



Pipeline assets and clinical trials appendix
Q3 2023

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Infectious disease

HIV

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Oncology

Opportunity driven



Innovation: Pipeline growth

Overview of potential new vaccines and medicines

67 potential new vaccines and medicines in pipeline

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

Phase I – 23 assets

| | | |
|---|--|---|
| 4429016 | Bioconjugated recombinant protein, adjuvanted* | <i>K. pneumoniae</i> |
| 4077164 | Bivalent GMMA* | Invasive non-typhoidal salmonella** |
| 3943104 | Recombinant protein, adjuvanted* | Therapeutic herpes simplex virus ¹ |
| 3536867 | Bivalent conjugate* | Salmonella (<i>typhoid + paratyphoid A</i>) |
| 2556286 | Mtb cholesterol dependent inhibitor* | Tuberculosis |
| 3186899 | CRK-12 inhibitor* ² | Visceral leishmaniasis |
| 3494245 | Proteasome inhibitor* | Visceral leishmaniasis |
| 3772701 | <i>P. falciparum</i> 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 |
| 4524184 | Integrase inhibitor* | HIV |
| 3888130 | Anti-IL7 antibody* | Autoimmune disease |
| 3915393 | TG2 inhibitor* | Pulmonary fibrosis |
| 4381562 | Anti-PVRIG antibody* | Cancer |
| 6097608 | Anti-CD96 antibody* | Cancer |
| XMT-2056 ⁴ (wholly owned by Mersana Therapeutics) | STING agonist ADC* | Cancer |
| belantamab (2857914) | Anti-BCMA antibody | Multiple myeloma |
| 4524101 | DNA polymerase theta inhibitor* ³ | Breast cancer ^{1,3} |
| 4172239 | DNMT1 inhibitor* | Sickle cell disease |

67 potential new vaccines and medicines in pipeline

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

Phase II – 27 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, 2 nd 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 | Gonorrhoea ¹ |
| 4382276 | mRNA* | Seasonal flu |
| 4396687 | mRNA* | COVID-19 |
| 3993129 | Adjuvanted recombinant subunit | Cytomegalovirus ¹ |
| 3036656 | Leucyl t-RNA synthetase inhibitor* | Tuberculosis |
| sanfetrinem cilxetil (GV118819) | Serine beta lactamase inhibitor* | Tuberculosis |
| BVL-GSK098 | Ethionamide booster* | Tuberculosis |
| VIR-2482 | Neutralizing monoclonal antibody* ⁵ | Influenza |
| 3810109 | Broadly neutralizing antibody* | HIV |
| 3739937 | Maturation inhibitor | HIV ⁶ |
| 4004280 | Capsid protein inhibitor | HIV ⁶ |
| 4011499 | Capsid protein inhibitor | HIV ⁶ |
| Benlysta (belimumab) | Anti-BLys antibody | Systemic sclerosis associated interstitial lung disease |
| 3858279 | Anti-CCL17 antibody* | Osteoarthritis pain** |
| 1070806 | Anti-IL18 antibody | Atopic dermatitis ⁶ |
| 4527226 (AL-101) | Anti-sortilin antibody* | Alzheimer's disease ⁶ |
| belrestotug (4428859) | Anti-TIGIT antibody* | Non-small cell lung cancer** |
| 4532990 | HSD17B13 siRNA* | Non-alcoholic steatohepatitis |



*In-licence 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. Phase I study start imminent 4. GSK has an exclusive global license option to co-develop and commercialise the candidate 5. GSK has exclusive option to co-develop post phase II 6. Phase II study start imminent 7. Phase III study start expected in 2023 8. Phase III trial in patients with progranulin gene mutation 9. Approved in US

