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Pipeline assets and clinical trials appendix

Q2 2023

Contents

Innovation: Pipeline growth

Overview of potential new vaccines and medicines

68 potential new vaccines and medicines in pipeline

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

Phase I – 32 assets

2904545	Recombinant protein, adjuvanted*	*C. difficile*
4429016	Bioconjugated recombinant protein, adjuvanted*	*K. pneumoniae*
3993129	Adjuvanted recombinant subunit	Cytomegalovirus[1]
4382276	mRNA*	Seasonal flu
4396687	mRNA*	COVID-19
4077164	Bivalent GMMA*	Invasive non-typhoidal salmonella**
3943104	Recombinant protein, adjuvanted*	Therapeutic herpes simplex virus[1]
3536867	Bivalent conjugate*	Salmonella (*typhoid + paratyphoid A*)
2556286	Mtb cholesterol dependent inhibitor*	Tuberculosis
3186899	CRK-12 inhibitor*[2]	Visceral leishmaniasis
3494245	Proteasome inhibitor*	Visceral leishmaniasis
3772701	*P. falciparum* whole cell inhibitor*	Malaria
3882347	FimH antagonist*	Uncomplicated UTI
3923868	PI4K beta inhibitor	Viral COPD exacerbations
4182137 (VIR-7832)	Anti-spike protein antibody*	COVID-19[1]
3965193	PAPD5/PAPD7 inhibitor	Hepatitis B virus[1]
5251738	TLR8 agonist*	Hepatitis B virus
cabotegravir (1265744)	Integrase inhibitor (400 mg/ml formulation)	HIV
3739937	Maturation inhibitor	HIV
4004280	Capsid protein inhibitor	HIV
4011499	Capsid protein inhibitor	HIV
4524184	Integrase inhibitor*	HIV
3888130	Anti-IL7 antibody*	Multiple sclerosis
1070806	Anti-IL18 antibody	Atopic dermatitis
4527226 (AL-101)	Anti-sortilin antibody*	Alzheimer's disease
4074386	Anti-LAG-3 antibody*	Cancer
4381562	Anti-PVRIG antibody*	Cancer
3745417	STING agonist	Cancer
6097608	Anti-CD96 antibody*	Cancer
XMT-2056[3] (wholly owned by Mersana Theraprutics)	STING agonist ADC*	Cancer
belantamab (2857914)	Anti-BCMA antibody	Multiple myeloma
4172239	DNMT1 inhibitor*	Sickle cell disease[4]

*In-license or other alliance relationship with third party ** Additional indications or candidates also under investigation ^ In registration
1. In phase I/II study 2. Transition activities underway to enable further progression by partner 3. GSK has an exclusive global license option to co-develop and commercialise the candidate 4. Imminent study start 5. GSK has exclusive option to co-develop post phase II 6. Phase II/III study start expected in 2023 7. Phase II study start expected in 2023 8. Approved in US and EU 9. Phase III study start expected in 2023 10. Phase III trial in patients with progranulin gene mutation

68 potential new vaccines and medicines in pipeline

Infectious diseases
HIV (ViiV)
Respiratory/Immunology
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Phase II – 19 assets

3437949	Recombinant protein, adjuvanted*	Malaria fractional dose
4406371	Live, attenuated	MMRV new strain
3536852	GMMA*	Shigella
3528869	Viral vector with recombinant protein, adjuvanted*	Therapeutic hepatitis B virus[1]**
4023393	Recombinant protein, OMV, conjugated vaccine	MenABCWY, 2nd Gen[1]
4178116	Live, attenuated	Varicella new strain
5101956	MAPS*	Adult pneumococcal disease, 24-valent
5101955	MAPS*	Paediatric pneumococcal disease, 24-valent
4106647	Recombinant protein, adjuvanted*	Human papillomavirus[1]
4348413	GMMA	Gonorrhea[1]
3036656	Leucyl t-RNA synthetase inhibitor*	Tuberculosis
sanfetrinem cilexetil (GV118819)	Serine beta lactamase inhibitor*	Tuberculosis
BVL-GSK098	Ethionamide booster*	Tuberculosis
VIR-2482	Neutralizing monoclonal antibody*[5]	Influenza
3810109	Broadly neutralizing antibody*	HIV
Benlysta (belimumab)	Anti-BLys antibody	Systemic sclerosis associated interstitial lung disease[6]
3858279	Anti-CCL17 antibody*	Osteoarthritis pain**[7]
belrestotug (4428859)	Anti-TIGIT antibody*	Non-small cell lung cancer
4532990	HSD17B13 siRNA*	Non-alcoholic steatohepatitis

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68 potential new vaccines and medicines in pipeline

Infectious diseases
HIV (ViiV)
Respiratory/Immunology
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Phase III / Registration – 17 assets

Arexvy (RSV vaccine)	Recombinant protein, adjuvanted*	RSV older adults^[8]
gepotidacin (2140944)	BTI inhibitor*	Uncomplicated UTI**
bepirovirsen (3228836)	Antisense oligonucleotide*	Hepatitis B virus**
Bexsero (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
MenABCWY vaccine (3536819)	Recombinant protein, OMV, conjugated vaccine	MenABCWY, 1st Gen
tebipenem pivoxil (3778712)	Antibacterial carbapenem*	Complicated UTI[9]
ibrexafungerp (5458448)	Antifungal glucan synthase inhibitor*	Invasive candidiasis
Nucala (mepolizumab)	Anti-IL5 antibody	COPD
depemokimab (3511294)	Long-acting anti-IL5 antibody*	Asthma**
latozinemab (4527223)	Anti-sortilin antibody*	Frontotemporal dementia[10]**
camlipixant (5464714)	P2X2/P2X3 receptor antagonist*	Refractory chronic cough
momelotinib (3070785)	JAK1, JAK2 and ACVR1 inhibitor*	Myelofibrosis^
Jemperli (dostarlimab)	Anti-PD-1 antibody*	Endometrial cancer^**
Zejula (niraparib)	PARP inhibitor*	Ovarian cancer**
Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma
cobolimab (4069889)	Anti-TIM-3 antibody*	Non-small cell lung cancer
linerixibat (2330672)	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis

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Infectious diseases
HIV (ViiV)
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Infectious diseases pipeline

Phase I – 17 assets

2904545	Recombinant protein, adjuvanted*	*C. difficile*
4429016	Bioconjugated recombinant protein, adjuvanted*	*K. pneumoniae*
3993129	Adjuvanted recombinant subunit	Cytomegalovirus[1]
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4182137 (VIR-7832)	Anti-spike protein antibody*	COVID-19[1]
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5251738	TLR8 agonist*	Hepatitis B virus

Phase II – 14 assets

3437949	Recombinant protein, adjuvanted*	Malaria fractional dose
4406371	Live, attenuated	MMRV new strain
3536852	GMMA*	Shigella
3528869	Viral vector with recombinant protein, adjuvanted*	Therapeutic hepatitis B virus[1]**
4023393	Recombinant protein, OMV, conjugated vaccine	MenABCWY, 2nd Gen[1]
4178116	Live, attenuated	Varicella new strain
5101956	MAPS*	Adult pneumococcal disease, 24-valent
5101955	MAPS*	Paediatric pneumococcal disease, 24-valent
4106647	Recombinant protein, adjuvanted*	Human papillomavirus[1]
4348413	GMMA	Gonorrhea[1]
3036656	Leucyl t-RNA synthetase inhibitor*	Tuberculosis
sanfetrinem cilexetil (GV118819)	Serine beta lactamase inhibitor*	Tuberculosis
BVL-GSK098	Ethionamide booster*	Tuberculosis
VIR-2482	Neutralizing monoclonal antibody*[5]	Influenza

Phase III & Registration – 7 assets

Arexvy (RSV vaccine)	Recombinant protein, adjuvanted*	RSV older adults^[8]
gepotidacin (2140944)	BTI inhibitor*	Uncomplicated UTI**
bepirovirsen (3228836)	Antisense oligonucleotide*	Hepatitis B virus**
Bexsero (MenB vaccine)	Recombinant protein, OMV	Meningitis B (infants US)
MenABCWY vaccine (3536819)	Recombinant protein, OMV, conjugated vaccine	MenABCWY, 1st Gen
tebipenem pivoxil (3778712)	Antibacterial carbapenem*	Complicated UTI[9]
ibrexafungerp (5458448)	Antifungal glucan synthase inhibitor*	Invasive candidiasis

GSK

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1. In phase I/II study 2. Transition activities underway to enable further progression by partner 5. GSK has exclusive option to co-develop post phase II 8. Approved in US and EU 9. Phase III study start expected in 2023

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

HIV pipeline

Phase I – 5 assets

cabotegravir (1265744)	Integrase inhibitor (400 mg/ml formulation)	HIV
3739937	Maturation inhibitor	HIV
4004280	Capsid protein inhibitor	HIV
4011499	Capsid protein inhibitor	HIV
4524184	Integrase inhibitor*	HIV

Phase II – 1 asset

3810109	Broadly neutralizing antibody*	HIV

*In-license or other alliance relationship with third party

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

Respiratory/Immunology pipeline

Phase I – 3 assets

3888130	Anti-IL7 antibody*	Multiple sclerosis
1070806	Anti-IL18 antibody	Atopic dermatitis
4527226 (AL-101)	Anti-sortilin antibody*	Alzheimer's disease

Phase II – 2 asset

Benlysta (belimumab)	Anti-BLys antibody	Systemic sclerosis associated interstitial lung disease[6]
3858279	Anti-CCL17 antibody*	Osteoarthritis pain**[7]

Phase III & Registration – 4 assets

Nucala (mepolizumab)	Anti-IL5 antibody	COPD
depemokimab (3511294)	Long-acting anti-IL5 antibody*	Asthma**
latozinemab (4527223)	Anti-sortilin antibody*	Frontotemporal dementia[10]**
camlipixant (5464714)	P2X2/P2X3 receptor antagonist*	Refractory chronic cough

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6. Phase II/III study start expected in 2023 7. Phase II study start expected in 2023 10. Phase III trial in patients with progranulin gene mutation

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

Oncology pipeline

Phase I – 6 assets

4074386	Anti-LAG-3 antibody*	Cancer
4381562	Anti-PVRIG antibody*	Cancer
3745417	STING agonist	Cancer
6097608	Anti-CD96 antibody*	Cancer
XMT-2056[3] (wholly owned by Mersana Theraprutics)	STING agonist ADC*	Cancer
belantamab (2857914)	Anti-BCMA antibody	Multiple myeloma

Phase II – 1 asset

belrestotug (4428859)	Anti-TIGIT antibody*	Non-small cell lung cancer

Phase III & Registration – 5 assets

momelotinib (3070785)	JAK1, JAK2 and ACVR1 inhibitor*	Myelofibrosis^
Jemperli (dostarlimab)	Anti-PD-1 antibody*	Endometrial cancer^**
Zejula (niraparib)	PARP inhibitor*	Ovarian cancer**
Blenrep (belantamab mafodotin)	Anti-BCMA ADC*	Multiple myeloma
cobolimab (4069889)	Anti-TIM-3 antibody*	Non-small cell lung cancer

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3. GSK has an exclusive global license option to co-develop and commercialise the candidate

