



**Pipeline assets and clinical trials appendix**  
Q4 2025

# Contents

Innovation: Pipeline growth

Clinical trials

Respiratory, Immunology and  
Inflammation (RI&I)

Oncology

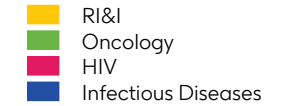
HIV

Infectious Diseases



# Innovation: Pipeline growth

Overview of potential new vaccines and medicines



# 58 potential new vaccines and medicines in pipeline

## Phase III / Registration

17

<b>Exdensur</b> (depemokimab)	Long-acting anti-IL5 antibody*	Asthma <sup>^**</sup>
<b>linerixibat</b> (GSK2330672)	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis <sup>^</sup>
<b>Nucala</b> (mepolizumab)	Anti-IL5 antibody	COPD <sup>1^</sup>
<b>camlipixant</b> (GSK5464714)	P2X3 receptor antagonist	Refractory chronic cough
<b>efimosfermin alfa</b> (GSK6519754)	FGF21 analog*	MASH <sup>2</sup>
Low carbon version of MDI <sup>3</sup> , <b>Ventolin</b> (salbutamol)	Beta 2 adrenergic receptor agonist	Asthma
<b>Blenrep</b> (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma <sup>^</sup>
<b>Jemperli</b> (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H colon cancer <sup>**</sup>
<b>risvutatug rezetecan</b> (GSK5764227)	ADC targeting B7-H3*	ES-SCLC <sup>4**</sup>
<b>velzatinib</b> (GSK6042981)	KIT inhibitor*	Gastrointestinal stromal tumours
<b>Zejula</b> (niraparib)	PARP inhibitor*	Newly diagnosed glioblastoma multiforme
<b>Arexvy</b> (RSV vaccine)	Recombinant protein, adjuvanted*	RSV adults (18-49 YoA <sup>5</sup> AIR <sup>6</sup> ) <sup>^**</sup>
<b>Blujepa</b> (gepotidacin)	BTI inhibitor*	Uncomplicated UTI <sup>7^</sup> <sup>**</sup>
<b>tebipenem pivoxil</b> (GSK3778712)	Antibacterial carbapenem*	Complicated UTI <sup>7^</sup>
<b>bepirovirsen</b> (GSK3228836)	Antisense oligonucleotide*	Chronic HBV <sup>8</sup> infection <sup>**</sup>
<b>Bexsero</b> (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
<b>GSK4178116</b>	Live, attenuated	Varicella new seed

# 58 potential new vaccines and medicines in pipeline

## Phase II

18

<span style="color: yellow;">■</span> <b>Benlysta (belimumab)</b>	Anti-BLys antibody	Systemic sclerosis associated ILD <sup>1,2**</sup>
<span style="color: yellow;">■</span> <b>GSK4532990</b>	HSD17B13 RNA interference*	MASH <sup>3**</sup>
<span style="color: yellow;">■</span> <b>GSK5784283</b>	TSLP monoclonal antibody*	Asthma
<span style="color: yellow;">■</span> <b>nivisnebart (GSK4527226)</b>	Anti-sortilin antibody*	Alzheimer's disease
<span style="color: green;">■</span> <b>Ojjaara/Omjara (momelotinib)</b>	JAK1, JAK2 and ACVR1 inhibitor*	Myelodysplastic syndrome**
<span style="color: magenta;">■</span> <b>cabotegravir (GSK1265744)</b>	Integrase inhibitor	HIV
<span style="color: magenta;">■</span> <b>VH3810109</b>	Broadly neutralizing antibody*	HIV
<span style="color: magenta;">■</span> <b>VH4011499</b>	Capsid protein inhibitor	HIV
<span style="color: magenta;">■</span> <b>VH4524184</b>	Integrase inhibitor*	HIV
<span style="color: blue;">■</span> <b>alpipectir (BVL-GSK3729098)</b>	Ethionamide booster*	Tuberculosis
<span style="color: blue;">■</span> <b>ganfeborole (GSK3036656)</b>	Leucyl t-RNA synthetase inhibitor*	Tuberculosis
<span style="color: blue;">■</span> <b>GSK4077164</b>	Bivalent GMMA and TCV*	Invasive non-typhoidal salmonella
<span style="color: blue;">■</span> <b>GSK4382276</b>	mRNA*	Seasonal flu
<span style="color: blue;">■</span> <b>GSK4396687</b>	mRNA*	COVID-19
<span style="color: blue;">■</span> <b>GSK4406371</b>	Live, attenuated	MMRV <sup>4</sup> new seed
<span style="color: blue;">■</span> <b>GSK5102188</b>	Recombinant subunit, adjuvanted	UTI <sup>5,6</sup>
<span style="color: blue;">■</span> <b>GSK5536522</b>	mRNA*	Flu H5N1 pre-pandemic <sup>6</sup>
<span style="color: blue;">■</span> <b>GSK5637608</b>	Hepatitis B virus-targeted siRNA*	Chronic HBV <sup>7</sup> infection

# 58 potential new vaccines and medicines in pipeline

## Phase I

23

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* PDE3/4	Autoimmune disease
GSK6582701	inhibitor*	COPD <sup>1</sup>
GSK6759821	siRNA*	COPD <sup>1</sup>
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>
mocertatug rezetecan (GSK5733584)	ADC targeting B7-H4*	Gynaecologic malignancies**
XMT-2056 <sup>4</sup> (wholly owned by Mersana Therapeutics)	STING agonist ADC*	Cancer
VH4527079	HIV entry inhibitor	HIV
GSK3772701	<i>P. falciparum</i> whole cell inhibitor*	Malaria
GSK3882347	FimH antagonist*	Uncomplicated UTI <sup>5</sup>
GSK3923868	PI4K beta inhibitor	Rhinovirus disease
GSK3965193	PAPD5/PAPD7 inhibitor	Chronic HBV <sup>6</sup> infection <sup>3</sup>
GSK4024484	<i>P. falciparum</i> whole cell inhibitor*	Malaria
GSK4424989	Recombinant/glycoconjugate vaccine*	Group A streptococcal infections
GSK5251738	TLR8 agonist*	Chronic HBV <sup>6</sup> infection
GSK5459248	MAPS Pneumococcal 30+ valent adults*	Pneumococcal disease
GSK5475152	mRNA*	Seasonal flu/COVID-19 <sup>3</sup>

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

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

## Phase III / Registration

6

<span style="color: yellow;">■</span> <i>Exdensur</i> (depemokimab)	Long-acting anti-IL5 antibody*	Asthma <sup>^**</sup>
<span style="color: yellow;">■</span> <i>linerixibat</i> (GSK2330672)	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis <sup>^</sup>
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<span style="color: yellow;">■</span> Low carbon version of MDI <sup>3</sup> , <i>Ventolin</i> (salbutamol)	Beta 2 adrenergic receptor agonist	Asthma

