



# Pipeline assets and clinical trials appendix

Q1 2026

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Respiratory, Immunology and  
Inflammation (RI&I)

Oncology

HIV

Infectious Diseases



# Innovation: Pipeline growth

Overview of potential new vaccines and medicines

# 57 potential new vaccines and medicines in pipeline

## Phase III / Registration

16

<span style="color: yellow;">■</span> <i>Lynavoy</i> (linerixibat)	IBAT inhibitor	Cholestatic pruritus in PBC <sup>1,2^</sup>
<span style="color: yellow;">■</span> <i>Benlysta</i> (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD <sup>3,4**</sup>
<span style="color: yellow;">■</span> camlipixant (GSK5464714)	P2X3 receptor antagonist	Refractory chronic cough
<span style="color: yellow;">■</span> efimosfermin alfa (GSK6519754)	FGF21 analog*	MASH <sup>5</sup>
<span style="color: yellow;">■</span> <i>Exdensus</i> (depemokimab)	Long-acting anti-IL5 antibody*	COPD <sup>6**</sup>
<span style="color: yellow;">■</span> Low carbon version of MDI <sup>7</sup> , <i>Ventolin</i> (salbutamol)	Beta 2 adrenergic receptor agonist	Asthma
<span style="color: green;">■</span> <i>Blenrep</i> (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma^
<span style="color: green;">■</span> <i>Jemperli</i> (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H colon cancer**
<span style="color: green;">■</span> risvutatug rezetecan (GSK5764227)	ADC targeting B7-H3*	ES-SCLC <sup>8**</sup>
<span style="color: green;">■</span> velzatinib (GSK6042981)	KIT inhibitor*	Gastrointestinal stromal tumours
<span style="color: green;">■</span> <i>Zejula</i> (niraparib)	PARP inhibitor*	Newly diagnosed glioblastoma multiforme
<span style="color: blue;">■</span> <i>Arexvy</i> (RSV vaccine)	Recombinant protein, adjuvanted*	RSV adults (60+ YoA <sup>9</sup> China) <sup>^**</sup>
<span style="color: blue;">■</span> bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV <sup>10</sup> infection <sup>^**</sup>
<span style="color: blue;">■</span> tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI <sup>11^</sup>
<span style="color: blue;">■</span> <i>Bexsero</i> (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
<span style="color: blue;">■</span> GSK4178116	Live, attenuated	Varicella new seed


















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

1. Primary biliary cholangitis 2. On 22 April 2026, GSK entered into a licence agreement under which Alfasigma S.p.A. acquired worldwide exclusive rights to develop, manufacture and commercialise *Lynavoy* (linerixibat) 3. Interstitial lung disease 4. In phase II/III study 5. Metabolic dysfunction-associated steatohepatitis 6. Chronic obstructive pulmonary disease 7. Metered dose inhaler 8. Extensive-stage small-cell lung cancer 9. Years of age 10. Hepatitis B virus 11. Urinary tract infection

# 57 potential new vaccines and medicines in pipeline

## Phase II

17

 gatuzosiran (GSK4532990)	HSD17B13 RNA interference*	MASH <sup>1**</sup>
 GSK5784283	TSLP monoclonal antibody*	Asthma
 nivisnebart (GSK4527226)	Anti-sortilin antibody*	Alzheimer's disease
 ozureprubart (GSK6775388)	Anti-IgE antibody*	Food allergies
 <i>Ojjaara/Omjara</i> (mometotinib)	JAK1, JAK2 and ACVR1 inhibitor*	Myelodysplastic syndrome**
 cabotegravir (GSK1265744)	Integrase inhibitor	HIV
 VH3810109	Broadly neutralizing antibody*	HIV
 VH4011499	Capsid protein inhibitor	HIV
 VH4524184	Integrase inhibitor*	HIV
 alpipectir (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 <sup>2</sup> new seed
 GSK5102188	Recombinant subunit, adjuvanted	UTI <sup>3,4</sup>
 GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV <sup>5</sup> infection

# 57 potential new vaccines and medicines in pipeline

## Phase I

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GSK3862995	Anti-IL33 antibody*	COPD <sup>1**</sup>
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 <sup>2</sup>
GSK5926371	Anti-CD19-CD20-CD3 trispecific antibody*	Autoimmune disease
GSK6582701	PDE3/4 inhibitor*	COPD <sup>1</sup>
GSK6759821	siRNA*	COPD <sup>1</sup>
GSK6792070	Activin signalling inhibitor	Pulmonary arterial hypertension**
belantamab (GSK2857914)	Anti-BCMA antibody	Multiple myeloma
GSK5458514	PSMAxCD3 T cell engaging bispecific antibody*	Prostate cancer <sup>3</sup>
GSK5460025	Nucleotide excision repair targeting agent*	Solid tumours <sup>3</sup>
GSK5471713	AR degrader	Prostate cancer <sup>3</sup>
GSK5533524	ADC targeting a tumour associated antigen	Solid tumours
mocertatug rezetecan (GSK5733584)	ADC targeting B7-H4*	Gynaecologic malignancies**
VH4527079	HIV entry inhibitor	HIV
GSK3772701	<i>P. falciparum</i> whole cell inhibitor*	Malaria
GSK3882347	FimH antagonist*	Uncomplicated UTI <sup>4</sup>
GSK3923868	PI4K beta inhibitor	Rhinovirus disease
GSK3965193	PAPD5/PAPD7 inhibitor	Chronic HBV <sup>5</sup> infection <sup>3</sup>
GSK4024484	<i>P. falciparum</i> whole cell inhibitor*	Malaria
GSK4424989	Recombinant/glycoconjugate vaccine*	Group A streptococcal infections
GSK5459248	MAPS Pneumococcal 30+ valent adults*	Pneumococcal disease
GSK5475152	mRNA*	Seasonal flu/COVID-19 <sup>3</sup>

