with COPD with type 2 inflammation	Patient	Adults with COPD with type 2 inflammation
Subjects	981	Subjects	960
Tue seture and severe	Arm A: depemokimab + SoC	T	Arm A: depemokimab + SoC
Treatment arms	Arm B: placebo + SoC	Treatment arms	Arm B: placebo + SoC
Description	A randomized, double-blind, placebo-controlled, parallel-group, multicenter study of the efficacy and safety of depemokimab in adult participants with COPD with type 2 inflammation	Description	A randomized, double-blind, placebo-controlled, parallel-group, multicenter study of the efficacy and safety of depemokimab in adult participants with COPD with type 2 inflammation
Timeline	Trial start: Q2 2025	Timeline	Trial start: Q2 2025
Key end points	Annualized rate of moderate/severe exacerbations up to 104 weeks	Key end points	Annualized rate of moderate/severe exacerbations up to 104 weeks
Clinicaltrials.gov	<u>Link</u>	Clinicaltrials.gov	Link



NCT07177339 - VIGILANT

Phase	III
Patient	Patients with COPD with Type 2 inflammation
Subjects	1196
T.,	Arm A: depemokimab + SoC
Treatment arms	Arm B: placebo + SoC
Description	A multicentre, randomized, double-blind, parallel group, placebo-controlled study of the efficacy and safety of early depemokimab initiation as add-on treatment in COPD patients with type 2 inflammation
Timeline	Trial start: Q4 2025
Key end points	Annualized rate of moderate/severe exacerbations up to 156 weeks
Clinicaltrials.gov	<u>Link</u>



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
Time aline	Trial start: Q3 2021
Timeline	Data reported: Q4 2024
Key end points	Change from baseline in monthly itch scores over 24 weeks using Numerical Rating Scale (NRS)
Clinicaltrials.gov	<u>Link</u>



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
reatment arms	Arm B: mepolizumab
Description	A multicentre randomised, double-blind, parallel-group, placebo-controlled trial of mepolizumab 100 mg subcutaneously as add-on treatment to triple therapy in participants with COPD experiencing frequent exacerbations and characterised by eosinophil levels
T: I:	Trial start: Q4 2019
Timeline	Primary data reported: Q3 2024
Key end points	Annualised rate of moderate or severe exacerbations
Clinicaltrials.gov	<u>Link</u>



Respiratory, Immunology and Inflammation camlipixant

NCT05599191 - CALM-1 NCT05600777 - CALM-2

Phase	III	Phase	III
Patient	Adult participants with refractory chronic cough, including unexplained chronic cough	Patient	Adult participants with refractory chronic cough, including unexplained chronic cough
Subjects	825	Subjects	975
	Arm A: camlipixant 25 mg twice a day		Arm A: camlipixant 25 mg twice a day
Treatment arms	Arm B: camlipixant 50 mg twice a day	Treatment arms	Arm B: camlipixant 50 mg twice a day
	Placebo 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	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: Q4 2022	Timeline	Trial start: Q1 2023
Key end points	24-hour cough frequency	Key end points	24-hour cough frequency
Clinicaltrials.gov	<u>Link</u>	Clinicaltrials.gov	<u>Link</u>
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Respiratory, Immunology and Inflammation Ventolin (low carbon version of MDI)

Phase	III
Patient	Participants aged 12 years and above with asthma
Subjects	412
-	Arm A: Salbutamol HFA-134a
Treatment arms	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	<u>Link</u>



Benlysta (belimumab)

NCT05878717 - BLISSc-ILD

Phase	11/111
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: Q3 2023
Key end points	Absolute change from baseline in Forced Vital Capacity (FVC) millilitre (mL) at week 52
Clinicaltrials.gov	<u>Link</u>

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	<u>Link</u>



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 mild cognitive impairment (MCI) due to Alzheimer's disease and mild Alzheimer's disease dementia.
Subjects	367
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	Clinical Dementia Rating - Sum of Boxes (CDR-SB) Score
Clinicaltrials.gov	<u>Link</u>



GSK4532990 (MASH)

NCT05583344 - HORIZON

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Phase	IIb	Phase	Ila
Patient	Adults with non-alcoholic steatohepatitis (NASH) and advanced fibrosis	Patient	Adult participants with NASH or suspected NASH
Subjects	285	Subjects	61
Treatment arms	Arm 1: high dose GSK4532990 Arm 2: low dose GSK4532990 Arm 3: placebo	Treatment arms	Arm 1: GSK4532990 Dose 1 Arm 2: GSK4532990 Dose 2 Arm 3: GSK4532990 Dose 3
	A placebo-controlled trial to evaluate the efficacy and safety of GSK4532990 in adults with advanced non-alcoholic steatohepatitis (NASH)		Arm 4: GSK4532990 Dose 4
	Trial start: Q1 2023	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
	Part 1: Percentage of participants achieving ≥ 1 stage improvement in histological fibrosis with no worsening of NASH (at week 52)	Timeline	Trial start: Q1 2024
Key end points	Part 2: Percentage of participants achieving NASH resolution with no worsening of fibrosis (at week 52)	Key end points	Predicted percent change from baseline in liver biopsy-derived HSD17B13 protein expression levels and mRNA expression levels
Clinicaltrials.gov	<u>Link</u>	Clinicaltrials.gov	<u>Link</u>