## Phase II

4

<span style="color: yellow;">■</span> <i>Benlysta</i> (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD <sup>4,5**</sup>
<span style="color: yellow;">■</span> GSK4532990	HSD17B13 RNA interference*	MASH <sup>2**</sup>
<span style="color: yellow;">■</span> GSK5784283	TSLP monoclonal antibody*	Asthma
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## Phase I

8

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<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>1</sup>
<span style="color: yellow;">■</span> GSK6759821	siRNA*	COPD <sup>1</sup>

# Oncology pipeline

## Phase III / Registration

5

<span style="color: green;">■</span> <i>Blenrep</i> (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma <sup>^</sup>
<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>1**</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

## Phase II

1

<span style="color: green;">■</span> <i>Ojjaara/Omjara</i> (mometotinib)	JAK1, JAK2 and ACVR1 inhibitor*	Myelodysplastic syndrome**
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## Phase I

5

<span style="color: green;">■</span> belantamab (GSK2857914)	Anti-BCMA antibody	Multiple myeloma
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<span style="color: green;">■</span> mocertatug rezetecan (GSK5733584)	ADC targeting B7-H4*	Gynaecologic malignancies**
<span style="color: green;">■</span> XMT-2056 <sup>3</sup> (wholly owned by Mersana Therapeutics)	STING agonist ADC*	Cancer



- RI&I
- Oncology
- HIV
- Infectious Diseases

# HIV pipeline

## Phase II

4

<span style="display: inline-block; width: 10px; height: 10px; background-color: #FF69B4; margin-right: 5px;"></span> cabotegravir (GSK1265744)	Integrase inhibitor	HIV
<span style="display: inline-block; width: 10px; height: 10px; background-color: #FF69B4; margin-right: 5px;"></span> VH3810109	Broadly neutralizing antibody*	HIV
<span style="display: inline-block; width: 10px; height: 10px; background-color: #FF69B4; margin-right: 5px;"></span> VH4011499	Capsid protein inhibitor	HIV
<span style="display: inline-block; width: 10px; height: 10px; background-color: #FF69B4; margin-right: 5px;"></span> VH4524184	Integrase inhibitor*	HIV

## Phase I

1

<span style="display: inline-block; width: 10px; height: 10px; background-color: #FF69B4; margin-right: 5px;"></span> VH4527079	HIV entry inhibitor	HIV
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# Infectious Diseases pipeline

■	RI&I
■	Oncology
■	HIV
■	Infectious Diseases

## Phase III / Registration

6

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

## Phase II

9

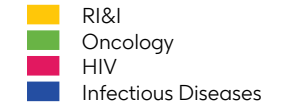
■	alpipectir (BVL-GSK3729098)	Ethionamide booster*	Tuberculosis
■	ganfeborole (GSK3036656)	Leucyl t-RNA synthetase inhibitor*	Tuberculosis
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■	GSK4382276	mRNA*	Seasonal flu
■	GSK4396687	mRNA*	COVID-19
■	GSK4406371	Live, attenuated	MMRV <sup>5</sup> new seed
■	GSK5102188	Recombinant subunit, adjuvanted	UTI <sup>3,6</sup>
■	GSK5536522	mRNA*	Flu H5N1 pre-pandemic <sup>6</sup>
■	GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV <sup>4</sup> infection

## Phase I

9

■	GSK3772701	<i>P. falciparum</i> whole cell inhibitor*	Malaria
■	GSK3882347	FimH antagonist*	Uncomplicated UTI <sup>3</sup>
■	GSK3923868	PI4K beta inhibitor	Rhinovirus disease
■	GSK3965193	PAPD5/PAPD7 inhibitor	Chronic HBV <sup>4</sup> infection <sup>6</sup>
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■	GSK5251738	TLR8 agonist*	Chronic HBV <sup>4</sup> infection
■	GSK5459248	MAPS Pneumococcal 30+ valent adults*	Pneumococcal disease
■	GSK5475152	mRNA*	Seasonal flu/COVID-19 <sup>6</sup>

\* 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. Measles, Mumps, Rubella, and Varicella 6. In phase I/II study



# Changes since Q3 2025

## Changes on pipeline

### Progressed to Phase III

- efimosfermin: FGF21 analog, MASH<sup>1</sup>
- velzatinib: KIT inhibitor, Gastrointestinal stromal tumours

### New to Phase I

- GSK6759821: siRNA, COPD<sup>2</sup>
- GSK5460025: Nucleotide excision repair targeting agent, Solid tumours

### Removed from Phase III

- latozinemab: Anti-sortilin antibody, Frontotemporal dementia

### Removed from Phase II

- GSK5101955: MAPS Pneumococcal 24 valent paed, Paediatric pneumococcal disease

### Removed from Phase I

- GSK3888130: Anti-IL7 antibody, Autoimmune disease
- GSK5462688: RNA-editing oligonucleotide, Alpha-1 antitrypsin deficiency
- GSK4418959: Werner helicase inhibitor, dMMR/MSI-H solid tumours
- GSK4524101: DNA polymerase theta inhibitor, Cancer

## Achieved pipeline catalysts

### Regulatory decisions

- Exdensur*: severe asthma US
- Exdensur*: severe asthma and CRSwNP<sup>3</sup> JP, UK
- Nucala*: COPD<sup>2</sup> CN
- Trelegy*: asthma CN
- Arexvy*: 18+ YoA<sup>4</sup> EU
- Blujepa*: GC<sup>5</sup> US
- Shingrix* liquid formulation EU

### Regulatory submission acceptances

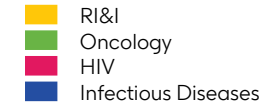
- Arexvy*: 18+ YoA<sup>4</sup> IC<sup>6</sup> US, EU, JP
- tebipenem pivoxil: complicated UTI US

### Late-stage readouts

- Arexvy*: Older adults 60+ YoA<sup>5</sup> (China) - Positive phase III readout
- bepirovirsen: B-WELL-1/2, chronic HBV<sup>7</sup> infection - Positive phase III readout

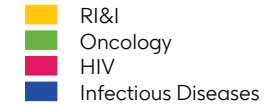
### Other news

- Exdensur*: severe asthma and CRSwNP<sup>3</sup> - Positive CHMP opinion (EU)
- Nucala*: COPD<sup>2</sup> - Positive CHMP opinion (EU)
- risvutatug rezetecan: ES-SCLC<sup>8</sup> - Orphan Drug Designation (US, EU)
- Jemperli*<sup>9</sup>: AZUR-1, rectal cancer - Commissioner's National Priority Voucher (US)