67 potential new vaccines and medicines in pipeline

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

Phase III / Registration – 17 assets

| | | |
|---------------------------------------|--|---|
| <i>Arexvy</i> (RSV vaccine) | Recombinant protein, adjuvanted* | RSV older adults (50-59 YoA) |
| <i>gepotidacin</i> (2140944) | BTI inhibitor* | Uncomplicated UTI** |
| <i>bepirovirsen</i> (3228836) | Antisense oligonucleotide* | Hepatitis B virus** |
| <i>Bexsero</i> (MenB vaccine) | Recombinant protein, OMV | Meningitis B (infants US) |
| <i>MenABCWY vaccine</i> (3536819) | Recombinant protein, OMV, conjugated vaccine | MenABCWY, 1 st Gen |
| <i>tebipenem pivoxil</i> (3778712) | Antibacterial carbapenem* | Complicated UTI ⁷ |
| <i>ibrexafungerp</i> (5458448) | Antifungal glucan synthase inhibitor* | Invasive candidiasis |
| <i>Nucala</i> (mepolizumab) | Anti-IL5 antibody | COPD |
| <i>depemokimab</i> (3511294) | Long-acting anti-IL5 antibody* | Asthma** |
| <i>latozinemab</i> (4527223) | Anti-sortilin antibody* | Frontotemporal dementia ^{8**} |
| <i>camlipixant</i> (5464714) | P2X3 receptor antagonist | Refractory chronic cough |
| <i>Ojjaara</i> (mometinib) | JAK1, JAK2 and ACVR1 inhibitor* | Myelofibrosis ⁹ |
| <i>Jemperli</i> (dostarlimab) | Anti-PD-1 antibody* | Endometrial cancer ^{^**} |
| <i>Zejula</i> (niraparib) | PARP inhibitor* | Ovarian cancer** |
| <i>Blenrep</i> (belantamab mafodotin) | Anti-BCMA ADC* | Multiple myeloma |
| <i>cobolimab</i> (4069889) | Anti-TIM-3 antibody* | Non-small cell lung cancer |
| <i>limerixibat</i> (2330672) | IBAT inhibitor | Cholestatic pruritus in primary biliary cholangitis |

Infectious diseases pipeline

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

Phase I – 13 assets

| | | |
|--------------------|--|---|
| 4429016 | Bioconjugated recombinant protein, adjuvanted* | <i>K. pneumoniae</i> |
| 4077164 | Bivalent GMMA* | Invasive non-typhoidal salmonella** |
| 3943104 | Recombinant protein, adjuvanted* | Therapeutic herpes simplex virus ¹ |
| 3536867 | Bivalent conjugate* | Salmonella (<i>typhoid + paratyphoid A</i>) |
| 2556286 | Mtb cholesterol dependent inhibitor* | Tuberculosis |
| 3186899 | CRK-12 inhibitor* ² | Visceral leishmaniasis |
| 3494245 | Proteasome inhibitor* | Visceral leishmaniasis |
| 3772701 | <i>P. falciparum</i> 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 |

Phase II – 17 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, 2 nd 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 | Gonorrhoea ¹ |
| 4382276 | mRNA* | Seasonal flu |
| 4396687 | mRNA* | COVID-19 |
| 3993129 | Adjuvanted recombinant subunit | Cytomegalovirus ¹ |
| 3036656 | Leucyl t-RNA synthetase inhibitor* | Tuberculosis |
| sanfetrinem cilxetil (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 (50-59 YoA) |
| 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, 1 st Gen |
| tebipenem pivoxil (3778712) | Antibacterial carbapenem* | Complicated UTI ⁷ |
| ibrexafungerp (5458448) | Antifungal glucan synthase inhibitor* | Invasive candidiasis |



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

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 7. Phase III study start expected in 2023

HIV pipeline

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

Phase I – 2 assets

| | | |
|------------------------|---|-----|
| cabotegravir (1265744) | Integrase inhibitor (400 mg/ml formulation) | HIV |
| 4524184 | Integrase inhibitor* | HIV |

Phase II – 4 assets

| | | |
|---------|--------------------------------|------------------|
| 3810109 | Broadly neutralizing antibody* | HIV |
| 3739937 | Maturation inhibitor | HIV ⁶ |
| 4004280 | Capsid protein inhibitor | HIV ⁶ |
| 4011499 | Capsid protein inhibitor | HIV ⁶ |

Respiratory/Immunology pipeline

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

Phase I – 2 assets

| | | |
|---------|--------------------|--------------------|
| 3888130 | Anti-IL7 antibody* | Autoimmune disease |
| 3915393 | TG2 inhibitor* | Pulmonary fibrosis |

Phase II – 4 assets

| | | |
|-----------------------------|-------------------------|---|
| <i>Benlysta</i> (belimumab) | Anti-BLys antibody | Systemic sclerosis associated interstitial lung disease |
| 3858279 | Anti-CCL17 antibody* | Osteoarthritis pain** |
| 1070806 | Anti-IL18 antibody | Atopic dermatitis ⁶ |
| 4527226 (AL-101) | Anti-sortilin antibody* | Alzheimer's disease ⁶ |