# Respiratory, Immunology and Inflammation pipeline

## Phase III / Registration

6

<span style="color: yellow;">■</span> <i>Lynavoy</i> (linerixibat)	IBAT inhibitor	Cholestatic pruritus in PBC <sup>1,2^</sup>
<span style="color: yellow;">■</span> <i>Benlysta</i> (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD <sup>3,4**</sup>
<span style="color: yellow;">■</span> camlipixant (GSK5464714)	P2X3 receptor antagonist	Refractory chronic cough
<span style="color: yellow;">■</span> efimosfermin alfa (GSK6519754)	FGF21 analog*	MASH <sup>5</sup>
<span style="color: yellow;">■</span> <i>Exdensur</i> (depemokimab)	Long-acting anti-IL5 antibody*	COPD <sup>6**</sup>
<span style="color: yellow;">■</span> Low carbon version of MDI <sup>7</sup> , <i>Ventolin</i> (salbutamol)	Beta 2 adrenergic receptor agonist	Asthma

## Phase II

4

<span style="color: yellow;">■</span> gatuzosiran (GSK4532990)	HSD17B13 RNA interference*	MASH <sup>5**</sup>
<span style="color: yellow;">■</span> GSK5784283	TSLP monoclonal antibody*	Asthma
<span style="color: yellow;">■</span> nivisnebart (GSK4527226)	Anti-sortilin antibody*	Alzheimer's disease
<span style="color: yellow;">■</span> ozureprubart (GSK6775388)	Anti-IgE antibody*	Food allergies

## Phase I

9

<span style="color: yellow;">■</span> GSK3862995	Anti-IL33 antibody*	COPD <sup>6**</sup>
<span style="color: yellow;">■</span> GSK4347859	Interferon pathway modulator	Systemic lupus erythematosus
<span style="color: yellow;">■</span> GSK4527363	B-cell modulator*	Systemic lupus erythematosus
<span style="color: yellow;">■</span> GSK4528287	Anti-IL23-IL18 bispecific antibody*	Inflammatory bowel disease
<span style="color: yellow;">■</span> GSK4771261	Monoclonal antibody against novel kidney target*	Autosomal dominant PKD <sup>8</sup>
<span style="color: yellow;">■</span> GSK5926371	Anti-CD19-CD20-CD3 trispecific antibody*	Autoimmune disease
<span style="color: yellow;">■</span> GSK6582701	PDE3/4 inhibitor*	COPD <sup>6</sup>
<span style="color: yellow;">■</span> GSK6759821	siRNA*	COPD <sup>6</sup>
<span style="color: yellow;">■</span> GSK6792070	Activin signalling inhibitor	Pulmonary arterial hypertension**

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1. Primary biliary cholangitis 2. On 22 April 2026, GSK entered into a licence agreement under which Alfasigma S.p.A. acquired worldwide exclusive rights to develop, manufacture and commercialise *Lynavoy* (linerixibat)  
3. Interstitial lung disease 4. In phase II/III study 5. Metabolic dysfunction-associated steatohepatitis 6. Chronic obstructive pulmonary disease 7. Metered dose inhaler 8. Polycystic kidney disease

# Oncology pipeline

## Phase III / Registration

5

 <i>Blenrep</i> (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma <sup>^</sup>
 <i>Jemperli</i> (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H colon cancer**
 risvutatug rezetecan (GSK5764227)	ADC targeting B7-H3*	ES-SCLC <sup>1**</sup>
 velzatinib (GSK6042981)	KIT inhibitor*	Gastrointestinal stromal tumours
 <i>Zejula</i> (niraparib)	PARP inhibitor*	Newly diagnosed glioblastoma multiforme







## Phase II

1

 <i>Ojjaara/Omjara</i> (mometotinib)	JAK1, JAK2 and ACVR1 inhibitor*	Myelodysplastic syndrome**
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## Phase I

6

 belantamab (GSK2857914)	Anti-BCMA antibody	Multiple myeloma
 GSK5458514	PSMAxCD3 T cell engaging bispecific antibody*	Prostate cancer <sup>2</sup>
 GSK5460025	Nucleotide excision repair targeting agent*	Solid tumours <sup>2</sup>
 GSK5471713	AR degrader	Prostate cancer <sup>2</sup>
 GSK5533524	ADC targeting a tumour associated antigen	Solid tumours
 mocertatug rezetecan (GSK5733584)	ADC targeting B7-H4*	Gynaecologic malignancies**



# HIV pipeline

RI&I  
Oncology  
HIV  
Infectious Diseases

## Phase II

4

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

## Phase I

1

 VH4527079	HIV entry inhibitor	HIV
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# Infectious Diseases pipeline

## Phase III / Registration

5

<span style="color: blue;">■</span> Arexvy (RSV vaccine)	Recombinant protein, adjuvanted*	RSV adults (60+ YoA <sup>1</sup> China) <sup>^**</sup>
<span style="color: blue;">■</span> bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV <sup>2</sup> infection <sup>^**</sup>
<span style="color: blue;">■</span> tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI <sup>3^</sup>
<span style="color: blue;">■</span> Bexsero (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
<span style="color: blue;">■</span> GSK4178116	Live, attenuated	Varicella new seed

## Phase II

8

<span style="color: blue;">■</span> alpipectir (BVL-GSK3729098)	Ethionamide booster*	Tuberculosis
<span style="color: blue;">■</span> ganfeborole (GSK3036656)	Leucyl t-RNA synthetase inhibitor*	Tuberculosis
<span style="color: blue;">■</span> GSK4077164	Bivalent GMMA and TCV*	Invasive non-typhoidal salmonella
<span style="color: blue;">■</span> GSK4382276	mRNA*	Seasonal flu
<span style="color: blue;">■</span> GSK4396687	mRNA*	COVID-19
<span style="color: blue;">■</span> GSK4406371	Live, attenuated	MMRV <sup>4</sup> new seed
<span style="color: blue;">■</span> GSK5102188	Recombinant subunit, adjuvanted	UTI <sup>3,5</sup>
<span style="color: blue;">■</span> GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV <sup>2</sup> infection