# Upcoming pipeline catalysts: 2026 and 2027

	H1 2026	H2 2026	2027
Regulatory decision	<i>Exdensus</i> : asthma EU, CN	<i>linerixibat</i> : cholestatic pruritus in PBC <sup>2</sup> EU	<i>camlipixant</i> RCC <sup>10</sup> US, EU, JP
	<i>Exdensus</i> : CRSwNP <sup>1</sup> EU, CN	<i>Arexvy</i> : 18+ YoA <sup>5</sup> IC <sup>8</sup> US, EU, JP	<i>Exdensus</i> : EGPA <sup>11</sup> US
	<i>linerixibat</i> : cholestatic pruritus in PBC <sup>2</sup> US	<i>bepirovirsen</i> : chronic HBV <sup>9</sup> infection US, JP	<i>linerixibat</i> : cholestatic pruritus in PBC <sup>2</sup> CN, JP
	<i>Nucala</i> : COPD <sup>3</sup> EU	<i>Bexsero</i> : Men B (infants) US	<i>Ventolin</i> (low carbon MDI <sup>12</sup> ): asthma EU
	<i>Blenrep</i> : DREAMM-7, 2L+ MM <sup>4</sup> CN		<i>Blenrep</i> : DREAMM-8, 2L+ MM <sup>4</sup> CN
	<i>Arexvy</i> : 18-49 YoA <sup>5</sup> AIR <sup>6</sup> US, JP		<i>Jemperli</i> <sup>13</sup> : rectal cancer <sup>14</sup> US, EU, JP
	<i>tebipenem pivoxil</i> : complicated UTI <sup>7</sup> US		<i>cabotegravir</i> Q4M PrEP <sup>15</sup> , HIV US
Regulatory submission acceptance	<i>linerixibat</i> : cholestatic pruritus in PBC <sup>2</sup> CN, JP	<i>camlipixant</i> : RCC <sup>10</sup> US, EU, JP	<i>Exdensus</i> : OCEAN, EGPA <sup>11</sup> US, EU, CN, JP
	<i>Arexvy</i> : Older adults 60+ YoA <sup>5</sup> (China) CN	<i>Ventolin</i> (low carbon MDI <sup>12</sup> ): asthma EU	<i>Jemperli</i> <sup>13</sup> : AZUR-1, rectal cancer <sup>14</sup> US, EU, CN, JP
	<i>bepirovirsen</i> : chronic HBV <sup>9</sup> infection US, EU, CN, JP	<i>Blenrep</i> : DREAMM-8, 2L+ MM <sup>4</sup> CN	<i>Blujepa</i> : uncomplicated UTI <sup>7</sup> EU
	<i>Bexsero</i> : Men B (infants) US	<i>cabotegravir</i> : Q4M PrEP <sup>15</sup> , HIV prevention US	<i>Blujepa</i> : GC <sup>16</sup> EU
Late-stage Phase III readouts		<i>camlipixant</i> : CALM-1/2, RCC <sup>10</sup>	<i>cabotegravir</i> + <i>rilpivirine</i> : CUATRO, Q4M Treatment, HIV
		<i>Exdensus</i> : OCEAN, EGPA <sup>11</sup>	
		<i>Jemperli</i> <sup>13</sup> : AZUR-1, rectal cancer <sup>14,17</sup>	
		<i>cabotegravir</i> : EXTEND4M, Q4M PrEP <sup>15</sup> , HIV prevention <sup>17</sup>	



# Designations in our pipeline

## Breakthrough Designation

	<i>Blenrep</i> (belantamab mafodotin)	Anti-BCMA ADC*	Relapsed or refractory multiple myeloma	CN
	<i>Jemperli</i> <sup>1</sup> (dostarlimab)	Anti-PD-1 antibody*	Neoadjuvant dMMR/MSI-H rectal cancer	US
	risvutatumab (GSK5764227)	ADC targeting B7-H3*	Relapsed or refractory ES-SCLC <sup>2</sup>	US, EU
	risvutatumab (GSK5764227)	ADC targeting B7-H3*	Relapsed or refractory osteosarcoma	US
	bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV <sup>3</sup> infection	CN
	GSK5637608	Hepatitis B virus-targeted siRNA*	Chronic HBV <sup>3</sup> infection	CN

## Fast Track

	<i>Jemperli</i> <sup>1</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>3</sup> infection
	GSK4382276	mRNA*	Seasonal flu
	tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI <sup>4</sup>

## Orphan Drug Designation

	<i>Benlysta</i> (belimumab)	Anti-BLys antibody	Systemic sclerosis associated ILD <sup>5</sup>	US
	<i>Exdensusur</i> (depemokimab)	Long-acting anti-IL5 antibody*	Hypereosinophilic syndrome	JP
	linerixibat (GSK2330672)	IBAT inhibitor	Cholestatic pruritus in PBC <sup>6</sup>	US, EU, JP
	GSK4771261	Monoclonal antibody against novel kidney target	Autosomal dominant PKD <sup>7</sup>	US, EU
	risvutatumab (GSK5764227)	ADC targeting B7-H3*	Relapsed or refractory ES-SCLC <sup>2</sup>	US, EU
	velzatinib (GSK6042981)	KIT inhibitor*	Gastrointestinal stromal tumours	US, EU
	<i>Zejula</i> <sup>1</sup> (niraparib)	PARP inhibitor*	Glioblastoma multiforme	US

## Priority Review

	<i>Blenrep</i> (belantamab mafodotin)	Anti-BCMA ADC*	Relapsed or refractory multiple myeloma	CN
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## Qualified Infectious Disease Product Designation

	tebipenem pivoxil (GSK3778712)	Antibacterial carbapenem*	Complicated UTI <sup>4</sup>
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## SENKU

	bepirovirsen (GSK3228836)	Antisense oligonucleotide*	Chronic HBV <sup>3</sup> infection
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## FDA Commissioner's National Priority Voucher

	<i>Jemperli</i> <sup>1</sup> (dostarlimab)	Anti-PD-1 antibody*	Neoadjuvant dMMR/MSI-H rectal cancer
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### ► 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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### ► 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. Tesaro asset 2. Extensive-stage small-cell lung cancer 3. Hepatitis B virus 4. Urinary tract infection 5. Interstitial lung disease 6. Primary biliary cholangitis 7. Polycystic kidney disease