Opportunity driven pipeline

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

Phase I – 1 asset

4172239	DNMT1 inhibitor*	Sickle cell disease[4]

Phase II – 1 asset

4532990	HSD17B13 siRNA*	Non-alcoholic steatohepatitis

Phase III & Registration – 1 asset

linerixibat (2330672)	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis

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4. Imminent study start

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

Changes since Q1 2023

Changes on pipeline

New to Phase II

- 4348413 – GMMA, gonorrhea
- 3858279 – Anti-CCL17 antibody, osteoarthritis pain**

New to Phase III

- ibrexafungerp – Antifungal glucan synthase inhibitor, invasive candidiasis
- camlipixant – P2X2/P2X3 receptor antagonist, refractory chronic cough

Removed from Registration

- *SKYCovione* – Recombinant protein nanoparticle, adjuvanted, COVID-19
- daprodustat – Prolyl hydroxylase inhibitor, anaemia of chronic kidney disease

Achieved pipeline catalysts

Regulatory submissions & acceptances

Jemperli[1] – RUBY, dMMR/MSI-H 1L endometrial cancer	US
Menveo – liquid formulation, Men ACWY	EU

Regulatory decisions

Arexvy – Adjuvanted recombinant protein, RSV older adults	US, EU
Shingrix – 18+ at increased risk of HZ	JP

Other events

- MenABCWY – Phase III data presentation at ESPID
- 4348413 – GMMA, gonorrhea – FDA Fast Track Designation
- cabotegravir (long-acting) pre-exposure – Positive CHMP opinion
- 3858279 – Anti-CCL17 antibody, osteoarthritis pain – FDA Fast Track Designation
- 3858279 – Anti-CCL17 antibody, diabetic peripheral neuropathic pain – FDA Fast Track Designation
- *Jemperli*[1] – RUBY, dMMR/MSI-H 1L endometrial cancer – FDA Priority Review
- *Jemperli*[1] – RUBY, dMMR/MSI-H 1L endometrial cancer – FDA Breakthrough Designation
- daprodustat – Positive CHMP opinion

** Additional indications or candidates also under investigation
1. Tesaro asset

Upcoming pipeline catalysts: 2023 and 2024

- Infectious diseases
- HIV (ViiV)
- Respiratory/Immunology
- Oncology
- Opportunity driven

	H2 2023	H1 2024	H2 2024
Regulatory decision	*Jemperli*[1] – RUBY, dMMR/MSI-H 1L endometrial cancer – US momelotinib – MOMENTUM, myelofibrosis – US cabotegravir (long-acting) pre-exposure – EU *Vocabria* – HIV treatment – CN RSV older adults vaccine candidate – ≥60 YoA – JP	*Jemperli*[1] – RUBY, dMMR/MSI-H 1L endometrial cancer – EU momelotinib – MOMENTUM, myelofibrosis – EU, JP	*Nucala* – severe asthma – CN *Nucala* – CRSwNP – JP gepotidacin – EAGLE-2/3, uUTI – US, EU *Arexvy* – 50-59 YoA – US, EU, JP
Regulatory submission & acceptance	*Nucala* – CRSwNP – CN, JP momelotinib – MOMENTUM, myelofibrosis – JP gepotidacin – EAGLE-2/3, uUTI – US, EU *Arexvy* – 50-59 YoA – US, EU, JP	*Blenrep* – DREAMM-7, 2L+ multiple myeloma – US, EU *Blenrep* – DREAMM-8, 2L+ multiple myeloma – US, EU *Jemperli*[1] – RUBY part 2, 1L endometrial cancer – US, EU MenABCWY vaccine 1st Gen – US, EU	*Nucala* – MATINEE, COPD – US gepotidacin – EAGLE-1, GC – US
Late stage readouts – *Phase III*	*Blenrep* – DREAMM-7, 2L+ multiple myeloma *Blenrep* – DREAMM-8, 2L+ multiple myeloma *Arexvy* – 50-59 YoA	*Jemperli*[1] – RUBY part 2, 1L endometrial cancer *Zejula*[1] – FIRST, 1L maintenance ovarian cancer gepotidacin – EAGLE-1, GC	linerixibat – GLISTEN, cholestatic pruritus in PBC depemokimab – SWIFT-1/2, asthma depemokimab – ANCHOR-1/2, CRSwNP *Nucala* – MATINEE, COPD cobolimab[1] – COSTAR, 2L NSCLC *Zejula*[1] – ZEAL, 1L maintenance NSCLC
Late stage readouts – *Phase II*	bepirovirsen – B-TOGETHER, HBV	MenABCWY vaccine 2nd Gen	

1. Tesaro asset

Designations in our pipeline

Infectious diseases
HIV (ViiV)
Respiratory/Immunology
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Breakthrough Designation

2

5101956	MAPS*	Adult pneumococcal disease, 24-valent
Jemperli (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H 1L endometrial cancer^

Fast Track

10

4382276	mRNA*	Seasonal flu
BVL-GSK098	Ethionamide booster*	Tuberculosis
4348413	GMMA	Gonorrhea
gepotidacin (2140944)	BTI inhibitor*	Urogenital gonorrhoea
tebipenem pivoxil (3778712)	Antibacterial carbapenem*	Complicated UTI
3858279	Anti-CCL17 antibody*	Osteoarthritis pain
3858279	Anti-CCL17 antibody*	Diabetic peripheral neuropathic pain
latozinemab (4527223)	Anti-sortilin antibody*	Frontotemporal dementia[10]
Jemperli (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H 1L rectal cancer
4172239	DNMT1 inhibitor*	Sickle cell disease

Priority Review

1

Jemperli (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H 1L endometrial cancer^

Orphan Drug Designation

6

ibrexafungerp (5458448) US	Antifungal glucan synthase inhibitor*	Invasive candidiasis
Benlysta (belimumab) US	Anti-BLys antibody	Systemic sclerosis associated interstitial lung disease
latozinemab (4527223) US, EU	Anti-sortilin antibody*	Frontotemporal dementia[10]
depemokimab (3511294) JP	Long-acting anti-IL5 antibody*	Hypereosinophilic syndrome
momelotinib (3070785) US, EU	JAK1, JAK2 and ACVR1 inhibitor*	Myelofibrosis^
linerixibat (2330672) US, EU	IBAT inhibitor	Cholestatic pruritus in primary biliary cholangitis

Project Orbis

1

Jemperli (dostarlimab)	Anti-PD-1 antibody*	dMMR/MSI-H 1L endometrial cancer^

Qualified Infectious Disease Product Designation

2

gepotidacin (2140944)	BTI inhibitor*	Uncomplicated UTI and urogenital gonorrhoea
tebipenem pivoxil (3778712)	Antibacterial carbapenem*	Complicated UTI

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

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

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

OPHAN DRUG DESIGNATION – intended for treatment, diagnosis or prevention of rare disease/disorders that affect fewer than 200,000 patients in the US, or not more than 5 in 10,000 in the EU or that affect more than this number of patients but are not expected to recover the costs of developing and marketing a treatment drug, or if intended for use in less than 50,000 patients in Japan and for which there is a high medical need

PROJECT ORBIS – a framework for concurrent submission and review of oncology products among international partners, coordinated by the US FDA and involving the regulatory authorities of UK (MHRA), Australia (TGA), Canada (Health Canada), Singapore (HAS), Switzerland (Swissmedic), and BRAZIL (ANVISA). It aims to deliver faster patient access to innovative cancer treatments with potential benefits over existing therapies.

QUALIFIED INFECTIOUS DISEASE PRODUCT DESIGNATION (US) – an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections

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10. Phase III trial in patients with progranulin gene mutation

Clinical Trials

Infectious diseases

Infectious diseases

Arexvy (RSV Older Adults)

NCT04732871 - RSV OA=ADJ-004

Phase	III
Patient	Adults ≥60 years of age
Subjects	1653
Treatment arms	Arm A: RSVPreF3 OA Day 1, 12 months & 24 months Arm B: RSVPreF3 OA Day 1 and 24 months Arm C: RSVPreF3 OA Day 1 then follow up
Description	A randomised, open-label, multi-country trial to evaluate the immunogenicity, safety, reactogenicity and persistence of a single dose of the RSVPreF3 OA investigational vaccine and different revaccination schedules in adults aged 60 years and above
Timeline	Trial start: Q1 2021 Primary data reported: Q2 2022
Key end points	Humoral immune response following a 1 dose primary schedule up to 12 months post dose 1
Clinicaltrials .gov	Link

NCT04886596 - RSV OA=ADJ-006

Phase	III
Patient	Adults ≥60 years of age
Subjects	24,966
Treatment arms	Arm A: RSVPreF3 OA Lot 1 Arm B: RSVPreF3 OA Lot 2 Arm C: RSVPreF3 OA Lot 3 Arm D: RSVPreF3 OA Lot 4 Arm E: Placebo
Description	A randomised, placebo-controlled, observer-blind, multi-country trial to demonstrate the efficacy of a single dose and annual revaccination doses of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above
Timeline	Trial start: Q2 2021 Primary data reported: Q2 2022; season two data reported Q2 2023
Key end points	Efficacy of a single dose and annual revaccination doses of RSVPreF3 OA vaccine in the prevention of RSV-LRTD in adults ≥ 60 yoa
Clinicaltrials .gov	Link

Infectious diseases

Arexvy (RSV Older Adults)

NCT04841577 - RSV OA=ADJ-007

Phase	III
Patient	Adults ≥60 years of age
Subjects	885
Treatment arms	Arm A: 1 dose of RSVPreF3 OA + 1 dose of FLU-QIV on Day 1 Arm B: 1 dose of FLU-QIV on Day 1, 1 dose of RSVPreF3 OA on Day 31
Description	An open-label, randomised, controlled, multi-country trial to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU-QIV vaccine in adults aged 60 years and above
Timeline	Trial start: Q2 2021 Primary data reported: Q4 2022
Key end points	Humoral immune response 1 month post vaccination upon co-administration compared to the immune response when vaccine is administered alone
Clinicaltrials .gov	Link

NCT05559476 - RSV OA=ADJ-008

Phase	III
Patient	Adults aged 65 years and above
Subjects	1028
Treatment arms	Arm A: 1 dose of RSVPreF3 OA + 1 dose of Flu-HD on day 1 Arm B: 1 dose of Flu HD on Day 1 ,1 dose of RSVPreF3 OA on Day 31
Description	An open-label, randomised, controlled, multi-country trial to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU HD vaccine in adults aged 65 years and above
Timeline	Trial start: Q4 2022 Primary data reported: Q2 2023
Key end points	Humoral immune response 1 month post vaccination upon co-administration compared to the immune response when vaccine is administered alone
Clinicaltrials .gov	Link

Infectious diseases

Arexvy (RSV Older Adults)

NCT05059301 - RSV OA=ADJ-009

Phase	III
Patient	Adults aged 60 years and above
Subjects	770
Treatment arms	Arm A: 1 dose of a combination of the RSVPreF3 antigen Lot 1 and AS01E adjuvant Lot A at day 1 Arm B: 1 dose of a combination of the RSVPreF3 antigen Lot 2 and AS01E adjuvant Lot B at day 1 Arm C: 1 dose of a combination of the RSVPreF3 antigen Lot 3 and AS01E adjuvant Lot C at Day 1
Description	A randomised, double-blind, multi-country trial to evaluate consistency, safety and reactogenicity of 3 lots of RSVPreF3 OA investigational vaccine administrated as a single dose in adults aged 60 years and above
Timeline	Trial start: Q4 2021 Trial end: Q2 2022
Key end points	RSVPreF3 Specific Immunoglobin (Ig)G antibody concentrations at 1 month post vaccination for three lots of RSVPreF3 OA investigational vaccine
Clinicaltrials .gov	Link