Respiratory, Immunology and Inflammation GSK4532990 (ALD)

NCT06613698 - STARLIGHT

Phase	II
Patient	Adults with alcohol-related liver disease (ALD)
Subjects	394
	Arm 1: GSK4532990 Dose 1
	Arm 2: GSK4532990 Dose 2
Treatment arms	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
	AEs, SAEs
Key end points	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	<u>Link</u>



Respiratory, Immunology and Inflammation GSK5784283 (Asthma)

NCT06748053 - NAZARE

Phase	II .
Patient	Adults aged 18 to 75 years of age with uncontrolled asthma
Subjects	300
Treatment arms	Part A: Dose finding: GSK5784283 or placebo Part B: Extended dosing: GSK5784283 or placebo
Description	A multicentre, randomized, double-blind, placebo controlled, dose finding phase 2 study of anti-TSLP antibody (GSK5784283) in adults aged 18 to 75 years of age with uncontrolled asthma.
Timeline	Trial start: Q1 2025
Key end points	Change from baseline in the fraction of exhaled nitric oxide (FeNo)
Clinicaltrials.gov	<u>Link</u>



GSK3862995 (COPD)

NCT06154837 NCT06979518

Phase	I
Patient	Part A: Healthy participants Part B: Participants with Chronic Obstructive Pulmonary Disease
Subjects	130
	Part A: Single ascending dose (SAD) of GSK3862995B
Treatment arms	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	<u>Link</u>

Phase	T and the second
Patient	Healthy Participants of Chinese, Japanese, and European Ancestry
Subjects	30
Treatment arms	Arm A: Single dose (SAD) of GSK3862995B
	Arm B: Placebo
Description	A study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of GSK3862995B administered as a single dose to healthy participants of Chinese, Japanese, and European ancestry
Timeline	Trial start: Q2 2025
Key end points	AEs and SAEs
Clinicaltrials.gov	<u>Link</u>



Respiratory, Immunology and Inflammation GSK3862995 (NCFB)

Phase	II
Patient	Adults (18 - 85 years) With Bronchiectasis
Subjects	400
	Arm A: GSK3862995B at dose level 1
Treatment arms	Arm B: GSK3862995B at dose level 2
	Arm C: Placebo
Description	A randomized, double-blind, placebo-controlled study to investigate efficacy, safety, immunogenicity, and pharmacokinetics, of GSK3862995B in participants with bronchiectasis
Timeline	Trial start anticipated: Q4 2025
Key end points	Annualized rate of exacerbations
Clinicaltrials.gov	<u>Link</u>



GSK4347859 (Systemic lupus erythematosus)

Phase	I .
Patient	Healthy participants
Subjects	65
	Part 1, cohort 1: GSK4347859 or placebo
	Part 1, cohort 2: GSK4347859 or placebo
Treatment arms	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	<u>Link</u>



GSK4527363 (Systemic lupus erythematosus)

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	138
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: Q3 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	<u>Link</u>



Respiratory, Immunology and Inflammation GSK4528287 (IBD)

Phase	I
Patient	Healthy participants
Subjects	48
	Part A: Dose 1 of GSK4528287
	Part B: Dose 2 of GSK4528287
	Part C: Dose 3 of GSK4528287
Treatment arms	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	<u>Link</u>



GSK4771261 (Autosomal dominant polycystic kidney disease)

Phase	I
Patient	Part A: Healthy participants Part B: Participants with autosomal dominant polycystic kidney disease (ADPKD)
Subjects	84
	Part A: Health participants receiving different doses of GSK4771261, or placebo
Treatment arms	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	<u>Link</u>





Blenrep (belantamab mafodotin)

NCT04246047 - DREAMM-7

Phase	III
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	494
Treatment arms	Arm A: belantamab mafodotin + bortezomib + dexamethasone (B-Vd)
	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, TTP, OS, PFS2, MRD negativity rate, safety
Clinicaltrials.gov	<u>Link</u>

NCT04484623 - DREAMM-8

Phase	III
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	302
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 (P-Vd)
Timeline	Trial start: Q4 2020
Imeline	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	<u>Link</u>



Blenrep (belantamab mafodotin)