# Clinical Trials

Phase II and III GSK-sponsored clinical trials

# Respiratory, Immunology and Inflammation

# Respiratory, Immunology and Inflammation

## Exdensur (depemokimab)

NCT04719832 - SWIFT-1

<b>Phase</b>	III
<b>Patient</b>	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype
<b>Subjects</b>	395
<b>Treatment arms</b>	Arm A: depemokimab + SoC Arm B: placebo + SoC
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q1 2021 Data reported: Q2 2024
<b>Key endpoints</b>	Annualised rate of clinically significant exacerbations over 52 weeks
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT04718103 - SWIFT-2

<b>Phase</b>	III
<b>Patient</b>	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype
<b>Subjects</b>	397
<b>Treatment arms</b>	Arm A: depemokimab + SoC Arm B: placebo + SoC
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q1 2021 Data reported: Q2 2024
<b>Key endpoints</b>	Annualised rate of clinically significant exacerbations over 52 weeks
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>



# Respiratory, Immunology and Inflammation

## *Exdensur* (depemokimab)

NCT05243680 - AGILE

<b>Phase</b>	III
<b>Patient</b>	Adult and adolescents with severe asthma with an eosinophilic phenotype from studies SWIFT-1 and SWIFT-2
<b>Subjects</b>	641
<b>Treatment arms</b>	Participants diagnosed with asthma receiving depemokimab
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q1 2022 Data reported: Q2 2025
<b>Key endpoints</b>	Number of participants with AEs and SAEs and incidence of immunogenicity over 52 weeks
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## Exdensur (depemokimab)

NCT05274750 - ANCHOR-1

<b>Phase</b>	III
<b>Patient</b>	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
<b>Subjects</b>	276
<b>Treatment arms</b>	Arm A: depemokimab + SoC Arm B: placebo + SoC
<b>Description</b>	A randomized, double-blind, parallel group trial to assess the efficacy and safety of 100 mg subcutaneous depemokimab in patients with CRSwNP
<b>Timeline</b>	Trial start: Q2 2022 Data reported: Q3 2024
<b>Key endpoints</b>	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
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT05281523 - ANCHOR-2

<b>Phase</b>	III
<b>Patient</b>	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
<b>Subjects</b>	264
<b>Treatment arms</b>	Arm A: depemokimab + SoC Arm B: placebo + SoC
<b>Description</b>	A randomized, double-blind, parallel group trial to assess the efficacy and safety of 100 mg subcutaneous depemokimab in patients with CRSwNP
<b>Timeline</b>	Trial start: Q2 2022 Data reported: Q3 2024
<b>Key endpoints</b>	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
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## Exdensur (depemokimab)

NCT05263934 - OCEAN

<b>Phase</b>	III
<b>Patient</b>	Adults with relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) receiving standard of care therapy
<b>Subjects</b>	163
<b>Treatment arms</b>	Arm A: depemokimab + placebo matching mepolizumab + SoC Arm B: mepolizumab + placebo matching depemokimab + SoC
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q3 2022
<b>Key endpoints</b>	Number of participants with remission up to 52 weeks
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT05334368 - DESTINY

<b>Phase</b>	III
<b>Patient</b>	Adults with uncontrolled hypereosinophilic syndrome (HES) receiving standard of care therapy
<b>Subjects</b>	123
<b>Treatment arms</b>	Arm A: depemokimab + SoC Arm B: placebo + SoC
<b>Description</b>	A randomised, double-blind, placebo-controlled trial to investigate the efficacy and safety of depemokimab in adults with HES
<b>Timeline</b>	Trial start: Q3 2022
<b>Key endpoints</b>	Frequency of HES flares up to 52 weeks
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## Exdensur (depemokimab)

NCT06959095 - ENDURA-1

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

NCT06961214 - ENDURA-2

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

# Respiratory, Immunology and Inflammation

## *Exdensur* (depemokimab)

NCT07177339 - VIGILANT

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<b>Phase</b>	III
<b>Patient</b>	Patients with COPD with Type 2 inflammation
<b>Subjects</b>	1196
<b>Treatment arms</b>	Arm A: depemokimab + SoC Arm B: placebo + SoC
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2025
<b>Key endpoints</b>	Annualized rate of moderate/severe exacerbations up to 156 weeks
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## linerixibat

NCT04950127 - GLISTEN

<b>Phase</b>	III
<b>Patient</b>	Participants with primary biliary cholangitis (PBC)
<b>Subjects</b>	238
<b>Treatment arms</b>	Arm A: linerixibat Arm B: linerixibat followed by placebo Arm C: placebo Arm D: placebo followed by linerixibat
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q3 2021 Data reported: Q4 2024
<b>Key endpoints</b>	Change from baseline in monthly itch scores over 24 weeks using Numerical Rating Scale (NRS)
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## *Nucala* (mepolizumab)

NCT04133909 - MATINEE

<b>Phase</b>	III
<b>Patient</b>	Participants with chronic obstructive pulmonary disease (COPD) experiencing frequent exacerbations and characterised by eosinophil levels
<b>Subjects</b>	806
<b>Treatment arms</b>	Arm A: placebo Arm B: mepolizumab
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2019 Primary data reported: Q3 2024
<b>Key endpoints</b>	Annualised rate of moderate or severe exacerbations
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## camlipixant

NCT05599191 - CALM-1

<b>Phase</b>	III
<b>Patient</b>	Adult participants with refractory chronic cough, including unexplained chronic cough
<b>Subjects</b>	825
<b>Treatment arms</b>	Arm A: camlipixant 25 mg twice a day Arm B: camlipixant 50 mg twice a day Placebo twice a day
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2022
<b>Key endpoints</b>	24-hour cough frequency
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT05600777 - CALM-2

<b>Phase</b>	III
<b>Patient</b>	Adult participants with refractory chronic cough, including unexplained chronic cough
<b>Subjects</b>	975
<b>Treatment arms</b>	Arm A: camlipixant 25 mg twice a day Arm B: camlipixant 50 mg twice a day Placebo twice a day
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q1 2023
<b>Key endpoints</b>	24-hour cough frequency
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>



# Respiratory, Immunology and Inflammation

## efimosfermin alfa

### NCT07221227 - ZENITH-1

<b>Phase</b>	III
<b>Patient</b>	Adults with biopsy-confirmed F2- or F3-stage metabolic dysfunction-associated steatohepatitis (MASH)
<b>Subjects</b>	1200
<b>Treatment arms</b>	Dose level 1 of efimosfermin alfa Dose level 2 of efimosfermin alfa Placebo comparator
<b>Description</b>	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)
<b>Timeline</b>	Trial start: Q4 2025
<b>Key endpoints</b>	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
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