## Phase I


8

<span style="color: blue;">■</span> GSK3772701	<i>P. falciparum</i> whole cell inhibitor*	Malaria
<span style="color: blue;">■</span> GSK3882347	FimH antagonist*	Uncomplicated UTI <sup>3</sup>
<span style="color: blue;">■</span> GSK3923868	PI4K beta inhibitor	Rhinovirus disease
<span style="color: blue;">■</span> GSK3965193	PAPD5/PAPD7 inhibitor	Chronic HBV <sup>2</sup> infection <sup>5</sup>
<span style="color: blue;">■</span> GSK4024484	<i>P. falciparum</i> whole cell inhibitor*	Malaria
<span style="color: blue;">■</span> GSK4424989	Recombinant/glycoconjugate vaccine*	Group A streptococcal infections
<span style="color: blue;">■</span> GSK5459248	MAPS Pneumococcal 30+ valent adults*	Pneumococcal disease
<span style="color: blue;">■</span> GSK5475152	mRNA*	Seasonal flu/COVID-19 <sup>5</sup>


# Changes since Q4 2025

## Changes on pipeline


### Progressed to Phase III

 *Benlysta*: Anti-BLys antibody, Systemic sclerosis associated ILD<sup>1</sup>


### New to Phase II

 ozureprubart: Anti-IgE antibody, Food allergy


### New to Phase I

 GSK6792070: Activin signalling inhibitor, PAH<sup>2</sup>

 GSK5471713: AR degrader, Prostate cancer

 GSK5533524: ADC, Solid tumours

### Removed from Phase III/Registration

 *Nucala*: Anti-IL5 antibody, COPD<sup>3</sup>

 *Blujepa*: BTI inhibitor, Uncomplicated UTI<sup>4</sup>

### Removed from Phase II

 GSK5536522: mRNA, Flu H5N1 pre-pandemic

### Removed from Phase I

 XMT-2056: STING agonist ADC, Cancer

 GSK5251738: TLR8 agonist, Chronic HBV<sup>5</sup> infection

## Achieved pipeline catalysts

### Regulatory decisions

 *Exdensur*: severe asthma and CRSwNP<sup>6</sup> EU, CN

 *Lynavoy*: Cholestatic pruritus in PBC<sup>7,8</sup> US

 *Nucala*: COPD<sup>3</sup> EU


 *Blenrep*: 2L+ MM<sup>9</sup> CN

 *Arexvy*: 18-49 YoA<sup>10</sup> AIR<sup>11</sup> US


### Regulatory submission acceptances

 *Lynavoy*: Cholestatic pruritus in PBC<sup>7,8</sup> CN

 *Arexvy*: Older adults 60+ YoA<sup>10</sup> CN

 bepirovirsen: chronic HBV<sup>5</sup> infection US, EU, CN, JP

### Late-stage readouts


 *Exdensur*: NIMBLE, asthma - phase III readout

### Other news


























 efimosfermin alfa: MASH<sup>12</sup> - Breakthrough Therapy Designation (US)

 efimosfermin alfa: MASH<sup>12</sup> - PRIME (EU)

 risvutatug rezetecan: ES-SCLC<sup>13</sup> - Orphan Drug Designation (JP)







 bepirovirsen: chronic HBV<sup>5</sup> infection - Breakthrough Therapy Designation (US)

# Upcoming pipeline catalysts: 2026 and 2027






	H1 2026	H2 2026	2027
Regulatory decision	 Arexvy: 18-49 YoA <sup>1</sup> AIR <sup>2</sup> JP  tebipenem pivoxil: complicated UTI <sup>3</sup> US	 Arexvy: 18+ YoA <sup>1</sup> IC <sup>4</sup> US, EU, JP  bepirovirsen: chronic HBV <sup>5</sup> infection US, JP	 camlipixant RCC <sup>6</sup> US, EU, JP  Exdensus: EGPA <sup>10</sup> US  Ventolin (low carbon MDI <sup>7</sup> ): asthma EU  Blenrep: DREAMM-8, 2L+ MM <sup>8</sup> CN  Jemperli <sup>11</sup> : rectal cancer <sup>12</sup> US, EU, JP  cabotegravir 3× yearly PrEP <sup>9</sup> , HIV US  Arexvy: 60+ YoA <sup>1</sup> CN  bepirovirsen: chronic HBV <sup>5</sup> infection EU, CN  Bexsero: Men B (infants) US
Regulatory submission acceptance		 camlipixant: RCC <sup>6</sup> US, EU, JP  Ventolin (low carbon MDI <sup>7</sup> ): asthma EU  Blenrep: DREAMM-8, 2L+ MM <sup>8</sup> CN  cabotegravir: 3× yearly PrEP <sup>9</sup> , HIV prevention US  Bexsero: Men B (infants) US	 Exdensus: EGPA <sup>10</sup> US, EU, CN, JP  Jemperli <sup>11</sup> : rectal cancer <sup>12</sup> US, EU, CN, JP
Late-stage Phase III readouts		 camlipixant: CALM-1/2, RCC <sup>6</sup>  Exdensus: OCEAN, EGPA <sup>10</sup>  Jemperli <sup>11</sup> : AZUR-1, rectal cancer <sup>12,13</sup>  cabotegravir: EXTEND4M, 3× yearly PrEP <sup>9</sup> , HIV prevention <sup>13</sup>	 cabotegravir + rilpivirine: CUATRO, 3× yearly Treatment, HIV