NCT04126200 - DREAMM-5

Phase	1/11
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	209
	Substudy 1: belantamab mafodotin + OX40 (GSK3174998)
	Substudy 2: belantamab mafodotin + feladilimab
	Substudy 3: belantamab mafodotin + nirogacestat (GSI)
	Substudy 4: belantamab mafodotin + dostarlimab
Treatment arms	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	<u>Link</u>

NCT04091126 - DREAMM-9

Phase	1
Patient	Patients with newly diagnosed multiple myeloma (MM)
Subjects	118
	Belantamab mafodotin, selected doses
	Bortezomib, administered subcutaneously or intravenously approximately 1 hour after the belantamab mafodotin infusion until Cycle 8
Treatment arms	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, relative dose intensity of lenalidomide and bortezomib, PK, PD, ORR, CRR, VGPR or better
Clinicaltrials.gov	<u>Link</u>



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	<u>Link</u>

NCT04398745 - DREAMM-12

Phase	
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	<u>Link</u>



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	<u>Link</u>

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	<u>Link</u>



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	811
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

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	<u>Link</u>



Oncology Jemperli (dostarlimab)

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	<u>Link</u>

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	<u>Link</u>



Jemperli (dostarlimab)

NCT02715284 - GARNET

Phase	1/11
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	<u>Link</u>



Ojjaara/Omjjara (momelotinib)

NCT06847867 - MIDAS

Phase	II
Patient	Participants with low-risk myelodysplastic syndromes (LR-MDS).
Subjects	80
Treatment arms	Arm A: Dose Optimisation: momelotinib Arm B: Dose Exploration: momelotinib
Description	A randomized, open-label, study of momelotinib in participants with anemia due to low-risk Myelodysplastic Syndrome
Timeline	Trial start: Q2 2025
Key end points	Percentage of participants with Red Blood Cells - transfusion independence (RBC-TI) for at least 12 weeks, rolling over 24 weeks SAEs, AEs,
Clinicaltrials.gov	<u>Link</u>
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NCT06517875 - ODYSSEY

Phase	II
Patient	Participants with transfusion dependence (TD) primary myelofibrosis (PMF) or Post-polycythemia vera (PV)/ essential thrombocythemia (ET) myelofibrosis (MF) who are either janus kinase (JAK) inhibitor (JAKi) naïve or experienced
Subjects	56
Treatment arms	momelotinib + luspatercept
Description	An open-label study to evaluate momelotinib in combination with luspatercept in participants with transfusion dependent primary or secondary myelofibrosis
Timeline	Trial start: Q1 2025
Key end points	Percentage of participants with TI response by Week 24, AEs, SAEs
Clinicaltrials.go v	<u>Link</u>



Oncology belantamab

NCT05714839 - DREAMM-20

Phase	1/11
Patient	Relapsed/refractory multiple myeloma (RRMM)
Subjects	55
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	<u>Link</u>



Oncology GSK4418959

NCT06710847 - SYLVER

Phase	1/11
Patient	Adult Participants With Mismatch Repair-deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid tumours
Subjects	73
Treatment arms	Part 1: GSK4418959 dose escalation Part 2: GSK4418959 dose expansion Part 3: 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 (DLTs), treatment emergent AEs, dose interruption, dose reductions, dose discontinuation within DLT period, and ORR per RECIST 1.1
Clinicaltrials.gov	<u>Link</u>



Oncology GSK4524101

Phase	1/11
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	<u>Link</u>



GSK5458514

Phase	Phase I/II
Patient	Adult participants with metastatic castration-resistant prostate cancer (mCRPC)
Subjects	85
Treatment arms	Part 1: Dose escalation of GSK5458514 monotherapy Part 2: Dose expansion of GSK5458514 monotherapy
Description	A first-time-in-human, open-label, multicentre, dose escalation and expansion study of GSK5458514 PSMA targeting T cell engager alone or in combination with other anti-cancer agents in adult participants with metastatic castration-resistant prostate cancer (mCRPC)
Timeline	Trial start: Q2 2025
Key end points	DLTs, safety, ORR
Clinicaltrials.gov	<u>Link</u>



GSK5733584

NCT06431594 (BEHOLD-1)

Phase	1
Patient	Adult participants with solid tumours
Subjects	385
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	<u>Link</u>

NCT06796907 (BEHOLD-2)

Phase	1/11
Patient	Participants with advanced solid tumours who have either not responded to standard treatments or cannot tolerate them or have no available effective treatment.
Subjects	392
Treatment arms	Arm 1: GSK5733584 +/- Dostarlimab Arm 2: GSK5733584 +/- Bevacizumab Arm 3: GSK5733584 + Anticancer therapy 3 +/- Dostarlimab or Bevacizumab Arm 4: GSK5733584 + Anticancer therapy 4 +/- Dostarlimab or Bevacizumab
Description	A trial to evaluate the evaluate the safety, tolerability, pharmacokinetics and clinical activity of GSK5733584 in combination with anti-cancer agents in participants with advanced solid tumours
Timeline	Trial start: Q1 2025
Key end points	Part A: DLT, AEs, PFS, ORR Part 2: ORR, OS
Clinicaltrials.gov	<u>Link</u>