NCT05568797 - RSV OA=ADJ-017

Phase	III
Patient	Adults aged 65 years and above
Subjects	880
Treatment arms	Arm A: 1 dose RSVPreF3 OA investigational vaccine and 1 dose of FLU aQIV vaccine on Day 1 Arm B: one dose of Flu aQIV on day 1 and 1 dose of RSVPreF3 OA on day 31
Description	An open-label, randomised, controlled, multi-country trial to evaluate the immune response, safety and reactogenicity of an RSVPreF3 OA investigational vaccine when co-administered with FLU aQIV (inactivated influenza vaccine – adjuvanted) in adults aged 65 years and above
Timeline	Trial start: Q4 2022 Primary data reported: Q2 2023
Key end points	Humoral immune response 1 month post vaccination upon co-administration compared to the immune response when vaccine is administered alone
Clinicaltrials .gov	Link

Infectious diseases

Arexvy (RSV Older Adults)

NCT05590403 - RSV OA-018

Phase	III
Patient	Adults 50-59 years of age, including adults at increased risk of respiratory syncytial virus lower respiratory tract disease, and older adults ≥60 years of age
Subjects	1520
Treatment arms	Arm A: adults HA-RSVPreF3 OA Group Arm B: adults HA-Placebo Group Arm C: adults AIR-RSVPReF3 OA Group Arm D: adults AIR-Placebo Group Arm E: OA-RSVPReF3 OA Group ≥60 years of age
Description	An observer-blind, randomised, placebo-controlled trial to evaluate the non-inferiority of the immune response and safety of the RSVPreF3 OA investigational vaccine in adults 50 59 years of age, including adults at increased risk of respiratory syncytial virus lower respiratory tract disease, compared to older adults ≥60 years of age
Timeline	Trial start: Q4 2022 Data anticipated: H2 2023
Key end points	Humoral immune response in healthy participants 50-59 years of age and in participants 50-59 years of age at increased risk of RSV-LRTD compared to OA (≥ 60 yoa)
Clinicaltrials.gov	Link

NCT05879107 - RSV OA=ADJ-019

Phase	III
Patient	Adults ≥60 years of age
Subjects	1090
Treatment arms	Arm A (co-ad group): RSVPreF3 OA investigational vaccine co-administered with PCV20 vaccine Arm B (control group): PCV20 vaccine on Day 1 and the RSVPreF3 OA investigational vaccine on Day 31.
Description	An open-label, randomised, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with PCV20 in adults aged 60 years and older
Timeline	Trial start: Q2 2023
Key end points	Opsonophagocytic antibody titers for each of the pneumococcal vaccine serotype, RSV-A & RSV B neutralizing Ab titers
Clinicaltrials.gov	Link

Infectious diseases

Arexvy (RSV Older Adults)

NCT05921903 - RSV OA=ADJ-023

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

Infectious diseases

gepotidacin

NCT04010539 - EAGLE 1

Phase	III
Patient	Uncomplicated urogenital gonorrhea infection caused by *Neisseria gonorrhoeae*
Subjects	1531
Treatment arms	Arm A: 2 x 3000 mg gepotidacin for one day Arm B: ceftriaxone (500mg IM), 1 g azithromycin
Description	A randomised, multicentre, open-label trial in adolescent and adult participants comparing the efficacy and safety of gepotidacin to ceftriaxone plus azithromycin in the treatment of uncomplicated urogenital gonorrhoea caused by *Neisseria gonorrhoeae*
Timeline	Trial start: Q4 2019 Data anticipated: H1 2024
Key end points	Number of participants with culture-confirmed bacterial eradication 4-8 days post treatment
Clinicaltrials .gov	Link

NCT04020341 - EAGLE 2

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

Infectious diseases

gepotidacin

NCT04187144 - EAGLE 3

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

Infectious diseases

bepirovirsen

NCT05630807 - B-WELL 1

Phase	III
Patient	Non-cirrhotic nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	534
Treatment arms	Arm A: bepirovirsen for 24 weeks Arm B: placebo
Description	Phase III multicentre, randomised, double blind trial to confirm the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus
Timeline	Trial start: Q1 2023 Data anticipated: 2025+
Key end points	Number of participants achieving functional cure (FC) with baseline HBsAg≤ 3000IU/mL
Clinicaltrials .gov	Link

NCT05630820 - B-WELL 2

Phase	III
Patient	Non-cirrhotic nucleos(t)ide analogue treated patients with chronic hepatitis B virus
Subjects	534
Treatment arms	Arm A: bepirovirsen for 24 weeks Arm B: placebo
Description	Phase III multicentre, randomised, double blind trial to confirm the efficacy and safety of treatment with bepirovirsen in participants with chronic hepatitis B virus
Timeline	Trial start: Q1 2023 Data anticipated: 2025+
Key end points	Number of participants achieving functional cure (FC) with baseline HBsAg≤ 3000IU/mL
Clinicaltrials .gov	Link

Infectious diseases

bepirovirsen

NCT04676724 - B-TOGETHER

Phase	IIb
Patient	Non-cirrhotic patients with chronic hepatitis B virus on stable nucleos(t)ide analog therapy
Subjects	100
Treatment arms	Arm A: bepirovirsen for 12 wks + PegIFN for =< 24 wks Arm B: bepirovirsen for 24 weeks + PegIFN =< 24 wks
Description	A multicentre, randomised, open label trial to assess the efficacy and safety of sequential treatment with bepirovirsen followed by Pegylated Interferon Alpha 2a in participants with chronic hepatitis B virus
Timeline	Trial start: Q1 2021 Data anticipated: H2 2023
Key end points	Sustained response for 24 weeks post treatment
Clinicaltrials .gov	Link

NCT05276297

Phase	II
Patient	Participants 18 to 65 years stable on NA treatment for CHB
Subjects	184
Treatment arms	ChAd155-hIi-HBV high dose formulation HBc-HBs/AS01B-4 high dose formulation MVA-HBV high dose formulation Placebo
Description	A single-blinded, randomised, controlled multi-country trial to evaluate the safety, reactogenicity, efficacy and immune response following sequential treatment with an anti-sense oligonucleotide against Chronic Hepatitis B (CHB) followed by Chronic Hepatitis B Targeted Immunotherapy (CHB-TI) in CHB patients receiving nucleos(t)ide analogue (NA) therapy
Timeline	Trial start: Q2 2022 Data anticipated: 2025+
Key end points	Percentage of participants reporting grade 3 AE from first dose of GSK3228836 up to trial end Percentage of participants who achieve sustained virologic response (SVR) for 24 weeks after the planned end of active treatment in the absence of rescue medication, and difference between treatment arms (corresponding to GSK3228836 regimens)
Clinicaltrials .gov	Link

Infectious diseases

MenABCWY

NCT04707391 - MenABCWY-019

Phase	IIIb
Patient	Healthy adolescents and adults aged 15-25 years
Subjects	1250
Treatment arms	Arm A: 2 doses of MenABCWY days 1, 181 + placebo day 211 Arm B: 1 dose MenABCWY day 1; 2 doses of MenB on Day 181 and Day 211
Description	A randomised, controlled, observer-blind trial to evaluate safety and immunogenicity of GSK's meningococcal ABCWY vaccine when administered in healthy adolescents and adults previously primed with meningococcal ACWY vaccine
Timeline	Trial start: Q1 2021 Trial end: Q2 2023
Key end points	hSBA titres
Clinicaltrials .gov	Link

NCT04502693 - MenABCWY V72 72

Phase	III
Patient	Healthy adolescents and adults ages 10-25 years
Subjects	3657
Treatment arms	Arm A: rMenB+OMV NZ (2/3 dose schedule) plus MenACWY Arm B: rMenB+OMV NZ (2 dose schedule) plus MenACWY plus placebo Arm C: placebo + MenABCWY lot 1 Arm D: placebo + MenABCWY lot 2 Arm E: placebo + MenABCWY lot 3 Arm F: rMenB+OMV NZ + MenACWY + placebo
Description	Effectiveness of GSK Biologicals S.A.'s Meningococcal Group B and combined ABCWY vaccines in healthy adolescents and young adults
Timeline	Trial start: Q3 2020 Data reported: Q1 2023
Key end points	hSBA titers
Clinicaltrials .gov	Link

Infectious diseases

MenABCWY

NCT05087056 - MenABCWY-020

Phase	IIb
Patient	Healthy adolescents ≥11 to <15 years of age
Subjects	300
Treatment arms	Arm A: ABCWY-24 Group Arm B: ABCWY-48 Group
Description	A randomised, observer-blind trial to describe the safety, tolerability and immunogenicity of MenABCWY administered on different dosing schedules in healthy adolescents
Timeline	Trial start: Q4 2021 Data anticipated: 2025+
Key end points	hSBA titers ≥ LLOQ of each *N. meningitidis* serogroup B indicator strains
Clinicaltrials .gov	Link

Infectious diseases

GSK4406371

NCT05630846

Phase	II
Patient	Healthy children 4-6 years of age
Subjects	800
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 Data anticipated: H1 2024
Key end points	Anti-measles, anti-mumps, anti-rubella, and anti-glycoprotein H antibodies geometric mean concentrations
Clinicaltrials .gov	Link

Infectious diseases

GSK3528869

NCT03866187

Phase	I/II
Patient	HBV suppressed subjects under nucleo(s)tide treatment
Subjects	148
Treatment arms	ChAd155-hIi-HBV low dose formulation ChAd155-hIi-HBV high dose formulation HBc-HBs/AS01B-4 low dose formulation HBc-HBs/AS01B-4 high dose formulation MVA-HBV low dose formulation MVA-HBV high dose formulation Placebo
Description	A first time in human trial on GSK's therapeutic vaccines to evaluate the reactogenicity, safety, immunogenicity and efficacy on reduction of serum HBV surface antigen in HBV suppressed subjects under nucleo(s)tide treatment.
Timeline	Trial start: Q1 2023 Data anticipated: 2025+
Key end points	Number of subjects reporting local and general AEs
Clinicaltrials.gov	Link

Infectious diseases

GSK4023393

NCT04886154

Phase	I/II
Patient	Healthy adults (phase I) and healthy adolescents and adults (phase II)
Subjects	1258
Treatment arms	Combination Product: MenABCWY-2Gen low dose vaccine Combination Product: MenABCWY-2Gen high dose vaccine Combination Product: Placebo Combination Product: MenB vaccine Biological: MenACWY vaccine
Description	A randomised, controlled trial to assess the safety, effectiveness and immune response of meningococcal combined ABCWY vaccine when administered to healthy adults (phase I) and to healthy adolescents and adults (phase II)
Timeline	Trial start: Q2 2021 Data anticipated: H1 2024
Key end points	AEs, including all SAEs, AEs leading to withdrawal and AEs of special interest (AESIs) Immunological vaccine effectiveness by enc-hSBA and immunogenicity by hSBA on indicator strains
Clinicaltrials .gov	Link

NCT05082285

Phase	II
Patient	Healthy infants
Subjects	688
Treatment arms	Combination Product: MenABCWY-2Gen low dose vaccine Combination Product: MenABCWY-2Gen high dose vaccine Combination Product: MenABCWY Combination Product: MenB + MenACWY-TT
Description	A randomised, partially blinded trial to assess the safety, tolerability and immunogenicity of meningococcal combined ABCWY vaccine when administered to healthy infants
Timeline	Trial start: Q4 2021 Data anticipated: H2 2024 (interim results)
Key end points	AEs, including all SAEs, AEs leading to withdrawal and AEs of special interest (AESIs), medical attended events (MAE) Immunogenicity by hSBA to indicator strains
EUDRACT	Link