### NCT07221188 - ZENITH-2

<b>Phase</b>	III
<b>Patient</b>	Adults with known or suspected F2- or F3-stage metabolic dysfunction-associated steatohepatitis (MASH)
<b>Subjects</b>	1250
<b>Treatment arms</b>	Dose level 1 of efimosfermin alfa Dose level 2 of efimosfermin alfa Placebo comparator
<b>Description</b>	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)
<b>Timeline</b>	Trial start: Q4 2025
<b>Key endpoints</b>	Number of participants with treatment-emergent adverse events (TEAEs) and TEAEs by severity
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## Ventolin (low carbon version of MDI)

NCT06261957

<b>Phase</b>	III
<b>Patient</b>	Participants aged 12 years and above with asthma
<b>Subjects</b>	412
<b>Treatment arms</b>	Arm A: Salbutamol HFA-134a Arm B: Salbutamol HFA-152a
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q2 2024 Data reported: Q4 2025
<b>Key endpoints</b>	AEs
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## Benlysta (belimumab)

NCT05878717 - BLISSc-ILD

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

NCT06572384 - BEconneCTD-ILD

<b>Phase</b>	III
<b>Patient</b>	Adults with Interstitial Lung Disease (ILD) associated with Connective Tissue Disease (CTD)
<b>Subjects</b>	440
<b>Treatment arms</b>	Arm A: belimumab + standard therapy Arm B: placebo + standard therapy
<b>Description</b>	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)
<b>Timeline</b>	Trial start: Q3 2024
<b>Key endpoints</b>	Absolute change from baseline in Forced Vital Capacity (FVC) millilitre (mL) at week 52
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## GSK4532990 (MASH)

NCT05583344 - HORIZON

<b>Phase</b>	IIb
<b>Patient</b>	Adults with non-alcoholic steatohepatitis (NASH) and advanced fibrosis
<b>Subjects</b>	284
<b>Treatment arms</b>	Arm 1: high dose GSK4532990 Arm 2: low dose GSK4532990 Arm 3: placebo
<b>Description</b>	A placebo-controlled trial to evaluate the efficacy and safety of GSK4532990 in adults with advanced non-alcoholic steatohepatitis (NASH)
<b>Timeline</b>	Trial start: Q1 2023
<b>Key endpoints</b>	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)
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT06104319 - SKYLINE

<b>Phase</b>	IIa
<b>Patient</b>	Adult participants with NASH or suspected NASH
<b>Subjects</b>	61
<b>Treatment arms</b>	Arm 1: GSK4532990 Dose 1 Arm 2: GSK4532990 Dose 2 Arm 3: GSK4532990 Dose 3 Arm 4: GSK4532990 Dose 4
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q1 2024
<b>Key endpoints</b>	Predicted percent change from baseline in liver biopsy-derived HSD17B13 protein expression levels and mRNA expression levels
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## GSK4532990 (ALD)

NCT06613698 - STARLIGHT

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

# Respiratory, Immunology and Inflammation

## GSK5784283 (Asthma)

NCT06748053 - NAZARE

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<b>Phase</b>	II
<b>Patient</b>	Adults aged 18 to 75 years of age with uncontrolled asthma
<b>Subjects</b>	300
<b>Treatment arms</b>	Part A: Dose finding: GSK5784283 or placebo Part B: Extended dosing: GSK5784283 or placebo
<b>Description</b>	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.
<b>Timeline</b>	Trial start: Q1 2025
<b>Key endpoints</b>	Change from baseline in the fraction of exhaled nitric oxide (FeNo)
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Respiratory, Immunology and Inflammation

## GSK3862995 (NCFB)

NCT07201051

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

# Respiratory, Immunology and Inflammation

## nivisnebart

NCT06079190 - PROGRESS-AD

<b>Phase</b>	II
<b>Patient</b>	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.
<b>Subjects</b>	367
<b>Treatment arms</b>	Arm 1: GSK4527226 Dose 1 Arm 2 GSK4527226 Dose 2 Arm 3: Placebo
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2023
<b>Key endpoints</b>	Clinical Dementia Rating - Sum of Boxes (CDR-SB) Score
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>



# Oncology

# Oncology

## Blenrep (belantamab mafodotin)

NCT04246047 - DREAMM-7

<b>Phase</b>	III
<b>Patient</b>	Participants with relapsed/refractory multiple myeloma (RRMM)
<b>Subjects</b>	494
<b>Treatment arms</b>	Arm A: belantamab mafodotin + bortezomib + dexamethasone (B-Vd) Arm B: daratumumab, bortezomib + dexamethasone (D-Vd)
<b>Description</b>	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)
<b>Timeline</b>	Trial start: Q2 2020 Primary data reported: Q4 2023
<b>Key endpoints</b>	PFS, CRR, ORR, DoR, TTR, TTP, OS, PFS2, MRD negativity rate, safety
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT04484623 - DREAMM-8

<b>Phase</b>	III
<b>Patient</b>	Participants with relapsed/refractory multiple myeloma (RRMM)
<b>Subjects</b>	302
<b>Treatment arms</b>	Arm A: belantamab mafodotin+ pomalidomide + dexamethasone (B-Pd) Arm B: Pomalidomide, bortezomib + dexamethasone (P-Vd)
<b>Description</b>	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)
<b>Timeline</b>	Trial start: Q4 2020 Primary data reported: Q1 2024
<b>Key endpoints</b>	PFS, MRD negativity rate, ORR, CRR, VGPR or better rate, DoR, TTBR, TTR, TTP, OS, PFS2, safety
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Oncology

## Blenrep (belantamab mafodotin)

NCT06679101 - DREAMM-10

<b>Phase</b>	III
<b>Patient</b>	Newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation (TI-NDMM)
<b>Subjects</b>	520
<b>Treatment arms</b>	Arm A: belantamab mafodotin + lenalidomide + dexamethasone Arm B: daratumumab + lenalidomide + dexamethasone
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2024
<b>Key endpoints</b>	PFS, MRD negativity rate
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Oncology

## Blenrep (belantamab mafodotin)

NCT07227311 - DREAMM-15

<b>Phase</b>	II
<b>Patient</b>	Participants with relapsed-refractory multiple myeloma
<b>Subjects</b>	200
<b>Treatment arms</b>	belantamab mafodotin + pomalidomide + dexamethasone (BPd) belantamab mafodotin + bortezomib + dexamethasone (BVd) belantamab mafodotin + carfilzomib + dexamethasone (BKd)
<b>Description</b>	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
<b>Timeline</b>	Trial start anticipated: H1 2026
<b>Key end points</b>	ORR
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT07224672 - ALANIS

<b>Phase</b>	II
<b>Patient</b>	Adult participants with newly diagnosed amyloid light chain amyloidosis
<b>Subjects</b>	60
<b>Treatment arms</b>	belantamab mafodotin + cyclophosphamide, bortezomib, and dexamethasone (CyBorD)
<b>Description</b>	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
<b>Timeline</b>	Trial start anticipated: H1 2026
<b>Key end points</b>	Overall complete hematologic response rate
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Oncology