# Designations in our pipeline








## Breakthrough Designation

 efimosfermin alfa (GSK6519754)	FGF21 analog	MASH <sup>1</sup>	US, EU
 Jemperi <sup>2</sup> (dostarlimab)	Anti-PD-1 antibody*	Neoadjuvant dMMR/MSI-H rectal cancer	US
 risvutatug rezetecan (GSK5764227)	ADC targeting B7-H3*	Relapsed or refractory ES-SCLC <sup>3</sup>	US, EU
 risvutatug rezetecan (GSK5764227)	ADC targeting B7-H3*	Relapsed or refractory osteosarcoma	US
 bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV <sup>4</sup> infection	US, CN
 GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV <sup>4</sup> infection	CN


## Fast Track

 Jemperi <sup>2</sup> (dostarlimab)	Anti-PD-1 antibody*	Neoadjuvant dMMR/MSI-H 1L rectal cancer
 velzatinib (GSK6042981)	KIT inhibitor*	Gastrointestinal stromal tumours
 alpipectir (BVL-GSK3729098)	Ethionamide booster*	Tuberculosis
 bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV <sup>4</sup> infection
 tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI <sup>5</sup>

## Orphan Drug Designation

 Benlysta (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD <sup>6</sup>	US
 Exdensusr (depemokimab)	Long-acting anti-IL5 antibody*	Hypereosinophilic syndrome	JP
 Lynavoy (linerixibat)	IBAT inhibitor	Cholestatic pruritus in PBC <sup>7,8</sup>	EU, JP
 GSK4771261	Monoclonal antibody against novel kidney target	Autosomal dominant PKD <sup>9</sup>	US, EU
 risvutatug rezetecan (GSK5764227)	ADC targeting B7-H3*	Relapsed or refractory ES-SCLC <sup>3</sup>	US, EU, JP
 velzatinib (GSK6042981)	KIT inhibitor*	Gastrointestinal stromal tumours	US, EU
 Zejula <sup>1</sup> (niraparib)	PARP inhibitor*	Glioblastoma multiforme	US

## Qualified Infectious Disease Product Designation

 tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI <sup>5</sup>
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## SENKU

 bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV <sup>4</sup> infection
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## FDA Commissioner's National Priority Voucher

 Jemperi <sup>2</sup> (dostarlimab)	Anti-PD-1 antibody*	Neoadjuvant dMMR/MSI-H rectal cancer
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\* In-license or other alliance relationship with third party

1. Metabolic dysfunction-associated steatohepatitis 2. Tesaro asset 3. Extensive-stage small-cell lung cancer 4. Hepatitis B virus 5. Urinary tract infection 6. Interstitial lung disease 7. Primary biliary cholangitis  
8. On 22 April 2026, GSK entered into a licence agreement under which Alfasigma S.p.A. acquired worldwide exclusive rights to develop, manufacture and commercialise Lynavoy (linerixibat) 9. Polycystic kidney disease

9

### ► BREAKTHROUGH DESIGNATION

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

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

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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

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

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► 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

# Clinical Trials

Phase II and III GSK-sponsored clinical trials

# Respiratory, Immunology and Inflammation

# Respiratory, Immunology and Inflammation

## Benlysta (belimumab)

NCT05878717 - BLISSc-ILD

Phase	II/III
Patient	Adults with systemic sclerosis associated interstitial lung disease (SSc-ILD)
Subjects	300
Treatment arms	Arm A: belimumab + standard therapy Arm B: placebo + standard therapy
Description	A randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy and safety of belimumab administered subcutaneously in adults with SSc-ILD
Timeline	Trial start: Q3 2023
Key endpoints	Absolute change from baseline in Forced Vital Capacity (FVC) millilitre (mL) at week 52
Clinicaltrials.gov	<a href="#">Link</a>

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 endpoints	Absolute change from baseline in Forced Vital Capacity (FVC) millilitre (mL) at week 52
Clinicaltrials.gov	<a href="#">Link</a>



# Respiratory, Immunology and Inflammation

## camlipixant

### NCT05599191 - CALM-1

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

### NCT05600777 - CALM-2

Phase	III
Patient	Adult participants with refractory chronic cough, including unexplained chronic cough
Subjects	975
Treatment arms	Arm A: camlipixant 25 mg twice a day Arm B: camlipixant 50 mg twice a day Placebo twice a day
Description	A 24-week, randomised, double-blind, placebo-controlled, parallel-arm efficacy and safety study with open-label extension of camlipixant in adult participants with refractory chronic cough, including unexplained chronic cough
Timeline	Trial start: Q1 2023
Key endpoints	24-hour cough frequency
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## efimosfermin alfa

### NCT07221227 - ZENITH-1

Phase	III
Patient	Adults with biopsy-confirmed F2- or F3-stage metabolic dysfunction-associated steatohepatitis (MASH)
Subjects	1200
Treatment arms	Dose level 1 of efimosfermin alfa Dose level 2 of efimosfermin alfa Placebo comparator
Description	A randomised, double-blind, placebo-controlled, 3-arm study to investigate the safety and Efficacy of Efimosfermin Alfa in Participants With Biopsy-Confirmed F2- or F3-Stage Metabolic Dysfunction-Associated Steatohepatitis (MASH) (ZENITH-1)
Timeline	Trial start: Q4 2025
Key endpoints	Improvement in fibrosis by $\geq 1$ stage and no worsening of steatohepatitis at Week 52 Resolution of steatohepatitis reading and no worsening of MASH CRN fibrosis score at Week 52
Clinicaltrials.gov	<a href="#">Link</a>