Infectious diseases

GSK4178116

NCT05084508

Phase	II
Patient	Healthy children between 12-15 months
Subjects	800
Treatment arms	Arm A: low potency varicella NS vaccine, plus routine schedule Arm B: medium potency varicella NS vaccine, plus routine schedule Arm C: high potency varicella NS vaccine, plus routine schedule Arm D: marketed varicella vaccine lot 1, plus routine schedule Arm E: marketed varicella vaccine lot 2, plus routine schedule
Description	A observer-blind, randomised, controlled trial to evaluate the immunogenicity and safety of a varicella vaccine at various potencies compared with Varivax as a first dose, administered in healthy children in their second year of life
Timeline	Trial start: Q4 2021 Data anticipated: H1 2024
Key end points	Anti-glycoprotein-E antibodies at day 43
Clinicaltrials .gov	Link

Infectious diseases

GSK5101955

NCT05412030

Phase	II
Patient	Healthy infants
Subjects	760
Treatment arms	Arm A: 1 mcg AFX3772 administered intramuscularly 4 times within 12 months Arm B: 2 mcg AFX3772 administered intramuscularly 4 times within 12 months Arm C: 5 mcg AFX3772 administered intramuscularly 4 times within 12 months Arm D: PCV13 administered intramuscularly 4 times within 12 months
Description	A randomised, double-blind, multi-dose, dose finding trial to evaluate the safety, tolerability and immunogenicity of AFX3772 compared with PCV13 in healthy infants
Timeline	Trial start: Q2 2022 Data anticipated: 2025+
Key end points	Safety, tolerability profiles of 3 different dose levels of AFX3772 compared with PCV13 with respect to the proportion of participants with AEs
Clinicaltrials .gov	Link

Infectious diseases

GSK4106647

NCT05496231

Phase	II
Patient	Healthy females 16 to 26 years of age
Subjects	1080
Treatment arms	Arm A: HPV9 High formulation Arm B: HPV9 Medium formulation Arm C: HPV9 Low formulation Arm D: Gardasil 9
Description	A randomized, observer-blinded, multi-country trial to evaluate safety and immunogenicity of investigational adjuvanted Human Papillomavirus Vaccine in females (16 to 26 years of age)
Timeline	Trial start: Q3 2022 Data anticipated: H1 2024
Key end points	AEs, SAEs, anti-HPV immunoglobulin G (IgG) antibody concentrations
Clinicaltrials .gov	Link

Infectious diseases

GSK4348413

NCT05630859

Phase	I/II	
Patient	Healthy adults 18 to 50 years of age	
Subjects	774	
Treatment arms	Phase I NgG low dose investigational vaccine NgG medium dose investigational vaccine NgG high dose investigational vaccine Placebo	Phase II NgG HTD investigational vaccine NgG below HTD investigational vaccine Placebo
Description	An observer-blind, randomized, placebo-controlled multi-country trial to assess safety and efficacy of GSK *Neisseria gonorrhoeae* GMMA (NgG) investigational vaccine when administered to healthy adults 18 to 50 years of age	
Timeline	Trial start: Q4 2022 Data anticipated: 2025+	
Key end points	AEs and SAEs Incidence rates of gonorrhea in trial phase II	
Clinicaltrials.gov	Link	

Infectious diseases

GSK2904545

NCT04026009

Phase	I
Patient	Healthy adults aged between 18-45 years and between 50-70 years
Subjects	140
Treatment arms	Arm A: CDIFF 18-45 years Arm B: 18-45 years (placebo) Arm C: CDIFF 50-70 years Arm D: CDIFF AS01B 50-70 years Arm F: 50-70 years (placebo)
Description	A single-centre, randomised, observer-blind placebo-controlled study to evaluate safety, reactogenicity and immunogenicity of GSK's *Clostridium difficile* investigational vaccine based on the F2 antigen with or without AS01B adjuvant when administered intramuscularly According to a 0, 1-month schedule
Timeline	Study start: Aug-19 Study end: May-22
Key end points	Number of subjects with any and Grade 3 solicited local symptoms
Clinicaltrials .gov	Link

Infectious diseases

GSK4429016

NCT04959344

Phase	I/II
Patient	Healthy adults
Subjects	166
Treatment arms	Arm A: Kleb4V target dose Arm B: Kleb4V target dose + AS03 Arm C: Kleb4V low dose Arm D: Kleb4V low dose + AS03 Arm F: placebo (diluent)
Description	Safety and immunogenicity of a *Klebsiella pneumoniae* tetravalent bioconjugate vaccine (Kleb4V)
Timeline	Study start: Jul-21 Study end: Sep-22
Key end points	Occurrence, severity and relationship of solicited local and general AEs
Clinicaltrials .gov	Link

Infectious diseases

GSK3993129

NCT05089630

Phase	I/II
Patient	Healthy adults
Subjects	320
Treatment arms	Arm A: pentamer (low)/gB(low)/adjuvant vaccine Arm B: pentamer (med)/gB(low)/adjuvant vaccine Arm C: pentamer (med)/gB(med)/adjuvant vaccine Arm D: pentamer (high)/gB(med)/adjuvant vaccine Arm F: placebo (saline)
Description	A randomised, observer-blind, placebo-controlled, dose escalation trial to assess safety, reactogenicity and immunogenicity of a candidate CMV vaccine comprising recombinant protein and adjuvant
Timeline	Trial start: Q4 2021 Data anticipated: H2 2024
Key end points	Safety, reactogenicity and immunogenicity
Clinicaltrials .gov	Link

Infectious diseases

GSK4382276

NCT05446740

Phase	I	
Patient	Healthy younger and older adults	
Subjects	336	
Treatment arms	GSK4382276A Dose level 1	GSK4382276A Dose level 7
	GSK4382276A Dose level 2	GSK4382276A Dose level 8
	GSK4382276A Dose level 3	GSK4382276A Dose level 9
	GSK4382276A Dose level 4	Combination Product: FDQ21A-NH
	GSK4382276A Dose level 6	Combination Product: FDQ22A-NH
Description	A randomized, observer-blind, dose-escalation trial to evaluate the safety, reactogenicity and immunogenicity of an mRNA-based monovalent influenza vaccine candidate in healthy younger and older adults	
Timeline	Trial start: Q3 2022 Final data anticipated: H1 2024	
Key end points	Number of participants reporting solicited administration site events	
Clinicaltrials .gov	Link	

NCT05823974

Phase	I
Patient	Healthy younger and older adults
Subjects	1512
Treatment arms	Biological: Flu mRNA Combination Product: Control 1 Combination Product: Control 2
Description	A trial to assess the safety and immune response of a vaccine against influenza in healthy younger and older adults
Timeline	Trial start: Q2 2023 Final data anticipated: H2 2024
Key end points	Number of participants reporting solicited administration site events
Clinicaltrials .gov	Link

Infectious diseases

GSK4396687

NCT05477186

Phase	I
Patient	Adults at least 18 years old
Subjects	180
Treatment arms	Arm A: CV0501 dose (12 µg) Arm B: CV0501 dose (25 µg) Arm C: CV0501 dose (50 µg) Arm D: CV0501 dose (75 µg or 100 µg) Arm E: Part A CV0501 dose (100 µg, 150 µg or 200 µg) Arm F: Part B CV0501 dose (3 µg) Arm G: CV0501 dose (6 µg)
Description	An open-label, safety and immunogenicity trial of a booster dose of the investigational CV0501 mRNA COVID-19 vaccine in adults at least 18 years old
Timeline	Trial start: Q3 2022 Data anticipated: H1 2024
Key end points	Percentage of participants with solicited local AE during 7 days after vaccination
Clinicaltrials .gov	Link

Infectious diseases

GSK3943104

NCT05298254

Phase	I/II	
Patient	Healthy participants aged 18-60 years negative for HSV-2 HSV-2 and HSV-1 patients with ≥3 episodes of GH in the previous year	
Subjects	Part 1: 245; Part 2: 240	
Treatment arms	Arm A: non-adjuvanted HSV formulation 1 - part 1 group Arm B: non-adjuvanted HSV formulation 2 - part 1 group Arm C: non-adjuvanted HSV formulation 3 - part 1 group Arm D: HSV formulation 1 with adjuvant 1 - part 1 group Arm E: HSV formulation 2 with adjuvant 1 - part 1 group Arm F: HSV formulation 3 with adjuvant 1 - part 1 group Arm G: HSV formulation 1 with adjuvant 2 - part 1 group	Arm H: HSV formulation 2 with adjuvant 2 - part 1 group Arm I: HSV formulation 3 with adjuvant 2 - part 1 group Arm J: part 1 group (placebo) Arm K: selected formulation - part 2 group Arm L: selected formulation - part 2 group Arm M: part 2 group (placebo)
Description	An observer-blind, randomised, placebo-controlled, multi-country trial to evaluate reactogenicity, safety, immune response and efficacy of an HSV vaccine	
Timeline	Trial start: Q1 2022 (part 1); Q4 2023 (part 2) Data anticipated: H1 2023 (part 1); H2 2024 (part 2)	
Key end points	Part 1: Percentage of participants reporting each solicited administration site event; dose selection Part 2: Clinical efficacy (TTFE)	
Clinicaltrials.gov	Link	

Infectious diseases

GSK3882347

NCT05138822

Phase	Ib
Patient	Female participants with acute uncomplicated urinary tract infection
Subjects	80
Treatment arms	GSK3882347 Nitrofurantoin
Description	A double-blind, double dummy, randomised, nitrofurantoin controlled, repeat oral dose trial to investigate the safety, tolerability, pharmacokinetics and microbiological response of GSK3882347 in female participants with acute uncomplicated urinary tract infection
Timeline	Trial start: Q4 2022 Data anticipated: H2 2024
Key end points	Numbers of participants with microbiological response (responder/non-responder of GSK3882347) at the TOC visit
Clinicaltrials .gov	Link

Infectious diseases

GSK3923868

NCT05398198

Phase	Ib
Patient	Participants with mild asthma
Subjects	68
Treatment arms	Arm A: GSK3923868 Arm B: placebo
Description	A randomised, double-blind, placebo controlled, repeat dose trial to assess the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of inhaled GSK3923868 during experimental human rhinovirus infection participants with mild asthma
Timeline	Trial start: Q2 2022 Data anticipated: H1 2024
Key end points	AUC of CfB in LRTS score from day of inoculation up to discharge
Clinicaltrials .gov	Link

Infectious diseases

GSK3965193

NCT05330455

Phase	I/II
Patient	Healthy participants and those living with chronic hepatitis B infection
Subjects	132
Treatment arms	Part 1 cohort 1: GSK3965193 and placebo Part 1 cohort 2: GSK3965193 and placebo Part 2A cohort 3: GSK3965193 or placebo Part 2A cohort 4: GSK3965193 or placebo Part 2A cohort 5: GSK3965193 or placebo Part 2B cohort 6: GSK3965193 Part 3 cohort 7: GSK3965193 or placebo Part 4 cohort 8: GSK3965193 and bepirovirsen or placebo and bepirovirsen
Description	Four-part, randomised, double-blind (Parts 1, 2A, 3 and 4), multi-centre, placebo-controlled trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of GSK3965193 monotherapy in healthy participants and in participants living with chronic hepatitis B infection; and GSK3965193 in combination with bepirovirsen
Timeline	Trial start: Q2 2022 Data anticipated: 2025+
Key end points	Number of participants with AEs, SAEs, and withdrawals due to AEs Part 3: Change from Baseline in HBsAg levels Part 4 : Number of participants achieving sustained virologic response
Clinicaltrials.gov	Link