## Jemperli (dostarlimab)

NCT05855200 - AZUR-2

<b>Phase</b>	III
<b>Patient</b>	Participants with untreated T4N0 or Stage III (resectable), mismatch repair deficient/high microsatellite instability (dMMR/MSI-H) colon cancer
<b>Subjects</b>	892
<b>Treatment arms</b>	Arm A: dostarlimab Arm B: Standard of care (FOLFOX/CAPEOX) or expectant observation post surgery.
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q3 2023
<b>Key endpoints</b>	EFS assessed by Blinded Independent Central Review (BICR)
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT05723562 - AZUR-1

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

# Oncology

## Jemperli (dostarlimab)

NCT06567782 - AZUR-4

<b>Phase</b>	II
<b>Patient</b>	Participants with previously untreated T4N0 or stage III MMRp/MSS colon cancer
<b>Subjects</b>	120
<b>Treatment arms</b>	Arm A: dostarlimab plus CAPEOX (chemotherapy) Arm B: CAPEOX (chemotherapy)
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q1 2025
<b>Key endpoints</b>	Major pathological response (mPR) rate, AEs, SAEs, immune-mediated AEs, and AEs leading to death or discontinuation of study intervention and by severity
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT06256588 - JADE

<b>Phase</b>	III
<b>Patient</b>	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.
<b>Subjects</b>	864
<b>Treatment arms</b>	Arm A: dostarlimab Arm B: Placebo
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q1 2024
<b>Key endpoints</b>	EFS assessed by Blinded Independent Central Review (BICR)
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Oncology

## risvutatumab rezetecan

NCT07099898 - EMBOLD-SCLC-301

Phase	III
Patient	Participants With Relapsed Small Cell Lung Cancer (SCLC)
Subjects	300
Treatment arms	Experimental arm: GSK5764227 Active Comparator arm: Topotecan
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)
Timeline	Trial start: Q3 2025
Key endpoints	ORR, OS, DoR, PFS, AEs, SAEs
Clinicaltrials.gov	<a href="#">Link</a>

# 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

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

NCT06517875 - ODYSSEY

<b>Phase</b>	II
<b>Patient</b>	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
<b>Subjects</b>	56
<b>Treatment arms</b>	mometotinib + luspatercept
<b>Description</b>	An open-label study to evaluate momelotinib in combination with luspatercept in participants with transfusion dependent primary or secondary myelofibrosis
<b>Timeline</b>	Trial start: Q1 2025
<b>Key endpoints</b>	Percentage of participants with TI response by Week 24, AEs, SAEs
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Oncology

## mocertatug rezetecan

NCT07286266 (BEHOLD-Ovarian01)

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

NCT07286331 (BEHOLD-Endometrial01)

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

# HIV

# HIV

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

NCT06741397

<b>Phase</b>	IIb
<b>Patient</b>	Healthy adolescent and adult participants
<b>Subjects</b>	229
<b>Treatment arms</b>	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
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2024
<b>Key endpoints</b>	CAB trough concentrations
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# HIV

## VH3810109

NCT05996471 - EMBRACE

<b>Phase</b>	IIb
<b>Patient</b>	Antiretroviral therapy (ART)-experienced adults living with HIV
<b>Subjects</b>	185
<b>Treatment arms</b>	Group 1: VH3810109 + cabotegravir Group 2: VH3810109 + rHuPH20 + cabotegravir Group 3: Active comparator - Participants receiving standard of care (SoC) antiretroviral therapy (ART)
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q3 2023
<b>Key endpoints</b>	Safety, plasma HIV-1 levels
<b>Clinicaltrials.gov</b>	<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>

NCT04886596 - RSV OA=ADJ-006

Phase	III
Patient	Adults ≥60 years of age
Subjects	26,675
Treatment arms	Arm A: RSVPreF3 OA Lot 1 Arm B: RSVPreF3 OA Lot 2 Arm C: RSVPreF3 OA Lot 3 Arm D: RSVPreF3 OA Lot 4 Arm E: Placebo
Description	A randomised, placebo-controlled, observer-blind, multi-country trial to demonstrate the efficacy of a single dose and revaccination prior to Season 2 of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above
Timeline	Trial start: Q2 2021 Primary data reported: Q2 2022; season two data reported: Q2 2023; season three data reported: Q4 2024
Key endpoints	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	<a href="#">Link</a>

# Infectious diseases

## Arexvy (RSV Adults)

NCT06534892 - RSV- OA=ADJ-012

<b>Phase</b>	IIIb
<b>Patient</b>	Adults aged 60 years and above
<b>Subjects</b>	10212
<b>Treatment arms</b>	<p>RSV_PreS4: Participants in this group will receive 1 dose of RSVPreF3 OA vaccine before RSV Season 4.</p> <p>RSV_PreS5: Participants in this group will receive 1 dose of RSVPreF3 OA vaccine before RSV Season 5.</p> <p>RSV_1Dose: Participants in this group will not receive any additional dose of RSV PreF3 OA vaccine.</p> <p>Crossover: Participants in this group will receive a single dose of RSVPreF3 OA vaccine.</p>
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q3 2024
<b>Key endpoints</b>	RSV-A, RSV-B neutralization titers

Clinicaltrials.gov [Link](#)



NCT05879107 - RSV OA=ADJ-019

<b>Phase</b>	III
<b>Patient</b>	Adults ≥60 years of age
<b>Subjects</b>	1113
<b>Treatment arms</b>	<p>Arm A (co-ad group): RSVPreF3 OA investigational vaccine co-administered with PCV20 vaccine</p> <p>Arm B (control group): PCV20 vaccine on Day 1 and the RSVPreF3 OA investigational vaccine on Day 31.</p>
<b>Description</b>	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
<b>Timeline</b>	<p>Trial start: Q2 2023</p> <p>Data reported: Q2 2025</p>
<b>Key endpoints</b>	Opsonophagocytic antibody titers for each of the pneumococcal vaccine serotypes and RSV-A & RSV-B serum neutralizing titers
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>



# Infectious diseases

## Arexvy (RSV Adults)

NCT05966090 - RSV OA=ADJ-020

<b>Phase</b>	III
<b>Patient</b>	Adults aged 50 years and older
<b>Subjects</b>	530
<b>Treatment arms</b>	<p>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.</p> <p>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.</p>
<b>Description</b>	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
<b>Timeline</b>	<p>Trial start: Q3 2023</p> <p>Primary data reported: Q3 2024</p>
<b>Key endpoints</b>	<p>Anti-gE antibody concentrations expressed as group geometric mean concentration ratio</p> <p>RSV-A &amp; -B serum neutralizing titers expressed as group geometric mean titer</p>
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT05921903 - RSV OA=ADJ-023