### NCT07221188 - ZENITH-2

Phase	III
Patient	Adults with known or suspected F2- or F3-stage metabolic dysfunction-associated steatohepatitis (MASH)
Subjects	1250
Treatment arms	Dose level 1 of efimosfermin alfa Dose level 2 of efimosfermin alfa Placebo comparator
Description	A randomised, double-blind, placebo-controlled, 3-arm study to investigate the safety and tolerability of efimosfermin alfa in participants with known or suspected F2- or F3-stage metabolic dysfunction-associated steatohepatitis (MASH)
Timeline	Trial start: Q4 2025
Key endpoints	Number of participants with treatment-emergent adverse events (TEAEs) and TEAEs by severity
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## Exdensur (depemokimab)

NCT06959095 - ENDURA-1

Phase	III
Patient	Adults with COPD with type 2 inflammation
Subjects	981
Treatment arms	Arm A: depemokimab + SoC 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
Timeline	Trial start: Q2 2025
Key endpoints	Annualized rate of moderate/severe exacerbations up to 104 weeks
Clinicaltrials.gov	<a href="#">Link</a>

NCT06961214 - ENDURA-2

Phase	III
Patient	Adults with COPD with type 2 inflammation
Subjects	960
Treatment arms	Arm A: depemokimab + SoC 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
Timeline	Trial start: Q2 2025
Key endpoints	Annualized rate of moderate/severe exacerbations up to 104 weeks
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## *Exdensur* (depemokimab)

NCT07177339 - VIGILANT

Phase	III
Patient	Patients with COPD with Type 2 inflammation
Subjects	1196
Treatment arms	Arm A: depemokimab + SoC 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 endpoints	Annualized rate of moderate/severe exacerbations up to 156 weeks
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## Exdensur (depemokimab)

NCT05274750 - ANCHOR-1

Phase	III
Patient	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
Subjects	276
Treatment arms	Arm A: depemokimab + 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
Timeline	Trial start: Q2 2022 Data reported: Q3 2024
Key endpoints	Change from baseline in total endoscopic nasal polyps (NP) score at week 52 Change from baseline in mean nasal obstruction verbal response scale (VRS) score from Week 49 through to Week 52
Clinicaltrials.gov	<a href="#">Link</a>

NCT05281523 - ANCHOR-2

Phase	III
Patient	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
Subjects	264
Treatment arms	Arm A: depemokimab + 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
Timeline	Trial start: Q2 2022 Data reported: Q3 2024
Key endpoints	Change from baseline in total endoscopic nasal polyps (NP) score at week 52 Change from baseline in mean nasal obstruction verbal response scale (VRS) score from Week 49 through to Week 52
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## Exdensur (depemokimab)

NCT05263934 - OCEAN

Phase	III
Patient	Adults with relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) receiving standard of care therapy
Subjects	163
Treatment arms	Arm A: depemokimab + placebo matching mepolizumab + SoC 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 endpoints	Number of participants with remission up to 52 weeks
Clinicaltrials.gov	<a href="#">Link</a>

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 endpoints	Frequency of HES flares up to 52 weeks
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## *Ventolin* (low carbon version of MDI)

NCT06261957

Phase	III
Patient	Participants aged 12 years and above with asthma
Subjects	477
Treatment arms	Arm A: Salbutamol HFA-134a Arm B: Salbutamol HFA-152a
Description	A randomized, double-blind, parallel group, multi-centre study to evaluate the long-term safety of salbutamol rescue medication when administered via metered dose inhalers containing the propellant HFA-152a or reference HFA-134a
Timeline	Trial start: Q2 2024 Data reported: Q4 2025
Key endpoints	AEs
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## gatuzosiran

NCT05583344 - HORIZON

Phase	IIb
Patient	Adults with non-alcoholic steatohepatitis (NASH) and advanced fibrosis
Subjects	284
Treatment arms	Arm 1: high dose GSK4532990 Arm 2: low dose GSK4532990 Arm 3: placebo
Description	A placebo-controlled trial to evaluate the efficacy and safety of GSK4532990 in adults with advanced non-alcoholic steatohepatitis (NASH)
Timeline	Trial start: Q1 2023 Primary completion: Q1 2026
Key endpoints	Part 1: Percentage of participants achieving $\geq 1$ stage improvement in histological fibrosis with no worsening of NASH (at week 52) Part 2: Percentage of participants achieving NASH resolution with no worsening of fibrosis (at week 52)
Clinicaltrials.gov	<a href="#">Link</a>

NCT06104319 - SKYLINE

Phase	IIa
Patient	Adult participants with NASH or suspected NASH
Subjects	61
Treatment arms	Arm 1: GSK4532990 Dose 1 Arm 2: GSK4532990 Dose 2 Arm 3: GSK4532990 Dose 3 Arm 4: GSK4532990 Dose 4
Description	A single dose, open-label, dose exploration study to assess the PK-PD activity, safety, and tolerability of GSK4532990 in adult participants with NASH or suspected NASH
Timeline	Trial start: Q1 2024 Trial complete: Q3 2025
Key endpoints	Predicted percent change from baseline in liver biopsy-derived HSD17B13 protein expression levels and mRNA expression levels
Clinicaltrials.gov	<a href="#">Link</a>



# Respiratory, Immunology and Inflammation

## gatuzosiran

NCT06613698 - STARLIGHT

Phase	II
Patient	Adults with alcohol-related liver disease (ALD)
Subjects	393
Treatment arms	Arm 1: GSK4532990 Dose 1 Arm 2: GSK4532990 Dose 2 Arm 3: GSK4532990 Dose 3 Arm 4: GSK4532990 Dose 4 Arm 5: Placebo
Description	A dose-finding, double-blind, placebo-controlled study to evaluate the efficacy and safety of GSK4532990 for steatohepatitis in adults with ALD
Timeline	Trial start: Q4 2024
Key endpoints	AEs, SAEs Change from baseline in Liver Stiffness measurement (LSM) reduction using FibroScan® at Week 52 (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 52
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## GSK5784283 (asthma)