Infectious diseases

GSK3437949

NCT03276962

Phase	IIb
Patient	Children aged 5-17 months
Subjects	1498
Treatment arms	R012-20 Group: a full dose of RTS,S/AS01E at Month 0, Month 1, Month 2 and Month 20 R012-14-mD Group: a full dose of RTS,S/AS01E at Month 0, Month 1, Month 2 Month 14, Month 26, Month 38 Fx012-14-mFxD Group: a full dose of RTS,S/AS01E at Month 0, Month 1 and RTS,S/AS01E 1/5th dose at Month 2, Month 14, Month 26, Month 38 Fx017-mFxD Group: a full dose of RTS,S/AS01E at Month 0, Month 1 and RTS,S/AS01E 1/5th dose at Month 7, Month 20, Month 32 Control Group: Subjects will receive rabies vaccine at Month 0, Month 1, Month 2
Description	A randomized, open-label, controlled, multi-centre trial of the efficacy, safety and immunogenicity of GSK Biologicals' candidate malaria vaccine RTS,S/AS01E evaluating schedules with or without fractional doses, early Dose 4 and yearly doses, in children 5-17 months of age living in sub-Saharan Africa.
Timeline	Trial start: Q3 2017 Data anticipated: H2 2023
Key end points	Incremental efficacy of a schedule with a fractional third dose at Month 2 over the standard schedule. To demonstrate the superiority of a 3-dose schedule of GSK Biologicals' malaria vaccine RTS,S/AS01E with a fractional third dose at Month 2 compared to a standard schedule of RTS,S/AS01E with three full doses in terms of vaccine efficacy against clinical malaria (primary case definition) over 12 months post-Dose 3.
Clinicaltrials.gov	Link

Infectious diseases

GSK3536852

NCT05073003

Phase	I/II
Patient	Adults in Europe (Stage 1) followed by age de-escalation from adults to children and infants and dose finding in infants in Africa (Stage 2)
Subjects	550
Treatment arms	Drug: altSonflex Placebo (adults stage 1 in Europe) Biological: altSonflex1-2-3 High Dose C (adults stage 1 in Europe, adults, children and infants stage 2 in Africa) Biological: altSonflex1-2-3 Medium Dose B (children and infants stage 2 in Africa) Biological: altSonflex1-2-3 Low Dose A (infants stage 2 in Africa) Comparators: Menveo and Boostrix (adults stage 2 in Africa) Comparators: Menveo and Typhim Vi (children stage 2 in Africa) Comparators: Menveo and Infanrix (infants stage 2 in Africa)
Description	A staged observer-blind, randomised, controlled, multi-country trial to evaluate the safety, reactogenicity, and immune responses to the GVGH altSonflex1-2-3 vaccine against *S. sonnei* and *S. flexneri* serotypes 1b, 2a, and 3a, in adults in Europe (Stage 1) followed by age de-escalation from adults to children and infants, and dose-finding in infants in africa (Stage 2)
Timeline	Trial start: Q4 2021 Data anticipated: 2025+
Key end points	Immune response to identify the preferred dose of each component of the altSonflex1-2-3 vaccine (low, medium, or high) for infants 9 months of age in Africa (Stage 2). To evaluate the safety and reactogenicity of the altSonflex1-2-3 vaccine in all participants in Europe and Africa (Stage 1 and Stage 2)
Clinicaltrials.gov	Link

Infectious diseases

GSK3036656

NCT05382312

Phase	IIa
Patient	Males and females aged 18 to 65 years inclusive with drug-sensitive (rifampicin-susceptible) pulmonary tuberculosis
Subjects	55
Treatment arms	Arm A: Participants receiving GSK3036656+bedaquiline Arm B: Participants receiving GSK3036656+delamanid Arm C: Participants receiving bedaquiline+delamanid Arm D: Participants receiving RIFAFOUR e-275
Description	A parallel group, randomised, open-label, 4 treatment arm trial to assess the early bactericidal activity, safety and tolerability of oral GSK3036656 in combination with either oral delamanid or oral bedaquiline, oral delamanid in combination with oral bedaquiline, or standard of care in males and females aged 18 to 65 years inclusive with drug-sensitive (rifampicin-susceptible) pulmonary tuberculosis
Timeline	Trial start: Q3 2022 Data anticipated: H1 2024
Key end points	Change from baseline in log10 CFU of *Mycobacterium tuberculosis*
Clinicaltrials .gov	Link

Infectious diseases

GSK4077164

NCT05480800

Phase	I/IIa	
Patient	Healthy European and African adults	
Subjects	**155**	
Treatment arms	Arm A: iNTS-TCV low dose group - Europe	Arm F: Step 2 group (placebo) - Europe
	Arm B: iNTS-GMMA and TCV low doses group - Europe	Arm G: iNTS-TCV full dose_2 group - Africa
	Arm C: Step 1 group (placebo) - Europe	Arm H: iNTS-GMMA and TCV full doses_2 group - Africa
	Arm D: iNTS-TCV full dose_1 group - Europe	Arm I: Stage 2 group (control) - Africa
	Arm E: iNTS-GMMA and TCV full doses_1 group - Europe	
Description	An observer-blind, randomised, controlled, two-stage, multi-country trial to evaluate the safety, reactogenicity and immune response of the trivalent vaccine against iNTS and Typhoid fever	
Timeline	Trial start: Q3 2022 Data anticipated: 2025+	
Key end points	To evaluate the safety, reactogenicity and immunogenicity profile of iNTS-TCV vaccine in healthy European/African adults	
Clinicaltrials.gov	Link	

Infectious diseases

GSK3536867

NCT05613205

Phase	I
Patient	Healthy adults aged 18-50 years in Europe
Subjects	**96**
Treatment arms	Arm A: Step 1a low dose without adjuvant group Arm B: Step 1a control group Arm C: Step 1b low dose with adjuvant group Arm D: Step 1b control group Arm E: Step 2 full dose without adjuvant group Arm F: Step 2 full dose with adjuvant group Arm G: Step 2 control group
Description	An observer-blind, randomised, controlled, single-centre trial to evaluate the safety, reactogenicity and immune responses to an adjuvanted and non-adjuvanted conjugate vaccine against Salmonella Typhi and Salmonella Paratyphi A
Timeline	Trial start: Q4 2022 Data anticipated: H1 2024
Key end points	Percentage of participants with solicited administration-site events, systemic events, unsolicited adverse event and any serious adverse events after the first vaccination
Clinicaltrials.gov	Link

Infectious diseases

GSK2556286

NCT04472897

Phase	I
Patient	Healthy adults
Subjects	120
Treatment arms	Arm A: Part A - GSK2556286 with up to11 cohorts Arm B: Part A - placebo Arm C: Part B - GSK2556286 with up to 4 cohorts Arm D: Part B - placebo
Description	A randomised, double blind (sponsor unblinded), placebo-controlled, first time in human trial to evaluate the safety, tolerability and pharmacokinetics of single and repeat oral doses and the food effect of GSK2556286
Timeline	Trial start: Q4 2020 Data anticipated: H1 2024
Key end points	SAEs and non-SAEs
Clinicaltrials .gov	Link

Infectious diseases

GSK3494245

NCT04504435

Phase	I
Patient	Healthy adult males
Subjects	54
Treatment arms	Cohort 1: maximum of 3 ascending doses GSK3494245 starting at 20 mg and placebo (fasted) Cohort 2: maximum of 3 ascending doses GSK3494245 starting at dose level 5 and placebo (fasted) Cohort 3: Participants receiving GSK3494245 (fasted then fed) Cohort 3: Participants receiving GSK3494245 (fed then fasted)
Description	A randomized, double-blind, placebo-controlled, first time in human trial to evaluate the safety, tolerability and pharmacokinetics of single (in both fed and fasted states) doses of GSK3494245 in healthy participants
Timeline	Trial start: Sep-20 Data anticipated: H2 2024
Key end points	Number of participants with AEs and SAEs
Clinicaltrials .gov	Link

HIV

HIV

VH3810109

NCT04871113 - B-NAB

Phase	II
Patient	Anti-retroviral naïve HIV-1 infected adults
Subjects	62
Treatment arms	Part 1 Cohort 1: '109A infusion (40mg/kg) Cohort 2: '109A infusion (280 mg/kg) Part 2 Cohort 3: '109A IV or SC – dosing determined from part 1 Cohort 4: '109A IV or SC – dosing determined from part 1 Cohort 5: '109A IV or SC – dosing determined from part 1
Description	A multicentre, randomised, open-label, two part adaptive design trial to evaluate the antiviral effect, safety and tolerability of GSK3810109A, an HIV-1 specific broadly neutralizing human monoclonal antibody in antiretroviral-naïve HIV-1-infected adults
Timeline	Trial start: Q2 2021 Data anticipated: H2 2023
Key end points	Safety, plasma HIV-1 levels
Clinicaltrials .gov	Link

HIV

cabotegravir

NCT05418868

Phase	I
Patient	Healthy adult volunteers
Subjects	60
Treatment arms	Part A: Participants receiving CAB 200 mg/mL with rHuPH20 Part C: Participants receiving CAB 400 mg/mL Part D: Participants receiving CAB 400 mg/mL with rHuPH20
Description	A multi-centre, open-label, single dose escalation trial to evaluate the pharmacokinetics, safety and tolerability of long-acting cabotegravir co-administered with recombinant human hyaluronidase PH20 (rHuPH20) in healthy adult volunteers
Timeline	Trial start: Q2 2022 Data anticipated: H1 2024
Key end points	Plasma concentrations of cabotegravir
Clinicaltrials .gov	Link

HIV

VH3739937

NCT04493684

Phase	I
Patient	Healthy participants
Subjects	91
Treatment arms	Arm A: Part 1 cohort 1 - GSK3738837 Arm B: Part 1 cohort 1 - placebo Arm C: Part 1 cohort 2 - GSK3739937 Arm D: Part 1 cohort 2 - placebo Arm E: Part 2 cohort 3 - GSK3738837 Arm F: Part 2 cohort 3 - placebo Arm G: Part 2 cohort 4 - GSK3739937 Arm H: Part 2 cohort 4 - placebo Arm I: Part 2 cohort 5 - GSK3739937 Arm J: Part 2 cohort 5 - placebo Arm K: Part 2 cohort 6 - GSK3739937 Arm L: Part 2 cohort 6 - placebo Arm M: Part 3 cohort 7 - treatment sequence ABC Arm N: Part 3 cohort 7 - treatment sequence BCA Arm O: Part 3 cohort 7 - treatment sequence CAB
Description	A double-blind (sponsor unblinded), randomised, placebo-controlled, single and repeated dose escalation trial to investigate the safety, tolerability and pharmacokinetics of GSK3739937
Timeline	Trial start: Q3 2020 Data reported: Q3 2021
Key end points	AEs and SAEs
Clinicaltrials.gov	Link