GSK5764227

NCT06551142

Phase	I
Patient	Adult participants with advanced solid tumours
Subjects	281
Treatment arms	Phase la: Dose escalation- GSK5764227 Monotherapy Phase la: Dose escalation- Combination therapy: Biological: GSK5764227 Drug: Cisplatin Drug: Carboplatin Biological: Atezolizumab Biological: Pembrolizumab Biological: Durvalumab Biological: Cetuximab Biological: Cetuximab Biological: Bevacizumab Biological: Bose optimisation/expansion- GSK5764227 Monotherapy
Description	A clinical study to evaluate the safety, tolerability, pharmacokinetics, and clinical activity of GSK5764227 as monotherapy and in combination in participants with advanced solid tumors
Timeline	Trial start: Q3 2024
Key end points	Phase Ia: AEs, SAEs, DLTs Phase Ib: PFS, ORR
Clinicaltrials.gov	<u>Link</u>

Phase	III
Patient	Participants With Relapsed Small Cell Lung Cancer (SCLC)
Subjects	300
Treatment arms	Experimental arm: GSK5764227 Active Comparator arm: Topotecan
Description	A Phase 3, Multicenter, Randomized, Open-label Clinical Study of GSK5764227, a B7-H3 Antibody Drug Conjugate (ADC), Compared With Topotecan in Participants With Relapsed Small Cell Lung Cancer (SCLC)
Timeline	Trial start: Q3 2025
Key end points	ORR, OS, DoR, PFS, AEs, SAEs
Clinicaltrials.gov	<u>Link</u>



Oncology GSK5764227

Phase	1/11
Patient	Participants With Previously Treated Advanced Unresectable or Metastatic Gastrointestinal Solid Tumors
Subjects	320
Treatment arms	Arm A: GSK5764227 (dose 1) Arm B: GSK5764227 (dose 2) Arm C: GSK5764227 (dose 3) Arm D: GSK5764227 (dose 4) Arm E: GSK5764227 (dose 5)
Description	A multicentre, randomized, open-label study to evaluate the efficacy and safety of GSK5764227 alone and in combination in participants with previously treated advanced unresectable or metastatic gastrointestinal solid tumors
Timeline	Trial start: Q2 2025
Key end points	ORR, DoR, PFS, AEs
Clinicaltrials.gov	<u>Link</u>



GSK6042981 (IDRX-42)

NCT05489237 - StrateGIST 1

Phase	I
Patient	Adult participants with participants with advanced (metastatic and/or surgically unresectable) GIST.
Subjects	269
	Phase 1: GSK6042981
	Phase 1b: Cohort 1: Participants with GIST progression after first-line imatinib therapy
	Phase 1b: Cohort 2: Participants with GIST progression after 2 or more lines of TKI therapy
Treatment arms	Phase 1b: Cohort 3: Participants with GIST who are treatment naïve
	Phase 1b: Cohort 4: Participants with GIST progression who meet the same criteria as Cohort 2 (third line or greater TKI therapy) and have had prior treatment with investigational agents NB003 or THE-630 or a line of therapy of bezuclastinib plus sunitinib combination.
Description	A clinical study to evaluate the safety, tolerability, PK, and preliminary antitumor activity of IDRX-42 in adult participants with advanced (metastatic and/or surgically unresectable) GIST.
Timeline	Trial start: Q1 2022
Key end points	Phase 1: Safety, ORR, PFS
	Phase 1b: treatment emergent AEs, ORR, OS
Clinicaltrials.gov	<u>Link</u>



HIV





cabotegravir ultra long-acting (ULA) for HIV Prevention

NCT06741397 NCT06786520

Phase	IIb
Patient	Healthy adolescent and adult participants
Subjects	228
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	<u>Link</u>

Phase	1
Patient	Healthy adult volunteers
Subjects	69
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	<u>Link</u>





cabotegravir

NCT05418868

Phase	1
Patient	Healthy adult volunteers
Subjects	180
	Part A: Participants receiving CAB 200 mg/mL with rHuPH20
Treatment arms	Part C: Participants receiving CAB 400 mg/mL
i reatment arms	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	<u>Link</u>

Phase	1
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	<u>Link</u>





VH3810109

NCT05996471 - EMBRACE

Phase	IIb
Patient	Antiretroviral therapy (ART)-experienced adults living with HIV
Subjects	128
	Group 1: VH3810109 + cabotegravir
Treatment arms	Group 2 VH3810109 + rHuPH20 + cabotegravir
reatment arms	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	<u>Link</u>