NCT06748053 - NAZARE

Phase	II
Patient	Adults aged 18 to 75 years of age with uncontrolled asthma
Subjects	307
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 endpoints	Change from baseline in the fraction of exhaled nitric oxide (FeNo)
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## GSK3862995 (NCFB)

NCT07201051

Phase	II
Patient	Adults (18 - 85 years) With Bronchiectasis
Subjects	400
Treatment arms	Arm A: GSK3862995B at dose level 1 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: Q3 2025
Key end points	Annualized rate of exacerbations
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## nivisnebart

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 endpoints	Clinical Dementia Rating - Sum of Boxes (CDR-SB) Score
Clinicaltrials.gov	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## ozureprubart

NCT07220811

Phase	IIb
Patient	Participants 12 to less than 56 years of age with IgE-mediated food allergy
Subjects	100
Treatment arms	Arm 1: RPT904 (Q8W) Arm 2: RPT904 (Q12W) Arm 3: Placebo (Q8W and Q12W)
Description	Randomized, double-blind, placebo-controlled study of RPT904 as monotherapy in participants with IgE-mediated food allergy
Timeline	Trial start: Q4 2025
Key end points	Ability to consume a food without dose-limiting symptoms during a double-blind, placebo-controlled food challenge after treatment with either RPT904 or placebo
Clinicaltrials.gov	<a href="#">Link</a>

# Oncology

# Oncology

## Blenrep (belantamab mafodotin)

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 Primary data reported: Q1 2024
Key endpoints	PFS, MRD negativity rate, ORR, CRR, VGPR or better rate, DoR, TTBR, TTR, TTP, OS, PFS2, safety
Clinicaltrials.gov	<a href="#">Link</a>

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 endpoints	PFS, MRD negativity rate
Clinicaltrials.gov	<a href="#">Link</a>

# Oncology

## Blenrep (belantamab mafodotin)

NCT07227311 - DREAMM-15

Phase	II
Patient	Participants with relapsed-refractory multiple myeloma
Subjects	200
Treatment arms	belantamab mafodotin + pomalidomide + dexamethasone (BPd) belantamab mafodotin + bortezomib + dexamethasone (BVd) belantamab mafodotin + carfilzomib + dexamethasone (BKd)
Description	A multicentre, open label, non-randomized study to evaluate the efficacy and safety of extended dosing of belantamab mafodotin in different combinations with standard of care regimens in participants with relapsed-refractory multiple myeloma
Timeline	Trial start anticipated: H1 2026
Key end points	ORR
Clinicaltrials.gov	<a href="#">Link</a>

NCT07224672 - ALANIS

Phase	II
Patient	Adult participants with newly diagnosed amyloid light chain amyloidosis
Subjects	60
Treatment arms	belantamab mafodotin + cyclophosphamide, bortezomib, and dexamethasone (CyBorD)
Description	An open-label, single-arm, proof-of-concept study evaluating the efficacy and safety of belantamab mafodotin administered in combination with cyclophosphamide, bortezomib, and dexamethasone in adult participants with newly diagnosed amyloid light chain amyloidosis
Timeline	Trial start anticipated: H1 2026
Key end points	Overall complete hematologic response rate
Clinicaltrials.gov	<a href="#">Link</a>



# 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	892
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 endpoints	EFS assessed by Blinded Independent Central Review (BICR)
Clinicaltrials.gov	<a href="#">Link</a>

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 endpoints	Sustained cCR for 12, 24 and 36 months, EFS at 3 years
Clinicaltrials.gov	<a href="#">Link</a>

# 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: Q1 2025
Key endpoints	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	<a href="#">Link</a>

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 endpoints	EFS assessed by Blinded Independent Central Review (BICR)
Clinicaltrials.gov	<a href="#">Link</a>

# Oncology

## risvutatug rezetecan

NCT07099898 - EMBOLD-SCLC-301

Phase	III
Patient	Participants With Relapsed Small Cell Lung Cancer (SCLC)
Subjects	420

Treatment arms	Experimental arm: GSK5764227 Active Comparator arm: Topotecan
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Description	A multicentre, 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)
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Timeline	Trial start: Q3 2025
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Key endpoints	ORR, OS, DoR, PFS, AEs, SAEs
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Clinicaltrials.gov	<a href="#">Link</a>
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# Oncology

## velzatinib

NCT07218926 – StrateGIST 3

Phase	III
Patient	Participants with gastrointestinal stromal tumors after imatinib therapy
Subjects	450
Treatment arms	Arm 1: IDRX-42 (GSK6042981) Arm 2: sunitinib
Description	A randomized, multicentre, open-label study of velzatinib (GSK6042981) versus sunitinib in participants with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) after imatinib therapy
Timeline	Trial start: Q4 2025
Key endpoints	PFS, OS
Clinicaltrials.gov	<a href="#">Link</a>

# Oncology

## Ojjaara/ Omjjara (mometotinib)

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 endpoints	Percentage of participants with Red Blood Cells - transfusion independence (RBC-TI) for at least 12 weeks, rolling over 24 weeks SAEs, AEs,
Clinicaltrials.gov	<a href="#">Link</a>

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	68
Treatment arms	mometotinib + 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 endpoints	Percentage of participants with TI response by Week 24, AEs, SAEs
Clinicaltrials.gov	<a href="#">Link</a>

# Oncology

## mocertatug rezetecan

NCT07286266 (BEHOLD-Ovarian01)

Phase	III
Patient	Adults with platinum-resistant ovarian cancer
Subjects	450
Treatment arms	Experimental: GSK5733584 Comparator: Standard of care chemotherapy (paclitaxel or pegylated liposomal doxorubicin or topotecan or gemcitabine) as per investigator's choice
Description	A randomized, open-label, multicentre, phase 3 study to investigate GSK5733584 compared with chemotherapy in participants with platinum-resistant ovarian cancer
Timeline	Trial start anticipated: H1 2026
Key endpoints	PFS, OS
Clinicaltrials.gov	<a href="#">Link</a>