HIV

VH4004280

NCT05163522

Phase	I
Patient	Healthy participants
Subjects	82
Treatment arms	Arm A: Part 1 VH4004280 Arm B: Part 1 placebo Arm C: Part 2 (MAD) Non DDI cohort - VH4004280 Arm D: Part 2 (MAD) Non DDI cohort - placebo Arm E: Part 2 (MAD) DDI cohort - VH4004280 + midazolam Arm F: Part 2 (MAD) DDI cohort - placebo + midazolam Arm G: Part 3 (single dose): VH4004280
Description	A randomised, double-blind (sponsor unblinded), placebo-controlled trial to evaluate the safety, tolerability and pharmacokinetics of orally administered VH4004280
Timeline	Trial start: Q4 2021 Data anticipated: H2 2023
Key end points	AEs, PK
Clinicaltrials.gov	Link

HIV

VH4011499

NCT05393271

Phase	I
Patient	Healthy participants
Subjects	51
Treatment arms	Arm A: Part 1 (SAD) - VH4011499 Arm B: Part 1 (SAD) - placebo Arm C: Part 2 (MAD) DDI cohort - VH4011499 + midazolam Arm D: Part 2 (MAD) DDI cohort - placebo + midazolam Arm E: Part 2 (MAD) non DDI cohort - VH4011499 Arm F: Part 2 (MAD) non DDI cohort - placebo Arm G: Part 3 (single dose): VH4011499
Description	A randomised, double-blind (sponsor unblinded), placebo-controlled trial to evaluate the safety, tolerability and pharmacokinetics of orally administered VH4011499
Timeline	Trial start: Q2 2022 Trial end: Q2 2023
Key end points	AEs, PK
Clinicaltrials.gov	Link

HIV

VH4524184

NCT05631704

Phase	I
Patient	Healthy participants
Subjects	84
Treatment arms	Arm A: Part 1 cohort 1 - VH4524184 DL1 Arm B: Part 1 cohort 1 - placebo Arm C: Part 1 cohort 2 - VH4524184 DL2 Arm D: Part 1 cohort 2 - placebo Arm E: Part 1 cohort 3 - VH4524184 DL3 Arm F: Part 1 cohort 3 - placebo Arm G: Part 1 cohort 4 - VH4524184 DL4 Arm H: Part 1 cohort 4 - placebo Arm I: Part 1 cohort 5 - VH4524184 DL5 Arm J: Part 1 cohort 5 - placebo Arm K: Part 2 cohort 7 - VH4524184 RL1 Arm L: Part 2 cohort 7 - placebo Arm M: Part 2 cohort 8 - VH4524184 RL2 Arm N: Part 2 cohort 8 - placebo Arm O: Part 3 cohort 10 - VH4524184 fasted / VH4524184 fed
Description	A double-blind (sponsor-unblinded), placebo-controlled randomised, single and multiple ascending dose first-time-in-human trial to investigate the safety, tolerability and pharmacokinetics of VH4524184 and the potential for changes in cytochrome P450 3A (CYP3A) activity
Timeline	Trial start: Q4 2022 Data anticipated: H2 2023
Key end points	SAE, non-SAE, and PK
Clinicaltrials.gov	Link

Respiratory/Immunology

Respiratory/Immunology

Nucala (mepolizumab)

NCT04133909 - MATINEE

Phase	III
Patient	Participants with chronic obstructive pulmonary disease (COPD) experiencing frequent exacerbations and characterised by eosinophil levels
Subjects	800
Treatment arms	Arm A: placebo Arm B: mepolizumab
Description	A multicentre randomised, double-blind, parallel-group, placebo-controlled trial of mepolizumab 100 mg subcutaneously as add-on treatment in participants with COPD experiencing frequent exacerbations and characterised by eosinophil levels
Timeline	Trial start: Q4 2019 Data anticipated: H2 2024
Key end points	Annualised rate of moderate or severe exacerbations
Clinicaltrials .gov	Link

Respiratory/Immunology

depemokimab

NCT04719832 - SWIFT-1

Phase	III
Patient	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype
Subjects	375
Treatment arms	Arm A: depemokimab plus SoC Arm B: placebo plus SoC
Description	A 52-week, randomised, double-blind, placebo-controlled, parallel-group, multi-centre trial of the efficacy and safety of depemokimab adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
Timeline	Trial start: Q1 2021 Data anticipated: H2 2024
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials .gov	Link

NCT04718103 - SWIFT-2

Phase	III
Patient	Adult and adolescents with severe uncontrolled asthma with an eosinophilic phenotype
Subjects	375
Treatment arms	Arm A: depemokimab plus SoC Arm B: placebo plus SoC
Description	A 52-week, randomised, double-blind, placebo-controlled, parallel-group, multi-centre trial of the efficacy and safety of depemokimab adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
Timeline	Trial start: Q1 2021 Data anticipated: H2 2024
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials .gov	Link

Respiratory/Immunology

depemokimab

NCT05243680 - AGILE

Phase	III
Patient	Adult and adolescents with severe asthma with an eosinophilic phenotype from studies SWIFT-1 and SWIFT-2
Subjects	637
Treatment arms	Participants diagnosed with asthma receiving depemokimab
Description	A 52-week, open label extension phase of SWIFT-1 and SWIFT-2 to assess the long-term safety and efficacy of depemokimab adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
Timeline	Trial start: Q1 2022 Data anticipated: 2025+
Key end points	Number of participants with AEs and SAEs and incidence of immunogenicity over 52 weeks
Clinicaltrials .gov	Link

NCT04718389 - NIMBLE

Phase	III
Patient	Adult and adolescent severe asthmatic participants with an eosinophilic phenotype treated with depemokimab compared with mepolizumab or benralizumab
Subjects	1700
Treatment arms	Arm A: participants receiving depemokimab plus placebo matching prior anti-IL-5/5R treatment Arm B: participants receiving prior anti-IL-5/5R treatment plus placebo matching depemokimab
Description	A 52-week, randomised, double-blind, double-dummy, parallel group, multi-centre, non-inferiority trial assessing exacerbation rate, additional measures of asthma control and safety in adult and adolescent severe asthmatic participants with an eosinophilic phenotype treated with depemokimab compared with mepolizumab or benralizumab
Timeline	Trial start: Q1 2021 Data anticipated: 2025+
Key end points	Annualised rate of clinically significant exacerbations over 52 weeks
Clinicaltrials .gov	Link

Respiratory/Immunology

depemokimab

NCT05274750 - ANCHOR-1

Phase	III
Patient	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
Subjects	250
Treatment arms	Arm A: depemokimab Arm B: placebo
Description	A randomized, double-blind, parallel group trial to assess the efficacy and safety of 100 mg subcutaneous depemokimab in patients with CRSwNP
Timeline	Trial start: Q2 2022 Data anticipated: H2 2024
Key end points	Change from baseline in total endoscopic nasal polyps (NP) score at week 52 Change from baseline in mean nasal obstruction visual analogue scale (VAS) score (scores on a scale)
Clinicaltrials .gov	Link

NCT05281523 - ANCHOR-2

Phase	III
Patient	Adults with chronic rhinosinusitis with nasal polyps (CRSwNP)
Subjects	250
Treatment arms	Arm A: depemokimab Arm B: placebo
Description	A randomized, double-blind, parallel group trial to assess the efficacy and safety of 100 mg subcutaneous depemokimab in patients with CRSwNP
Timeline	Trial start: Q2 2022 Data anticipated: H2 2024
Key end points	Change from baseline in total endoscopic nasal polyps (NP) score at week 52 Change from baseline in mean nasal obstruction visual analogue scale (VAS) score (scores on a scale)
Clinicaltrials .gov	Link

Respiratory/Immunology

depemokimab

NCT05263934 - OCEAN

Phase	III
Patient	Adults with relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) receiving standard of care therapy
Subjects	160
Treatment arms	Arm A: depemokimab + placebo matching mepolizumab Arm B: mepolizumab + placebo matching depemokimab
Description	A 52-week randomised, double-blind, double-dummy, parallel-group, multicentre, non-inferiority trial to investigate the efficacy and safety of depemokimab compared with mepolizumab in adults with relapsing or refractory EGPA receiving standard of care therapy
Timeline	Trial start: Q3 2022 Data anticipated: 2025+
Key end points	Number of participants with remission
Clinicaltrials .gov	Link

NCT05334368 - DESTINY

Phase	III
Patient	Adults with hypereosinophilic syndrome (HES) receiving standard of care therapy
Subjects	120
Treatment arms	Arm A: depemokimab Arm B: placebo
Description	A randomised, double-blind, placebo-controlled trial to investigate the efficacy and safety of depemokimab in adults with HES
Timeline	Trial start: Q3 3022 Data anticipated: 2025+
Key end points	Frequency of HES flares
Clinicaltrials .gov	Link

Respiratory/Immunology

camlipixant

NCT05599191 - CALM-1

Phase	III
Patient	Adult participants with refractory chronic cough, including unexplained chronic cough
Subjects	675
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 Data anticipated: 2025+
Key end points	24-hour cough frequency
Clinicaltrials .gov	Link

NCT05600777 - CALM-2

Phase	III
Patient	Adult participants with refractory chronic cough, including unexplained chronic cough
Subjects	675
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 Data anticipated: 2025+
Key end points	24-hour cough frequency
Clinicaltrials .gov	Link

Respiratory/Immunology

belimumab

NCT05878717

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 anticipated: H2 2023 Data anticipated: 2025+
Key end points	Absolute change from baseline in Forced Vital Capacity (FVC) millilitre (mL) at week 52
Clinicaltrials .gov	Link

Respiratory/Immunology

GSK3858279

NCT05838755 - NEPTUNE-17

Phase	II
Patient	Adult participants with chronic diabetic peripheral neuropathic pain (DPNP)
Subjects	240
Treatment arms	Arm A: GSK3858279 dose 1 Arm B: GSK3858279 dose 2 Arm C: placebo
Description	A multicentre randomised, double-blind, placebo-controlled trial to evaluate efficacy, safety, tolerability, pharmacokinetics and target engagement of GSK3858279 in adult participants with chronic DPNP
Timeline	Trial start anticipated: Q4 2023 Data anticipated: 2025+
Key end points	Change from baseline in the weekly average of average daily pain intensity at week 12, assessed on Numeric Rating Scale (NRS)
Clinicaltrials .gov	Link

NCT05838742 - MARS-17

Phase	II
Patient	Adult participants with moderate to severe pain due to knee osteoarthritis
Subjects	420
Treatment arms	Arm A: GSK3858279 dose 1 Arm B: GSK3858279 dose 2 Arm C: GSK3858279 dose 3 Arm D: GSK3858279 dose 4 Arm E: placebo
Description	A multicentre randomised, double-blind, placebo controlled, dose-finding trial of GSK3858279 in adult participants with moderate to severe pain due to knee osteoarthritis
Timeline	Trial start anticipated: Q4 2023 Data anticipated: 2025+
Key end points	Change from baseline in the weekly average of average daily knee pain intensity at week 12, assessed on Numeric Rating Scale (NRS)
Clinicaltrials .gov	Link