NCT07053384 - ENTRANCE

Phase	lb
Patient	Adults living with HIV-1
Subjects	100
Treatment arms	Biological: VH3810109 Drug: Fostemsavir (FTR) Drug: standard of care INSTI-based ART
Description	An exploratory multicentre, randomised, open-label study to investigate the impact of the administration of intravenous VH3810109 with or without oral fostemsavir in combination with integrase inhibitor-based antiretroviral therapy on the viral reservoir in adults living with HIV-1
Timeline	Trial start: Q3 2025
Key end points	Cell-associated HIV-1 RNA transcripts per million CD4+ T cells
Clinicaltrials.gov	<u>Link</u>
Description Timeline Key end points	Drug: Fostemsavir (FTR) Drug: standard of care INSTI-based ART An exploratory multicentre, randomised, open-label study to investigate the impact of the administration of intravenous VH3810109 with or without oral fostemsavir in combination with integrase inhibitor-based antiretroviral therapy on the viral reservoir in adults living with HIV-1 Trial start: Q3 2025 Cell-associated HIV-1 RNA transcripts per million CD4+ T cells





VH4011499

NCT06012136

Phase	1
Patient	Healthy adults
Subjects	85
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	<u>Link</u>

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	<u>Link</u>





VH4524184

Phase	1
Patient	Healthy adult participants
Subjects	124
	Drug: VH4524184
	Drug: Itraconazole
Treatment arms	Drug: Rifabutin
	Drug: Phenytoin
	Drug: Metformin
Description	An open-label study to evaluate the relative bioavailability and the effect of food on VH4524184 tablet formulations, and to evaluate the potential for VH4524184 drug-drug-interactions in healthy adult participants
Timeline	Trial start: Q3 2025
Key end points	PK, AEs
Clinicaltrials.gov	<u>Link</u>



HIV VH4527079

Phase	1
Patient	Healthy adults and persons with HIV
Subjects	102
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	<u>Link</u>



Arexvy (RSV Adults)

NCT04732871 - RSV OA=ADJ-004

Phase	III
Patient	Adults ≥60 years of age
Subjects	1720
	Arm A: RSVPreF3 OA Day 1, 12 months & 24 months
Treatment arms	Arm B: RSVPreF3 OA Day 1, 24 and 48 months
Treatment anns	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
i imeiine	Primary data reported: Q2 2022
Key end points	Humoral immune response
Clinicaltrials.gov	<u>Link</u>

NCT04886596 - RSV OA=ADJ-006

Phase	III
Patient	Adults ≥60 years of age
Subjects	26,675
	Arm A: RSVPreF3 OA Lot 1
	Arm B: RSVPreF3 OA Lot 2
Treatment arms	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	<u>Link</u>



Arexvy (RSV Adults)

NCT06534892 - RSV- OA=ADJ-012

Phase	IIIb
Patient	Adults aged 60 years and above
Subjects	10356
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.
	Crossover: Participants in this group will receive a single dose of RSVPreF3 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	<u>Link</u>

NCT05879107 - RSV OA=ADJ-019

Phase	III
Patient	Adults ≥60 years of age
Subjects	1113
_	Arm A (co-ad group): RSVPreF3 OA investigational vaccine co-administered with PCV20 vaccine
Treatment arms	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	<u>Link</u>

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
ımeline	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	<u>Link</u>

NCT05921903 - RSV OA=ADJ-023

Phase

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Patient	Immunocompromised (IC) adults 50 years of age and above
Subjects	386
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	<u>Link</u>



Arexvy (RSV Adults)

NCT06374394 - RSV OA=ADJ-013

Phase	III
Patient	Adults aged 50 years and above
Subjects	842
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	<u>Link</u>

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	1459
	Part A: RSV-A-AIR Group, RSVPreF3 OA investigational vaccine
Treatment arms	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
ımeline	Primary data reported: Q3 2024
Voy and paints	RSV-A, RSV-B neutralizing titers
Key end points	Seroresponse rate (SRR) in RSV-A and RSV-B neutralizing titers
Clinicaltrials.gov	<u>Link</u>



Arexvy (RSV Adults)

NCT06551181 - RSV OA=ADJ-021

Phase	III
Patient	Adults aged 60 years and above
Subjects	2621
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
Kay and nainte	RSV-A, RSV-B neutralization titers
Key end points	Seroresponse rate (SRR) in RSV-A and RSV-B neutralizing titers
Clinicaltrials.gov	<u>Link</u>



Blujepa (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	<u>Link</u>

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
reatment arms	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
imeline	Data reported: Q2 2023
Key end points	Number of participants with therapeutic response (combined per participant clinical and microbiological response)
Clinicaltrials.gov	<u>Link</u>