<b>Phase</b>	IIb
<b>Patient</b>	Immunocompromised (IC) adults 50 years of age and above
<b>Subjects</b>	386
<b>Treatment arms</b>	<p>Arm A: RSV_IC_1 group, IC patients receiving 1 dose of RSVPreF3 OA investigational vaccine at Visit 1 (Day 1).</p> <p>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)</p> <p>Arm C: RSV_HA group, healthy participants receiving 1 dose of RSVPreF3 OA investigational vaccine at Visit 1 (Day 1).</p>
<b>Description</b>	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
<b>Timeline</b>	<p>Trial start: Q3 2023</p> <p>Primary data reported: Q4 2024</p>
<b>Key endpoints</b>	RSV-A & -B serum neutralizing titers expressed as mean geometric increase post Dose 2 over post Dose 1
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## Arexvy (RSV Adults)

NCT06374394 - RSV OA=ADJ-013

<b>Phase</b>	III
<b>Patient</b>	Adults aged 50 years and above
<b>Subjects</b>	841
<b>Treatment arms</b>	RSVPreF3 OA investigational vaccine COVID-19 mRNA vaccine
<b>Description</b>	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)
<b>Timeline</b>	Trial start: Q2 2024 Data reported: Q3 2025
<b>Key endpoints</b>	RSV-A, RSV-B neutralization titers SARS-CoV-2 Omicron XBB.1.5 neutralization titers
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT06389487 - RSV OA=ADJ-025

<b>Phase</b>	IIIb
<b>Patient</b>	Adult participants, 18-49 YOA, at increased risk (AIR) for RSV disease and older adults (OA) participants, ≥60 YOA
<b>Subjects</b>	1459
<b>Treatment arms</b>	Part A: RSV-A-AIR Group, RSVPreF3 OA investigational vaccine Part B: RSV-OA Group, RSVPreF3 OA investigational vaccine Part C: RSV-A-AIR Group, RSVPreF3 OA investigational vaccine
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q2 2024 Primary data reported: Q3 2024
<b>Key endpoints</b>	RSV-A, RSV-B neutralizing titers Seroresponse rate (SRR) in RSV-A and RSV-B neutralizing titers
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## 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
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>

NCT06614725 - RSV OA=ADJ-024

Phase	III
Patient	Adults aged 60 years and above and adults 50-59 yoa at increased risk of RSV disease
Subjects	751
Treatment arms	Arm A: Older Adults - RSVPreF3 OA investigational vaccine Arm B: Older Adults - placebo Arm C: Adults AIR - RSVPreF3 OA investigational vaccine Arm D: Adults AIR - Placebo Group
Description	A randomized, placebo-controlled, observer-blind study in India to evaluate immune response, reactogenicity and safety of the RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of RSV disease.
Timeline	Trial start: Q4 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

<b>Phase</b>	III
<b>Patient</b>	Adults aged 18-59 YOA at increased risk (AIR) of RSV disease
<b>Subjects</b>	750
<b>Treatment arms</b>	China: participants 18-59 AIR , RSVPreF3 OA investigational vaccine China: participants 18-59 AIR, Placebo
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2025
<b>Key endpoints</b>	RSV-A, RSV-B neutralization titers Seroresponse rate (SRR) in RSV-A and RSV-B neutralizing titers
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## 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 endpoints	Number of participants with therapeutic response (combined per participant clinical and microbiological response)
Clinicaltrials.gov	<a href="#">Link</a>

NCT04187144 - EAGLE 3

Phase	III
Patient	Females with uUTI / acute cystitis
Subjects	1606
Treatment arms	Arm A: 1500 mg BID gepotidacin + placebo x 5 days Arm B: 100 mg BID nitrofurantoin + placebo x 5 days
Description	A randomised, multicentre, parallel-group, double-blind, double-dummy trial in adolescent and adult female participants comparing the efficacy and safety of gepotidacin to nitrofurantoin in the treatment of uncomplicated urinary tract infection (acute cystitis)
Timeline	Trial start: Q2 2020 Data reported: Q2 2023
Key endpoints	Number of participants with therapeutic response (combined per participant clinical and microbiological response)
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## Blujepa (gepotidacin)

NCT04010539 - EAGLE 1

Phase	III
Patient	Uncomplicated urogenital gonorrhoea caused by <i>Neisseria gonorrhoeae</i>
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 <i>Neisseria gonorrhoeae</i>
Timeline	Trial start: Q4 2019 Data reported: Q1 2024
Key endpoints	Number of participants with culture-confirmed bacterial eradication 4-8 days post treatment
Clinicaltrials.gov	<a href="#">Link</a>

# Infectious diseases

## bepirovirsen

NCT05630807 - B-WELL 1

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

NCT05630820 - B-WELL 2

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

# Infectious diseases

## bepirovirsen

NCT06497504 - B-FOCUS

<b>Phase</b>	II
<b>Patient</b>	Participants living with human immunodeficiency virus and chronic hepatitis B virus infection on antiretroviral treatment
<b>Subjects</b>	150
<b>Treatment arms</b>	Arm A: bepirovirsen Arm B: placebo
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q3 2024
<b>Key endpoints</b>	Percentage of participants achieving hepatitis B virus (HBV) virologic response at 36 weeks after scheduled end of study treatment in absence of rescue medication
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>



# Infectious diseases

## GSK4178116 (Varicella new seed)

NCT06693895

<b>Phase</b>	III
<b>Patient</b>	Healthy children aged 12 to 15 months
<b>Subjects</b>	750
<b>Treatment arms</b>	<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>
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2024
<b>Key endpoints</b>	AEs, SAEs
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT06740630

<b>Phase</b>	III
<b>Patient</b>	Healthy children 12 to 15 months of age
<b>Subjects</b>	1840
<b>Treatment arms</b>	<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>
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q1 2025
<b>Key endpoints</b>	Anti-glycoprotein-E antibodies at day 43
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## GSK4178116 (Varicella new seed)

NCT06806137

<b>Phase</b>	III
<b>Patient</b>	Healthy children aged 12 to 15 months
<b>Subjects</b>	600
<b>Treatment arms</b>	<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>
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q2 2025
<b>Key endpoints</b>	% 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

<b>Phase</b>	III
<b>Patient</b>	Healthy children 12 to 15 months of age
<b>Subjects</b>	900
<b>Treatment arms</b>	<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>
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q2 2025
<b>Key endpoints</b>	Percentage of participants with seroresponse to Varicella Zoster Virus (VZV) anti-glycoprotein E (gE) Immunoglobulin (IgG), AEs, SAEs
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## ganfeborole