Respiratory/Immunology

GSK3888130

NCT05131971

Phase	I
Patient	Healthy participants aged 18-55 inclusive
Subjects	54
Treatment arms	Cohort 1: GSK3888130B at dose level 1 (placebo comparator) Cohort 2: GSK3888130B at dose level 2 (placebo comparator) Cohort 3: GSK3888130B at dose level 3 (placebo comparator) Cohort 4: GSK3888130B at dose level 4 (placebo comparator) Cohort 5: GSK3888130B at dose level 5 (placebo comparator) Cohort 6: GSK3888130B at dose level 6 (placebo comparator) Cohort 7: GSK3888130B at dose level 7 (placebo comparator)
Description	A randomised, double-blind, placebo controlled, single dose escalation trial to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of GSK3888130B
Timeline	Trial start: Q4 2021 Data anticipated: H2 2023
Key end points	Number of participants with AEs and SAEs
Clinicaltrials .gov	Link

Respiratory/Immunology

GSK1070806

NCT04975438

Phase	Ib
Patient	Patients with moderate to severe atopic dermatitis
Subjects	34
Treatment arms	Arm A: Group 1 - biologic naïve participants receiving GSK1070806 Arm B: Group 1 - biologic naïve participants receiving placebo Arm C: Group 2 - dupilumab inadequate responders receiving GSK1070806 Arm D: Group 2 - dupilumab inadequate responders receiving placebo
Description	A randomized, double-blind, parallel group, placebo-controlled trial of the clinical effect, safety and tolerability of a single intravenous infusion of GSK1070806
Timeline	Trial start: Q4 2021 Data anticipated: H2 2023
Key end points	Percent change from baseline in eczema area and severity index (EASI) at Week 12 in Group 1
Clinicaltrials .gov	Link

Oncology

Oncology

momelotinib

NCT03441113

Phase	II
Patient	Participants with primary myelofibrosis (PMF) or post-polycythemia vera or post-essential thrombocythemia myelofibrosis (post-PV/ET MF)
Subjects	237
Treatment arms	Arm A: Study GS-US-352-0101 Arm B: Study GS-US-352-1214 Arm C: Study GS-US-352-1154 Arm D: Study SRA-MMB-301
Description	Extended access and assess long-term safety of momelotinib (MMB) in participants with PMF or post-PV/ET MF
Timeline	Trial start: Q3 2018 Anticipated trial end: 2025+
Key end points	Number of patients who had access to and received the intervention
Clinicaltrials.gov	Link

Oncology

Jemperli (dostarlimab)

NCT03981796 - RUBY ENGOT-EN6 GOG-3031

Phase	III
Patient	Patients with recurrent or primary advanced endometrial cancer
Subjects	785
Treatment arms	Arm A: dostarlimab + SoC followed by dostarlimab Arm B: placebo + SoC followed by placebo Arm C: dostarlimab + SoC followed by dostarlimab+niraparib Arm D: placebo (+chemo) followed by PBO
Description	A randomised, double-blind, multi-centre trial of dostarlimab plus carboplatin-paclitaxel with and without niraparib maintenance versus placebo plus carboplatin-paclitaxel in patients with recurrent or primary advanced endometrial cancer
Timeline	Trial start: Q3 2019 Part 1 data reported: Q4 2022; Part 2 data anticipated: H1 2024
Key end points	Part 1: PFS by IA (dMMR/MSI-H and ITT) and OS (ITT) Part 2: PFS (ITT)
Clinicaltrials .gov	Link

NCT04581824 - PERLA

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

Oncology

Jemperli (dostarlimab)

NCT02715284 - GARNET

Phase	I/II
Patient	Participants with advanced solid tumors
Subjects	740
Treatment arms	Part 1: dostarlimab at ascending weight doses Part 2A: dostarlimab fixed dose of 500mg Q3W or 1000mg administered Q6W dose Part 2B: Cohort A1 dMMR/MSI-H endometrial Part 2B: Cohort A2 MMR proficient/MSS endometrial Part 2B: Cohort E: NSCLC Part 2B: Cohort F non-endometrial dMMR/MSI-H & POLE-mutation Part 2B: Cohort G PROC without known BRCA
Description	A multi-centre, open-label, first-in-human trial evaluating dostarlimab in participants with advanced solid tumors who have limited available treatment options
Timeline	Trial start: Q1 2016 Primary data reported: Q1 2019
Key end points	ORR, DoR, safety
Clinicaltrials .gov	Link

NCT05723562 - AZUR-1

Phase	II
Patient	Patients with untreated stage II/III mismatch repair deficient/high microsatellite instability (dMMR/MSI-H) locally advanced rectal cancer
Subjects	100
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 Data anticipated: 2025+
Key end points	Sustained cCR for 12, 24 and 36 months, EFS at 3 years
Clinicaltrials .gov	Link

Oncology

Jemperli (dostarlimab)

NCT05855200 - AZUR-2

Phase	III
Patient	Participants with untreated T4N0 or Stage III (resectable), mismatch repair deficient/high microsatellite instability (dMMR/MSI-H) colon cancer
Subjects	711
Treatment arms	Arm A: dostarlimab Arm B: Standard of care (FOLFOX/CAPEOX) or expectant observation post surgery.
Description	An open-label, randomized trial of perioperative dostarlimab monotherapy versus standard of care in participants with untreated T4N0 or Stage III dMMR/MSI-H resectable colon cancer
Timeline	Trial start: Q2 2023 Data anticipated: 2025+
Key end points	EFS assessed by Blinded Independent Central Review (BICR)
Clinicaltrials .gov	Link

Oncology

Zejula (niraparib)

NCT03602859 - FIRST

Phase	III
Patient	Participants with Stage III or IV nonmucinous epithelial ovarian cancer
Subjects	1332 (with N=1138 in ARM B and C)
Treatment arms	Arm A: SOC (carboplatin + paclitaxel + bevacizumab) +placebo Arm B: SOC + niraparib Arm C: SOC + dostarlimab + niraparib
Description	A randomised, double-blind comparison of platinum-based therapy with TSR-042 and niraparib versus standard of care platinum-based therapy as first-line treatment of Stage III or IV nonmucinous epithelial ovarian cancer
Timeline	Study start: Q4 2018 Data anticipated: H1 2024
Key end points	PFS for PD-L1 positive participants. Primary analysis is ARM B vs ARM C. This is an adaptive study with ARM A closed post topline.
Clinicaltrials .gov	Link

NCT04475939 - ZEAL-1L

Phase	III
Patient	Participants whose disease has remained stable or responded to 1L platinum based chemo with pembrolizumab for stage IIIB/IIIC or IV NSCLC
Subjects	666
Treatment arms	Arm A: niraparib plus pembrolizumab Arm B: placebo plus pembrolizumab
Description	A randomised, double-blind, placebo-controlled, multicentre study comparing niraparib plus pembrolizumab versus placebo plus pembrolizumab as maintenance therapy
Timeline	Study start: Q4 2020 Data anticipated: H2 2024
Key end points	OS, PFS assessed by BICR using Response Evaluation Criteria in Solid Tumors (RECIST)
Clinicaltrials .gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT04126200 - DREAMM-5

Phase	I/II
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	464
Treatment arms	Substudy 1: belantamab mafodotin + OX40 (GSK3174998) Substudy 2: belanatamab mafodotin + feladilimab Substudy 3: belantamab mafodotin + nirogacestat (GSI) Substudy 4: belantamab mafodotin + dostarlimab Substudy 5: belantamab mafodotin + isatuximab Substudy 6: belantamab mafodotin + nirogacestat + lenalidomide + dexamethasone Substudy 7: belantamab mafodotin + nirogacestat + pomalidomide + dexamethasone
Description	A randomised, open-label platform trial utilizing a master protocol to trial belantamab mafodotin as monotherapy and in combination with anti-cancer treatments
Timeline	Trial start: Q4 2019 Data anticipated: 2025+
Key end points	Dose escalation phase: DLT, safety, ORR Cohort expansion phase: ORR, CBR, safety
Clinicaltrials.gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT03544281 - DREAMM-6

Phase	I/II
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	152
Treatment arms	Arm A: belantamab mafodotin + lenalidomide + dexamethasone Arm B: belantamab mafodotin + bortezomib + dexamethasone
Description	An open-label, dose escalation and expansion trial to evaluate safety, tolerability and clinical activity of the antibody-drug conjugate belantamab mafodotin administered in combination with lenalidomide plus dexamethasone (Arm A), or bortezomib plus dexamethasone (Arm B)
Timeline	Trial start: Q3 2018 Data anticipated: H1 2024
Key end points	DLT, safety, ORR, PK
Clinicaltrials .gov	Link

NCT04246047 - DREAMM-7

Phase	III
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	571
Treatment arms	Arm A: belantamab mafodotin + bortezomib + dexamethasone (B-Vd) Arm B: daratumumab, bortezomib + dexamethasone (D-Vd)
Description	A multicentre, open-label, randomised trial to evaluate the efficacy and safety of the combination of belantamab mafodotin, bortezomib and dexamethasone (B-Vd) compared with the combination of daratumumab, bortezomib and dexamethasone (D-Vd)
Timeline	Trial start: Q2 2020 Data anticipated: H2 2023
Key end points	PFS, CRR, ORR, DoR, TTR, TTP, OS, PFS2, MRD negativity rate, safety
Clinicaltrials .gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT04246047 - DREAMM-8

Phase	III
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	300
Treatment arms	Arm A: belantamab mafodotin+ pomalidomide + dexamethasone (B-Pd) Arm B: Pomalidomide, bortezomib + dexamethasone (P-Vd)
Description	A multicentre, open-label, randomised trial to evaluate the efficacy and safety of belantamab mafodotin in combination with pomalidomide and dexamethasone (B-Pd) versus pomalidomide plus bortezomib and dexamethasone (PVd)
Timeline	Trial start: Q4 2020 Data anticipated: H2 2023
Key end points	PFS, MRD negativity rate, ORR, CRR, VGPR or better rate, DoR, TTBR, TTR, TTP, OS, PFS2, safety
Clinicaltrials .gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT04091126 - DREAMM-9

Phase	I
Patient	Patients with newly diagnosed multiple myeloma (MM)
Subjects	144
Treatment arms	Belantamab mafodotin, selected doses Bortezomib, administered subcutaneously or intravenously approximately 1 hour after the belantamab mafodotin infusion until Cycle 8 Lenalidomide, administered as 25 or 10 mg orally, depending upon renal function. Dexamethasone, administered orally as 20 mg in cycles 1-8 and 40 mg in Cycle 9 onwards
Description	A randomised, dose and schedule evaluation trial to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of belantamab mafodotin administered in combination with standard of care
Timeline	Trial start: Q4 2019 Data anticipated: 2025+
Key end points	DLT, safety, RDI of lenalidomide and bortezomib, PK, PD, ORR, CRR, VGPR or better
Clinicaltrials.gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT04398745 - DREAMM-12

Phase	I
Patient	Relapsed/refractory multiple myeloma (RRMM) who have normal and varying degrees of impaired renal function
Subjects	36
Treatment arms	belantamab mafodotin monotherapy
Description	A trial to evaluate the pharmacokinetics and safety of belantamab mafodotin monotherapy
Timeline	Trial start: Q4 2020 Data anticipated: 2025+
Key end points	PK, change in vital signs, safety
Clinicaltrials .gov	Link

NCT04398680 - DREAMM-13

Phase	I
Patient	Relapsed/refractory multiple myeloma (RRMM) who have normal and impaired hepatic function
Subjects	28
Treatment arms	belantamab mafodotin monotherapy
Description	A trial to evaluate the pharmacokinetics and safety of belantamab mafodotin monotherapy in participants who have normal and impaired hepatic function
Timeline	Trial start: Q2 2021 Data anticipated: 2025+
Key end points	PK, change in vital signs, safety
Clinicaltrials .gov	Link