Phase III & Registration – 4 assets

| | | |
|-----------------------------|--------------------------------|---|
| <i>Nucala</i> (mepolizumab) | Anti-IL5 antibody | COPD |
| depemokimab (3511294) | Long-acting anti-IL5 antibody* | Asthma** |
| latozinemab (4527223) | Anti-sortilin antibody* | Frontotemporal dementia ⁸ ** |
| camlipixant (5464714) | P2X3 receptor antagonist | Refractory chronic cough |



*In-licence or other alliance relationship with third party ** Additional indications or candidates also under investigation
 3. Phase I study start imminent 6. Phase II study start imminent 8. Phase III trial in patients with progranulin gene mutation

Oncology pipeline

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

Phase I – 5 assets

| | | |
|--|---------------------------------|------------------------------|
| 4381562 | Anti-PVRIG antibody* | Cancer |
| 6097608 | Anti-CD96 antibody* | Cancer |
| XMT-2056 ⁴ <small>(wholly owned by Mersana Therapeutics)</small> | STING agonist ADC* | Cancer |
| belantamab (2857914) | Anti-BCMA antibody | Multiple myeloma |
| 4524101 | DNA polymerase theta inhibitor* | Breast cancer ^{1,3} |

Phase II – 1 asset

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

Phase III & Registration – 5 assets

| | | |
|---------------------------------------|---------------------------------|-----------------------------------|
| <i>Ojjaara</i> (mometinib) | JAK1, JAK2 and ACVR1 inhibitor* | Myelofibrosis ⁹ |
| <i>Jemperli</i> (dostarlimab) | Anti-PD-1 antibody* | Endometrial cancer ^{^**} |
| <i>Zejula</i> (niraparib) | PARP inhibitor* | Ovarian cancer** |
| <i>Blenrep</i> (belantamab mafodotin) | Anti-BCMA ADC* | Multiple myeloma |
| cobolimab (4069889) | Anti-TIM-3 antibody* | Non-small cell lung cancer |



*In-licence or other alliance relationship with third party ** Additional indications or candidates also under investigation ^ In registration
 1. In phase I/II study 3. Phase I study start imminent 4. GSK has an exclusive global license option to co-develop and commercialise the candidate 9. Approved in US

Opportunity driven pipeline

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

Phase I – 1 asset

4172239 DNMT1 inhibitor* Sickle cell disease

Phase II – 1 asset

4532990 HSD17B13 siRNA* Non-alcoholic steatohepatitis

Phase III & Registration – 1 asset

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

Changes since Q2 2023

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

Changes on pipeline

New to Phase I

- 3915393 – TG2 inhibitor, pulmonary fibrosis
- 4524101 – DNA polymerase theta inhibitor, breast cancer

Removed from Phase I

- 2904545 – Recombinant protein, adjuvanted, *C. difficile*
- 4074386 – Anti-LAG-3 antibody, cancer
- 3745417 – STING agonist, cancer

Progressed to Phase II

- 4382276 – mRNA, seasonal flu
- 4396687 – mRNA, COVID-19
- 3993129 – Adjuvanted recombinant subunit, cytomegalovirus
- 3739937 – Maturation inhibitor, HIV
- 4004280 – Capsid protein inhibitor, HIV
- 4011499 – Capsid protein inhibitor, HIV
- 1070806 – Anti-IL18 antibody, atopic dermatitis
- 4527226 (AL-101) – Anti-sortilin antibody, Alzheimer’s disease

Achieved pipeline catalysts

Regulatory decisions

- *Arexvy* – Adjuvanted recombinant protein, RSV older adults JP
- *Apretude* – Pre-exposure prophylaxis (PrEP) EU
- *Vocabria* – HIV, combination with rilpivirine long-acting injection CN
- *Jemperli*¹ – RUBY, dMMR/MSI-H 1L endometrial cancer US
- *Ojjaara* (momelotinib) – MOMENTUM, myelofibrosis US

Regulatory submissions & acceptances

- *Nucala* – CRSwNP JP
- momelotinib – SIMPLIFY-1 & MOMENTUM, myelofibrosis JP

Other events

- *Arexvy* – 50-59 YoA – Positive phase III data readout
- bepirovirsen – B-TOGETHER phase IIb data, AASLD abstract
- *Shingrix* – Positive phase III data (China)
- tebipenem – FDA SPA agreement for phase III PIVOT-PO study
- *Jemperli*¹ – RUBY, dMMR/MSI-H 1L endometrial cancer – Positive CHMP opinion
- *Jemperli*¹ – RUBY part 1 OS overall population, 1L endometrial cancer – Positive phase III data