Blujepa (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	<u>Link</u>



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: Q4 2022
Key end points	Number of participants with baseline HBsAg≤ 3000IU/mL achieving functional cure (FC)
Clinicaltrials.gov	<u>Link</u>

NCT05630820 - B-WELL 2

Phase	III
Patient	Non-cirrhotic nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	871
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: Q4 2022
Key end points	Number of participants with baseline HBsAg≤ 3000IU/mL achieving functional cure (FC)
Clinicaltrials.gov	<u>Link</u>



GSK4178116 (Varicella new seed)

NCT06693895

Phase	
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	An 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	<u>Link</u>

NCT06740630

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Phase

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	An 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	<u>Link</u>



GSK4178116 (Varicella new seed)

NCT06806137

Phase	III
Patient	Healthy children aged 12 to 15 months
Subjects	600
Treatment arms	Participants receive 2 doses of a VV vaccine on Day 1 and Day 91. 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 2 doses of a VNS vaccine on Day 1 and Day 91. 1 doses of MMR vaccine, 1 dose of HAV vaccine, and 1 dose of PCV (either PCV 13, Vaxneuvance or PCV 20) on Day 1.
	Participants receive 1 dose of VV vaccine on Day 1, 1 dose of VNS Vaccine on Day 91. 1 doses of MMR vaccine, 1 dose of HAV, and 1 dose of PCV (either PCV 13, Vaxneuvance or PCV 20) on Day 1.
Description	A Phase 3a, Observer-blind, Randomized, Controlled, Study to Evaluate the Immunogenicity and Safety of an Investigational Varicella Vaccine Compared With Varivax, When Given as a Second Dose to Healthy Children, 3 Months After the Administration of a First Dose at 12 to 15 Months of Age
Timeline	Trial start: Q1 2025
Key end points	% of participants with seroresponse to Varicella Zoster Virus (VZV) anti- glycoprotein E (gE) IgG and Geometric Mean Concentration (GMC) of anti- VZV gE IgG for 2 doses of VNS vaccine compared to 2 doses of VV
Clinicaltrials.gov	<u>Link</u>

NCT06855160

Phase

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Patient	Healthy children 12 to 15 months of age
Subjects	900
Treatment arms	Participants receive 1 dose of the candidate varicella vaccine (VNS vaccine), 1 dose of a measles, mumps, and rubella (MMR) vaccine, 1 dose of a hepatitis A virus (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 varicella vaccine (VV), 1 dose of a MMR vaccine, 1 dose of a HAV vaccine, and 1 dose of PCV (either PCV 13 or Vaxneuvance or PCV 20) on Day 1.
Description	A Phase 3a, Open-Label, Randomized, Controlled Study to Evaluate the Immunogenicity and Safety of Intramuscular Administration of an Investigational Varicella Vaccine and Priorix Compared With Subcutaneous Administration of Varivax and Priorix, When Given as a First Dose to Healthy Children 12 to 15 Months of Age
Timeline	Trial start: Q2 2025
Key end points	Percentage of participants with seroresponse to Varicella Zoster Virus (VZV) anti- glycoprotein E (gE) Immunoglobulin (IgG), AEs, SAEs
Clinicaltrials.gov	<u>Link</u>



ganfeborole

Phase	lla
Patient	Males and females aged 18 to 65 years inclusive with drug-sensitive (rifampicin-susceptible) pulmonary tuberculosis
Subjects	127
Treatment arms	Arm 1: GSK3036656 + delamanid Arm 2: GSK3036656 + bedaquiline Arm 3: GSK3036656 + BTZ-043 Arm 4: GSK3036656 + pretomanid Arm 5: GSK3036656 + moxifloxacin Arm 6: GSK3036656 + linezolid Arm 7: Delamanid + bedaquiline Arm 8: Standard of Care (Rifafour e-275)
Description	A parallel group, Phase 2A, randomised, open label treatment study to assess the early bactericidal activity, safety and tolerability of GSK3036656 administered as a two drug combination with novel and established antitubercular agents, or standard of care in adults with rifampicin-susceptible pulmonary tuberculosis.
Timeline	Trial start: Q3 2022
Key end points	Change from baseline in log10 CFU of Mycobacterium tuberculosis
Clinicaltrials.gov	<u>Link</u>



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

Phase	lla	
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	
	Stage 1: Age-de-escalation	
	Adults (dose C or control)	
Tue adms and annes	Children (dose B or C or control)	
Treatment arms	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 <i>S. typhimurium</i> and <i>S. enteritidis</i> , 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	<u>Link</u>	



GSK4382276 (mRNA Seasonal Flu)