Oncology

Blenrep (belantamab mafodotin)

NCT05064358 - DREAMM-14

Phase	II
Patient	Participants with relapsed/refractory multiple myeloma (RRMM)
Subjects	180
Treatment arms	Arm A: belantamab mafodotin
Description	A randomised, parallel, open-label study to investigate the safety, efficacy and pharmacokinetics of various dosing regimens of single-agent belantamab mafodotin (GSK2857916)
Timeline	Study start: Mar-22 Data anticipated: H2 2024
Key end points	% of patients with >= Gr 2 ocular events, safety, ORR, TTR, DoR, TTP, PFS, OS
Clinicaltrials .gov	Link

Oncology

cobolimab

NCT04655976 - COSTAR LUNG

Phase	II/III
Patient	Patients with advanced non-small cell lung cancer (NSCLC) who have progressed on prior anti-PD-(L)1 therapy and chemotherapy
Subjects	750
Treatment arms	Arm A: cobolimab+dostarlimab+docetaxel Arm B: dostarlimab+docetaxel Arm C: docetaxel
Description	A randomised, open label trial comparing cobolimab + dostarlimab + docetaxel to dostarlimab + docetaxel to docetaxel alone
Timeline	Trial start: Q4 2020 Data anticipated: H2 2024
Key end points	OS, ORR, PFS, DoR, TTD
Clinicaltrials .gov	Link

Oncology

belrestotug

NCT05565378 - GALAXIES LUNG-201

Phase	II
Patient	Participants with previously untreated, locally advanced/metastatic, Programmed Death Ligand 1-selected non small cell lung cancer (NSCLC)
Subjects	300
Treatment arms	Comparator Arm: pembrolizumab monotherapy Intervention Arm: dostarlimab monotherapy Substudy 1A: dostarlimab + GSK4428859A (Dose A) Substudy 1B: dostarlimab + GSK4428859A (Dose B) Substudy 1C: dostarlimab + GSK4428859A (Dose C)
Description	A randomized, open-label, platform trial utilizing a master protocol to evaluate novel immunotherapy combinations in participants with previously untreated, locally advanced/metastatic, Programmed Death Ligand 1-selected NSCLC
Timeline	Trial start: Q4 2022 Data anticipated: 2025+
Key end points	ORR
Clinicaltrials .gov	Link

NCT03739710 – ENTRÉE

Phase	II	
Patient	Participants with non-small cell lung cancer (NSCLC)	
Subjects	185	
Treatment arms	Part 1 Arm A: feladilimab + ipilimumab Arm B: dostarlimab + GSK4428859A Arm C: dostarlimab + GSK4428859A + GSK6097608	Part 2 SoC: docetaxel feladilimab and docetaxel
Description	A randomized, open-label platform trial utilizing a master protocol to trial novel regimens versus standard of care treatment in NSCLC participants	
Timeline	Trial start: Q1 2019 Data anticipated: 2025+	
Key end points	Part 1: Number of participants with AEs, SAEs, DLT, clinically significant changes in vital signs, physical examination and laboratory parameters. Number of participants requiring dose modifications. Part 2: Overall survival	
Clinicaltrials .gov	Link	

Oncology

GSK4381562

NCT05277051

Phase	I
Patient	Participants with selected advanced solid tumors
Subjects	162
Treatment arms	Arm A: GSK4381562 monotherapy Arm B: GSK4381562 plus dostarlimab Arm C: GSK4381562 plus dostarlimab plus GSK4428859A
Description	An open-label study of GSK4381562 administered as monotherapy and in combination with anticancer agents
Timeline	Study start: Q1 2022 Data anticipated: 2025+
Key end points	Participants with DLT
Clinicaltrials .gov	Link

Oncology

GSK3745417

NCT05424380

Phase	I
Patient	Participants with relapsed or refractory myeloid malignancies including acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (HR-MDS)
Subjects	72
Treatment arms	Arm A: dose escalation GSK3745417 Arm B: dose expansion GSK3745417
Description	An open label trial of intravenous GSK3745417 to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics and determine recommended phase II dose and schedule
Timeline	Trial start: Q3 2022 Data anticipated: 2025+
Key end points	AEs and number of participants per severity grade of AE in total population
Clinicaltrials .gov	Link

Oncology

GSK6097608

NCT04446351

Phase	I
Patient	Participants with advanced solid tumours
Subjects	184
Treatment arms	Arm A: GSK6097608 Arm B: GSK6097608 + dostarlimab Arm C: dostarlimab Arm D: dostarlimab + belrestotug Arm E: dostarlimab + belrestotug + GSK6097608 Arm D: dostarlimab + cobolimab
Description	A first time in human, open-label trial of GSK6097608 administered as monotherapy and in combination with anticancer agents
Timeline	Trial start: Q1 2020 Data anticipated: 2025+
Key end points	DLT, AEs and SAEs
Clinicaltrials .gov	Link

Oncology

belantamab

NCT05714839 - DREAMM-20

Phase	I/II
Patient	Relapsed/refractory multiple myeloma (RRMM) [Parts 1 and 2] Transplant-ineligible newly diagnosed multiple myeloma (TI NDMM) [Part 3]
Subjects	124
Treatment arms	Part 1: belantamab (may switch to belantamab mafodotin in case of PD) Part 2: Bela-xRd and Belamaf-xRd. The combination treatment xRd includes lenalidomide (R) and dexamethasone (d). x will be either a standard of care (SoC) or an emerging treatment. Part 3: Participants with TI NDMM will receive Bela-xRd and Belamaf-xRd. The combination treatment xRd includes lenalidomide (R) and dexamethasone (d). x will be either a standard of care (SoC) or an emerging treatment
Description	An open-lab multicentre, dose escalation and expansion trial to investigate the safety, tolerability and clinical activity of belantamab as monotherapy and in combination with other treatments in participants with multiple myeloma
Timeline	Trial start: Q3 2023 Data anticipated: 2025+
Key end points	Part 1: Safety and tolerability (including DLTs), PK and recommended Part 2 dose Part 2: Safety and tolerability, PK and recommended phase II dose Part 3: Safety and tolerability, PK and efficacy
Clinicaltrials.gov	Link

Opportunity driven

Opportunity driven

linerixibat

NCT04950127 - GLISTEN

Phase	III
Patient	Participants with primary biliary cholangitis (PBC)
Subjects	230
Treatment arms	Arm A: linerixibat Arm B: linerixibat followed by placebo Arm C: placebo Arm D: placebo followed by linerixibat
Description	A two-part randomised, placebo controlled, double blind, multicentre trial to evaluate the efficacy and safety of linerixibat for the treatment of cholestatic pruritus in participants with primary biliary cholangitis
Timeline	Trial start: Q3 2021 Data anticipated: H2 2024
Key end points	Change from baseline in monthly itch scores over 24 weeks using Numerical Rating Scale (NRS)
Clinicaltrials .gov	Link

Opportunity driven

GSK4532990

NCT05583344

Phase	IIb
Patient	Adults with non-alcoholic steatohepatitis (NASH) and advanced fibrosis
Subjects	246
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 pre-cirrhotic non-alcoholic steatohepatitis (NASH)
Timeline	Trial start: Q1 2023 Data anticipated: 2025+
Key end points	Part 1: Percentage of participants achieving ≥ 1 stage improvement in histological fibrosis with no worsening of NASH (at week 52) Part 2: Percentage of participants achieving NASH resolution with no worsening of fibrosis (at week 52)
Clinicaltrials.gov	Link

Opportunity driven

GSK4172239

NCT05660265

Phase	I
Patient	Participants with sickle cell disease
Subjects	40
Treatment arms	Cohort 1: GSK4172239D (Dose 1) Cohort 2: GSK4172239D (Dose 2) Cohort 3: GSK4172239D (Dose 3) Cohort 4: GSK4172239D (Dose 4) Cohort 5: GSK4172239D (Dose 5) Food effect cohort
Description	A randomised, placebo-controlled, double-blind (sponsor unblind), parallel group, single dose, dose escalation to evaluate the safety, tolerability and pharmacokinetics of GSK4172239D
Timeline	Trial start anticipated: H2 2023 Data anticipated: 2025+
Key end points	Area under curve zero to time infinity (AUC 0-inf) for GSK4106401 after a single oral dose of GSK4172239D
Clinicaltrials.gov	Link

Glossary

Glossary

ADC	Antibody drug conjugate
AE	Adverse event
AESI	Adverse event of special interest
AUC	Area under curve
BCMA	B-cell maturation antigen
BICR	Blinded Independent Central Review
BRCA	Breast cancer
CAE	Corneal adverse events
CBR	Clinical benefit rate
cCR	Complete clinical response
CKD	Chronic kidney disease
CfB	Change from baseline
CMV	Cytomegalovirus
CN	China
COPD	Chronic obstructive pulmonary disease
CP	Cholestatic pruritus
CRR	Complete response rate
CRSwNP	Chronic rhinosinusitis with nasal polyps
cUTI	Complicated urinary tract infection
CV	Cardiovascular
DDI	Drug-drug interaction
DFS	Disease-freee survival
DL	Dose level
DLT	Dose-limiting toxicity
dMMR	Deficient mismatch repair
DoR	Duration of response
DPNP	Diabetic peripheral neuropathic pain
EASI	Eczema Area and Severity Index
EGPA	Eosinophilic granulomatosis with polyangiitis
FVC	Forced vital capacity
GC	Urogenital gonorrhea
GMMA	Generalised Modules for Membrane Antigens
GSI	Gamma secretase inhibitor
HA	Healthy adults
HBV	Hepatitis B virus
HES	Hypereosinophilic syndrome
Hgb	Hemoglobin
hSBA	Human serum bactericidal assay
HZ	Herpes zoster
IC	Immunocompromised
ICR	Independent central review
iNTS	Invasive non-typhoidal salmonella
ITT	Intention-to-treat
JP	Japan
LLOQ	Lower limit of quantitation
LRTS	Lower respiratory tract symptoms
MAD	Multiple ascending dose
MAE	Medical attended events
MAPS	Mulitple Antigen Presenting System
MM	Multiple myeloma
MMR	Measles, mumps and rubella
MMRV	Measles, mumps, rubella and varicella
MRD	Multiple rising dose
MSI-H	Microsatellite instability high
NASH	Nonalcoholic steatohepatitis
NRS	Numeric Rating Scale
NSCLC	Non-small cell lung cancer
OMV	Outer membrane vesicle
ORR	Overall response rate
OS	Overall surival
PBC	Primary biliry cholangitis
PFS	Progression-free survival
PFS2	Time to second disease progression or death
PK	Pharmacokinetic
PMF	Primary myelofibrosis
Post-PV/ET MF	Post-essential thrombocythemia myelofibrosis
RL	Repeat dose level
RRMM	Relapsed/refractory multiple myeloma
RSV	Respiratory syncytial virus
SAD	Single ascending dose
SAE	Serious adverse event
siRNA	Small interfering RNA
SoC	Standard of care
SSc-ILD	Systemic sclerosis associated interstitial lung disease
TOC	Test of cure
TTBR	Time to best response
TTD	Time to treatment discontinuation
TTP	Time to tumour progression
TTR	Time to treatment response
UTI	Urinary tract infection
uUTI	Uncomplicated urinary tract infection
VGPR	Very good partial remission
VSP	Vital sign parameters
YoA	Years of age