NCT05382312

<b>Phase</b>	IIa
<b>Patient</b>	Males and females aged 18 to 65 years inclusive with drug-sensitive (rifampicin-susceptible) pulmonary tuberculosis
<b>Subjects</b>	127
<b>Treatment arms</b>	<p>Arm 1: GSK3036656 + delamanid</p> <p>Arm 2: GSK3036656 + bedaquiline</p> <p>Arm 3: GSK3036656 + BTZ-043</p> <p>Arm 4: GSK3036656 + pretomanid</p> <p>Arm 5: GSK3036656 + moxifloxacin</p> <p>Arm 6: GSK3036656 + linezolid</p> <p>Arm 7: Delamanid + bedaquiline</p> <p>Arm 8: Standard of Care (Rifafour e-275)</p>
<b>Description</b>	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.
<b>Timeline</b>	Trial start: Q3 2022
<b>Key endpoints</b>	Change from baseline in log <sub>10</sub> CFU of <i>Mycobacterium tuberculosis</i>
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

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

NCT06213506

<b>Phase</b>	IIa
<b>Patient</b>	Adults, children and infants, including dose-finding in infants in Africa (Ghana)
<b>Subjects</b>	20 adults/40 children/60 infants 9 months/ 396 infants 6 weeks
<b>Treatment arms</b>	<p>Stage 1: Age-de-escalation</p> <ul style="list-style-type: none"> <li>Adults (dose C or control)</li> <li>Children (dose B or C or control)</li> <li>Infants, 9 months (dose A, B, C or control)</li> <li>Infants, 6 months (dose A, B, C, or control)</li> </ul> <p>Stage 2: Dose finding in infants 6 weeks of age</p>
<b>Description</b>	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)
<b>Timeline</b>	Trial start: Q1 2024
<b>Key endpoints</b>	To evaluate the safety, reactogenicity and immunogenicity profile of iNTS-GMMA vaccine in adults, children and infants (Ghana)
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## GSK4382276 (mRNA Seasonal Flu)

NCT06431607

<b>Phase</b>	IIa
<b>Patient</b>	Adults 18 years of age and older
<b>Subjects</b>	840
<b>Treatment arms</b>	<p>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</p>
<b>Description</b>	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
<b>Timeline</b>	<p>Trial start: Q2 2024            Primary completion: Q4 2024</p>
<b>Key endpoints</b>	Antigen I antibody titres
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## GSK4382276 (mRNA Seasonal Flu)

NCT07121192 - FLU SV MRNA-027

<b>Phase</b>	II
<b>Patient</b>	Adults 18 Years of Age And Older
<b>Subjects</b>	776
<b>Treatment arms</b>	<p>Biological: Flu mRNA (Formulation A) Young adults</p> <p>Biological: Flu mRNA (Formulation B) Young adults</p> <p>Combination Product: Comparator 1 Young adults</p> <p>Combination Product: Comparator 2 Young adults</p> <p>Biological: Flu mRNA (Formulation A) Older adults</p> <p>Biological: Flu mRNA (Formulation B) Older adults</p> <p>Combination Product: Comparator 1 Older adults</p> <p>Combination Product: Comparator 2 Older adults</p> <p>Combination Product: Comparator 3 Older adults</p>
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q3 2025
<b>Key endpoints</b>	<p>Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events</p> <p>Serum anti-influenza antigen seroconversion rates and geometric mean titers</p>
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

NCT07204964 - FLU SV MRNA-028

<b>Phase</b>	II
<b>Patient</b>	Adults 18 Years of Age And Older
<b>Subjects</b>	960
<b>Treatment arms</b>	<p>Biological: Flu mRNA (Formulation B1) Young adults</p> <p>Biological: Flu mRNA (Formulation B3) Young adults</p> <p>Biological: Flu mRNA (Formulation A) Young adults</p> <p>Combination Product: Comparator 1 Young adults</p> <p>Combination Product: Comparator 2 Young adults</p> <p>Biological: Flu mRNA (Formulation B1) Older adults</p> <p>Biological: Flu mRNA (Formulation B3) Older adults</p> <p>Biological: Flu mRNA (Formulation A) Older adults</p> <p>Combination Product: Comparator 1 Older adults</p> <p>Combination Product: Comparator 3 Older adults</p>
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q3 2025
<b>Key endpoints</b>	Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## GSK4406371 (MMRV new seed vaccine)

NCT05630846

<b>Phase</b>	II
<b>Patient</b>	Healthy children 4-6 years of age
<b>Subjects</b>	801
<b>Treatment arms</b>	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
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2022 Primary completion: Q4 2024
<b>Key endpoints</b>	Anti-measles, anti-mumps, anti-rubella, and anti-glycoprotein H antibodies geometric mean concentrations
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>

# Infectious diseases

## GSK5101955 (Paediatric Pneumococcal disease)

NCT05412030

<b>Phase</b>	II
<b>Patient</b>	Healthy infants
<b>Subjects</b>	388
<b>Treatment arms</b>	<p>Arm A: 1 mcg AFX3772 administered intramuscularly 4 times within 12 months</p> <p>Arm B: 2 mcg AFX3772 administered intramuscularly 4 times within 12 months</p> <p>Arm C: 5 mcg AFX3772 administered intramuscularly 4 times within 12 months</p> <p>Arm D: PCV13 and PCV20 administered intramuscularly 4 times within 12 months</p>
<b>Description</b>	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
<b>Timeline</b>	<p>Trial start: Q2 2022</p> <p>Primary completion: Q3 2025</p>
<b>Key endpoints</b>	Safety, tolerability profiles of 3 different dose levels of AFX3772 compared with PCV13 and PCV20 with respect to the proportion of participants with AEs
<b>Clinicaltrials.gov</b>	<a href="#">Link</a>



# Infectious diseases

## GSK5637608 (Chronic HBV infection)

NCT06537414 - B-UNITED

<b>Phase</b>	IIb
<b>Patient</b>	Participants with chronic hepatitis B virus on background nucleos(t)ide analogue therapy
<b>Subjects</b>	283
<b>Treatment arms</b>	Arms 1A & 2A: daplusiran/tomligisiran dose level 1 + bepirovirsen Arms 1B & 2B: daplusiran/tomligisiran dose level 2 + bepirovirsen Arm 2C: placebo + bepirovirsen
<b>Description</b>	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
<b>Timeline</b>	Trial start: Q4 2024
<b>Key end points</b>	Number of participants achieving functional cure
<b>Clinicaltrials.gov</b>	<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 gonorrhoea

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