NCT05823974

Patient Healthy younger and older adults Subjects 1275 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	Phase	1/11
Treatment arms Biological: Flu mRNA Combination Product: Control 1 Combination Product: Control 2 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 Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events Serum anti-influenza antigen seroconversion rates and geometric mean titers	Patient	Healthy younger and older adults
Treatment arms Combination Product: Control 1 Combination Product: Control 2 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 Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events Serum anti-influenza antigen seroconversion rates and geometric mean titers	Subjects	1275
Combination Product: Control 2 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 Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events Serum anti-influenza antigen seroconversion rates and geometric mean titers		Biological: Flu mRNA
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 Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events Serum anti-influenza antigen seroconversion rates and geometric mean titers	Treatment arms	Combination Product: Control 1
Timeline Trial start: Q2 2023 Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events Serum anti-influenza antigen seroconversion rates and geometric mean titers		Combination Product: Control 2
Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events Serum anti-influenza antigen seroconversion rates and geometric mean titers	Description	reactogenicity, safety and immunogenicity of mRNA-based multivalent seasonal influenza vaccine candidates administered in healthy younger and
Key end points and solicited administration site events Serum anti-influenza antigen seroconversion rates and geometric mean titers	Timeline	Trial start: Q2 2023
	Key end points	
Clinicaltrials.gov <u>Link</u>		Serum anti-influenza antigen seroconversion rates and geometric mean titers
	Clinicaltrials.gov	<u>Link</u>

NCT06431607

Phase

lla

Patient	Adults 18 years of age and older
Subjects	840
	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
T	OA_Active Comparator Group 2: Active Comparator 2
Treatment arms	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	<u>Link</u>
	74



Phase

Infectious diseases

GSK4382276 (mRNA Seasonal Flu)

NCT07121192 - FLU SV MRNA-027

Phase	II
Patient	Adults 18 Years of Age And Older
Subjects	770
	Biological: Flu mRNA (Formulation A) Young adults
	Biological: Flu mRNA (Formulation B) Young adults
	Combination Product: Comparator 1 Young adults
	Combination Product: Comparator 2 Young adults
Treatment arms	Biological: Flu mRNA (Formulation A) Older adults
	Biological: Flu mRNA (Formulation B) Older adults
	Combination Product: Comparator 1 Older adults
	Combination Product: Comparator 2 Older adults
	Combination Product: Comparator 3 Older adults
Description	A Randomized, Observer-Blind, 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: Q3 2025
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	<u>Link</u>

NCT07204964 - FLU SV MRNA-028

Patient	Adults 18 Years of Age And Older
Subjects	960
	Biological: Flu mRNA (Formulation B1) Young adults
	Biological: Flu mRNA (Formulation B3) Young adults
	Biological: Flu mRNA (Formulation A) Young adults
	Combination Product: Comparator 1 Young adults
-	Combination Product: Comparator 2 Young adults
Treatment arms	Biological: Flu mRNA (Formulation B1) Older adults
	Biological: Flu mRNA (Formulation B3) Older adults
	Biological: Flu mRNA (Formulation A) Older adults
	Combination Product: Comparator 1 Older adults
	Combination Product: Comparator 3 Older adults
Description	A Randomized, Observer-Blind, 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: Q3 2025
Key end points	Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events
Clinicaltrials.gov	<u>Link</u>



GSK4406371 (MMRV new seed vaccine)

Phase	Ш
Patient	Healthy children 4-6 years of age
Subjects	801
	Investigational MMRV(H)NS vaccine
Treatment arms	Investigational MM(H)RVNS vaccine
reatment arms	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	<u>Link</u>



GSK5101955 (Paediatric Pneumococcal disease)

Phase	II .
Patient	Healthy infants
Subjects	472
	Arm A: 1 mcg AFX3772 administered intramuscularly 4 times within 12 months
	Arm B: 2 mcg AFX3772 administered intramuscularly 4 times within 12 months
Treatment arms	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	<u>Link</u>



GSK5102188 (UTI)

Phase	1/11
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	<u>Link</u>



GSK5536522 (mRNA Flu H5N1 pre-pandemic)

Phase	1/11
Patient	Healthy younger and older adults
Subjects	996
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	<u>Link</u>



GSK5637608 (Chronic HBV infection)

NCT06537414 - B-UNITED

Phase	Ilb
Patient	Participants with chronic hepatitis B virus on background nucleos(t)ide analogue therapy
Subjects	283
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	<u>Link</u>



GSK3882347 (Uncomplicated UTI)

Phase	Ib
Patient	Female participants with acute uncomplicated urinary tract infection
Subjects	140
Tue artine and annua	GSK3882347
Treatment arms	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
Ilmeline	Study completed: Q4 2024
Key end points	Numbers of participants with microbiological response (responder/non-responder of GSK3882347) at the TOC visit
Clinicaltrials.gov	<u>Link</u>



GSK3965193 (Chronic HBV infection)

Phase	I/II
Patient	Healthy participants and those living with chronic hepatitis B infection
Subjects	74
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	<u>Link</u>



GSK4024484 (Malaria)