NCT07286331 (BEHOLD-Endometrial01)

Phase	III
Patient	Adults with recurrent endometrial cancer
Subjects	600
Treatment arms	Experimental: GSK5733584 Comparator: Standard of care chemotherapy (paclitaxel or doxorubicin) as per investigator's discretion
Description	A randomized, open-label, multicentre, phase 3 study to investigate GSK5733584 compared with chemotherapy in participants with recurrent endometrial cancer
Timeline	Trial start anticipated: H1 2026
Key endpoints	ORR, PFS
Clinicaltrials.gov	<a href="#">Link</a>

# HIV

# HIV

## cabotegravir ultra long-acting (ULA) for HIV Prevention

NCT06741397

Phase	IIb
Patient	Healthy adolescent and adult participants
Subjects	229
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 endpoints	CAB trough concentrations
Clinicaltrials.gov	<a href="#">Link</a>



# HIV

## VH3810109

NCT05996471 - EMBRACE

Phase	IIb
Patient	Antiretroviral therapy (ART)-experienced adults living with HIV
Subjects	185
Treatment arms	Group 1: VH3810109 + cabotegravir Group 2 VH3810109 + rHuPH20 + cabotegravir Group 3: Active comparator - Participants receiving standard of care (SoC) antiretroviral therapy (ART)
Description	A multicentre, randomised, open-label, trial comparing the efficacy, safety, PK, and tolerability of VH3810109, administered either intravenously or as a subcutaneous infusion with rHuPH20, in combination with cabotegravir given intramuscularly, to standard of care in virologically suppressed, antiretroviral therapy (ART)-experienced adults living with HIV
Timeline	Trial start: Q3 2023
Key endpoints	Safety, plasma HIV-1 levels
Clinicaltrials.gov	<a href="#">Link</a>

HIV

VH4524184

NCT07202546 - INNOVATE

Phase	IIb
Patient	Treatment naïve persons with HIV-1
Subjects	150
Treatment arms	Experimental: VH4524184 Dose A+ FTC / TAF Experimental: VH4524184 Dose B + FTC / TAF Active Comparator: DTG + 3TC Experimental: VH4524184 selected dose + FTC / TAF
Description	A randomized, open-label active controlled study evaluating the safety and efficacy of oral VH4524184 coadministered with emtricitabine and tenofovir alafenamide in treatment naïve viremic persons with HIV-1
Timeline	Trial start: Q1 2026
Key endpoints	Percentage of participants achieving plasma HIV-1 RNA suppression
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

# Infectious diseases

## Arexvy (RSV Adults)

NCT04732871 - RSV OA=ADJ-004

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

NCT06534892 - RSV- OA=ADJ-012

Phase	IIIb
Patient	Adults aged 60 years and above
Subjects	10212
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 endpoints	RSV-A, RSV-B neutralization titers
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## Arexvy (RSV Adults)

NCT07220109 - RSV OA=ADJ-028

Phase	III
Patient	Adults aged 18-59 YOA at increased risk (AIR) of RSV disease
Subjects	750
Treatment arms	China: participants 18-59 AIR , RSVPreF3 OA investigational vaccine China: participants 18-59 AIR, Placebo
Description	A study on the immune response and safety of vaccine against respiratory syncytial virus given to Chinese adults 18 to 59 years of age at increased risk of respiratory syncytial virus disease
Timeline	Trial start: Q4 2025
Key endpoints	RSV-A, RSV-B neutralization titers Seroresponse rate (SRR) in RSV-A and RSV-B neutralizing titers
Clinicaltrials.gov	<a href="#">Link</a>

NCT07092865 - RSV OA=ADJ-031

Phase	II
Patient	Immunocompromised (IC) adults 18 years of age and above
Subjects	184
Treatment arms	Lung or kidney transplant recipients undergoing chronic immunosuppressive therapy who received 1 and 2 doses of the adjuvanted RSVPreF3 vaccine (IC_1 and IC_2 groups respectively) in the RSV OA=ADJ-023 parent study will receive a revaccination dose of adjuvanted RSVPreF3 vaccine at Visit 1 (Day 1) in the current study.
Description	A non-randomized, controlled, open-label, extension study to evaluate the persistence of immune response of the adjuvanted RSVPreF3 vaccine and the safety and immunogenicity following revaccination in lung and kidney transplant recipients (>=18 years of age)
Timeline	Trial start: Q3 2025
Key endpoints	RSV-A & -B serum neutralizing titers
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## bepirovirsen

### NCT05630807 - B-WELL 1

Phase	III
Patient	Non-cirrhotic nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	981
Treatment arms	Arm A: bepiovirsen for 24 weeks Arm B: placebo
Description	A multicentre, randomised, double blind trial to confirm the efficacy and safety of treatment with bepiovirsen in participants with chronic hepatitis B virus
Timeline	Trial start: Q4 2022 Data reported: Q1 2026
Key endpoints	Number of participants with baseline HBsAg $\leq$ 3000IU/mL achieving functional cure (FC)
Clinicaltrials.gov	<a href="#">Link</a>

### NCT05630820 - B-WELL 2

Phase	III
Patient	Non-cirrhotic nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	857
Treatment arms	Arm A: bepiovirsen for 24 weeks Arm B: placebo
Description	A multicentre, randomised, double blind trial to confirm the efficacy and safety of treatment with bepiovirsen in participants with chronic hepatitis B virus
Timeline	Trial start: Q4 2022 Data reported: Q1 2026
Key endpoints	Number of participants with baseline HBsAg $\leq$ 3000IU/mL achieving functional cure (FC)
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## bepirovirsen