Phase	1
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)
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	<u>Link</u>



GSK4424989 (Group A Streptococcus)

Phase	1
Patient	Healthy Adults 18 to 25 Years of Age
Subjects	108
Treatment arms	Low dose Strep A Alum Group Medium dose Strep A Alum Group High dose Strep A Alum Group Low dose Strep A AS37 Group Medium dose Strep A AS37 Group High dose Strep A AS37 Group Strep A AS37 Group
Description	A Phase 1, Randomized, Placebo-controlled, Observer-blind Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of the GSK 4-component Vaccine Against Group A Streptococcus Pyogenes (Strep A) With Alum or AS37 in Healthy Adults 18 to 25 Years of Age in Australia
Timeline	Trial start: Q3 2025
Key end points	Safety, Reactogenicity, and Immunogenicity
Clinicaltrials.gov <u>Link</u>	



GSK5459248 (Pneumococcal disease)

Phase	1
Patient	Adults 50 to 64 Years of Age
Subjects	120
Treatment arms	Biological: Pn-MAPS30plus
	Active Comparator: PCV20
Description	A Phase 1, Observer-Blind, Randomized, Active Controlled Trial to Evaluate the Safety and Immunogenicity of An Investigational Pneumococcal Vaccine in Adults 50 To 64 Years of Age
Timeline	Trial start: Q3 2025
Key end points	Safety
Clinicaltrials.gov	<u>Link</u>



GSK5475152 (mRNA Seasonal Flu/COVID-19 combo)

Phase	1/11
Patient	Healthy adults
Subjects	106
	mRNA Flu/COVID-19 Dose 1 Group
	mRNA Flu/COVID-19 Dose 2 Group
T	Flu+COVID-19 Group
Treatment arms	mRNA Flu Group
	mRNA COVID-19 Dose 1 Group
	mRNA COVID-19 Dose 2 Group
Description	A Phase 1/2, Randomized, Controlled Study to Evaluate the Reactogenicity, 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	<u>Link</u>



Glossary



Glossary

ADC	Antibody-drug conjugate
AE	Adverse event
AESI	Adverse event of special interest
AIR	At increased risk
ALD	Alcohol-related liver disease
ART	Antiviral therapy
BCMA	B-cell maturation antigen
BICR	Blinded Independent Central Review
CBR	Clinical benefit rate
cCR	Complete clinical response
CHMP	Committee for Medicinal Products for Human Use
CMV	Cytomegalovirus
CN	China
COPD	Chronic obstructive pulmonary disease
CRR	Complete response rate
CRSwNP	Chronic rhinosinusitis with nasal polyps
CTD	Connective tissue disease
cUTI	Complicated urinary tract infection
DLT	Dose-limiting toxicity
dMMR	Deficient mismatch repair
DoR	Duration of response
EFS	Event-free survival
EGPA	Eosinophilic granulomatosis with polyangiitis
FTD-GRN	Frontotemporal dementia with progranulin gene mutation
GC	Urogenital gonorrhea

GIST	Gastrointestinal stromal tumor
GMMA	Generalised Modules for Membrane Antigens
HBV	Hepatitis B virus
HES	Hypereosinophilic syndrome
IC	Immunocompromised
ILD	Interstitial lung disease
iNTS	Invasive non-typhoidal salmonella
JP	Japan
MAD	Multiple ascending dose
MASH	Metabolic dysfunction-associated steatohepatitis
MDI	Metered dose inhaler
MM	Multiple myeloma
MMRp	Mismatch repair proficient
MMRV	Measles, mumps, rubella and varicella
MRD	Multiple rising dose
MSI-H	Microsatellite instability high
MSS	Microsatellite stability
NASH	Non-alcoholic steatohepatitis
NSCLC	Non-small cell lung cancer
OMV	Outer membrane vesicle
ORR	Overall response rate
OS	Overall survival
PBC	Primary biliary cholangitis
PD	Pharmacodynamics
PFS	Progression-free survival

PFS2	Time to second disease progression or death
PK	Pharmacokinetics
PKD	Polycystic kidney disease
PrEP	Pre-exposure prophylaxis
RCC	Refractory chronic cough
RRMM	Relapsed/refractory multiple myeloma
RSV	Respiratory syncytial virus
SAD	Single ascending dose
SAE	Serious adverse event
SCLC	Small cell lung cancer
iRNA	Small interfering RNA
SLE	Systemic lupus erythematosus
SoC	Standard of care
SSc	Systemic sclerosis associated
CV	Typhoid conjugate vaccine
TBR	Time to best response
TD	Time to treatment discontinuation
TP	Time to tumour progression
TR	Time to treatment response
JLA	Ultra long acting
JTI	Urinary tract infection
ıUTI	Uncomplicated urinary tract infection
/GPR	Very good partial remission
/oA	Years of age