NCT06497504 - B-FOCUS

Phase	II
Patient	Participants living with human immunodeficiency virus and chronic hepatitis B virus infection on antiretroviral treatment
Subjects	157
Treatment arms	Arm A: bepirovirsen Arm B: placebo
Description	A multicentre, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of treatment with bepirovirsen in participants living with human immunodeficiency virus and chronic hepatitis B virus infection on antiretroviral treatment
Timeline	Trial start: Q3 2024
Key endpoints	Percentage of participants achieving hepatitis B virus (HBV) virologic response at 36 weeks after scheduled end of study treatment in absence of rescue medication
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## GSK4178116 (Varicella new seed)

NCT06693895

Phase	III
Patient	Healthy children aged 12 to 15 months
Subjects	750
Treatment arms	<p>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.</p> <p>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.</p>
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 endpoints	AEs, SAEs
Clinicaltrials.gov	<a href="#">Link</a>

NCT06740630

Phase	III
Patient	Healthy children 12 to 15 months of age
Subjects	1840
Treatment arms	<p>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.</p> <p>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.</p>
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 endpoints	Anti-glycoprotein-E antibodies at day 43
Clinicaltrials.gov	<a href="#">Link</a>



# Infectious diseases

## GSK4178116 (Varicella new seed)

NCT06806137

Phase	III
Patient	Healthy children aged 12 to 15 months
Subjects	600
Treatment arms	<p>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.</p> <p>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.</p> <p>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.</p>
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: Q2 2025
Key endpoints	% 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 [Link](#)

NCT06855160

Phase	III
Patient	Healthy children 12 to 15 months of age
Subjects	900
Treatment arms	<p>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.</p> <p>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.</p>
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 endpoints	Percentage of participants with seroresponse to Varicella Zoster Virus (VZV) anti- glycoprotein E (gE) Immunoglobulin (IgG), AEs, SAEs
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## ganfeborole

NCT05382312

Phase	Ila
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 endpoints	Change from baseline in log10 CFU of <i>Mycobacterium tuberculosis</i>
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

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

NCT06213506

Phase	IIa
Patient	Adults, children and infants, including dose-finding in infants in Africa (Ghana)
Subjects	20 adults/40 children/60 infants 9 months/ 396 infants 6 weeks
Treatment arms	Stage 1: Age-de-escalation Adults (dose C or control) Children (dose B or C or control) Infants, 9 months (dose A, B, C or control) Infants, 6 months (dose A, B, C, or control) Stage 2: Dose finding in infants 6 weeks of age
Description	An observer-blind, randomized, controlled, age-de-escalation, single centre interventional study to evaluate the safety, reactogenicity, and immune response of the GVGH iNTS vaccine against <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 endpoints	To evaluate the safety, reactogenicity and immunogenicity profile of iNTS-GMMA vaccine in adults, children and infants (Ghana)
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## GSK4382276 (mRNA Seasonal Flu)

NCT06431607

Phase	IIa
Patient	Adults 18 years of age and older
Subjects	845
Treatment arms	Flu mRNA_YA_Groups: Formulations 1, 2, 3, 4 YA_Active Comparator Group 1: Active Comparator 1 Flu mRNA_OA_Groups: Formulation 5, 6, 7, 8 OA_Active Comparator Group 2: Active Comparator 2 Flu mRNA_YA_Group: Formulation 9 YA_Active Comparator Group 3: Active Comparator 3 Flu mRNA_OA_Group 5: Formulation 10 OA_Active Comparator Group 4: Comparator 4
Description	A randomized, observer-blind, dose-finding study to evaluate the immunogenicity and safety of mRNA-based multivalent seasonal influenza vaccine candidates in adults 18 years of age and older
Timeline	Trial start: Q2 2024 Primary completion: Q4 2024
Key endpoints	Antigen 1 antibody titres
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## GSK4382276 (mRNA Seasonal Flu)

NCT07121192 - FLU SV MRNA-027

Phase	II
Patient	Adults 18 Years of Age And Older
Subjects	776
Treatment arms	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 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 endpoints	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	<a href="#">Link</a>

NCT07204964 - FLU SV MRNA-028

Phase	II
Patient	Adults 18 Years of Age And Older
Subjects	971
Treatment arms	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 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 endpoints	Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## GSK4406371 (MMRV new seed vaccine)

NCT05630846

Phase	II
Patient	Healthy children 4-6 years of age
Subjects	801
Treatment arms	Investigational MMRV(H)NS vaccine Investigational MM(H)RVNS vaccine Investigational M(L)M(L)R(L)V(L)NS vaccine Marketed MMRV_Lot 1 and Lot 2 vaccine
Description	A single-blind, randomized, controlled trial to evaluate the immunogenicity and safety of a measles, mumps, rubella, varicella vaccine compared with ProQuad, administered in healthy children 4-6 years of age
Timeline	Trial start: Q4 2022 Primary completion: Q4 2024
Key endpoints	Anti-measles, anti-mumps, anti-rubella, and anti-glycoprotein H antibodies geometric mean concentrations
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## GSK5637608 (Chronic HBV infection)

NCT06537414 - B-UNITED

Phase	IIb
Patient	Participants with chronic hepatitis B virus on background nucleos(t)ide analogue therapy
Subjects	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	<a href="#">Link</a>

# 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
siRNA	Small interfering RNA
SLE	Systemic lupus erythematosus
SoC	Standard of care
SSc	Systemic sclerosis associated
TCV	Typhoid conjugate vaccine
TTBR	Time to best response
TTD	Time to treatment discontinuation
TTP	Time to tumour progression
TTR	Time to treatment response
ULA	Ultra long acting
UTI	Urinary tract infection
uUTI	Uncomplicated urinary tract infection
VGPR	Very good partial remission
YoA	Years of age