Upcoming pipeline catalysts: 2023 and 2024

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

| | H2 2023 | H1 2024 | H2 2024 |
|--|---|---|---|
| Regulatory decision | | <ul style="list-style-type: none"> ■ <i>Jemperi</i>³: RUBY, dMMR/MSI-H 1L EC⁴ EU ■ <i>Ojjaara</i>: MOMENTUM, myelofibrosis EU, JP | <ul style="list-style-type: none"> ■ <i>Arexvy</i>: 50-59 YoA¹ US, EU, JP ■ <i>Nucala</i>: CRSwNP² JP ■ <i>Nucala</i>: severe asthma CN |
| Regulatory submission and acceptance | <ul style="list-style-type: none"> ■ <i>Arexvy</i>: 50-59 YoA¹ US, EU, JP ■ <i>Nucala</i>: CRSwNP² CN | <ul style="list-style-type: none"> ■ MenABCWY vaccine 1st Gen US, EU ■ <i>Jemperi</i>³: RUBY (Part 2), 1L EC⁴ US, EU ■ <i>Jemperi</i>³: RUBY (Part 1), 1L EC⁴ US | <ul style="list-style-type: none"> ■ gepotidacin: EAGLE-2/3, uUTI¹⁰ US ■ depemokimab: SWIFT-1/2, asthma US ■ depemokimab: ANCHOR-1/2, CRSwNP US ■ <i>Nucala</i>: MATINEE, COPD¹¹ US |
| Late-stage phase III and phase II readouts | | <ul style="list-style-type: none"> ■ gepotidacin: EAGLE-1, GC⁵ ■ depemokimab: SWIFT-1/2, asthma ■ <i>Blenrep</i>: DREAMM-7, 2L+ MM⁶ ■ <i>Jemperi</i>³: RUBY (Part 2), 1L EC⁴ ■ <i>Jemperi</i>³: RUBY (Part 1)⁷, 1L EC⁴ ■ <i>Zejula</i>¹: FIRST, 1L maintenance OC⁸ | <ul style="list-style-type: none"> ■ depemokimab: ANCHOR-1/2, CRSwNP² ■ <i>Nucala</i>: MATINEE, COPD¹¹ ■ cobolimab³: COSTAR, 2L NSCLC¹² ■ <i>Blenrep</i>: DREAMM-8, 2L+ MM⁶ ■ <i>Zejula</i>¹: ZEAL, 1L maintenance NSCLC¹² ■ linerixibat: GLISTEN, PBC¹³ |
| | | <ul style="list-style-type: none"> ■ MenABCWY vaccine 2nd Gen⁹ | |



1. Years of age 2. Chronic rhinosinusitis with nasal polyps 3. Tesaro asset 4. Endometrial cancer 5. Urogenital gonorrhoea 6. Multiple myeloma 7. Overall survival population 8. Ovarian cancer
 9. Phase II 10. Uncomplicated urinary tract infection 11. Chronic obstructive pulmonary disorder 12. Non-small cell lung cancer 13. Treatment of cholestatic pruritus in primary biliary cholangitis

Designations in our pipeline

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

Breakthrough Designation

| | | |
|---------|-------|---------------------------------------|
| 5101956 | MAPS* | Adult pneumococcal disease, 24-valent |
|---------|-------|---------------------------------------|

1

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

| | | |
|-----------------------------|---------------------------|---|
| 4382276 | mRNA* | Seasonal flu |
| BVL-GSK098 | Ethionamide booster* | Tuberculosis |
| 4348413 | GMMA | Gonorrhoea |
| 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 ⁹ |
| Jemperli (dostarlimab) | Anti-PD-1 antibody* | Neoadjuvant dMMR/MSI-H 1L rectal cancer |
| 4172239 | DNMT1 inhibitor* | Sickle cell disease |

10

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

Orphan Drug Designation

| | | |
|------------------------------|---------------------------------------|---|
| 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 ⁹ |
| depemokimab (3511294) JP | Long-acting anti-IL5 antibody* | Hypereosinophilic syndrome |
| linciclib (2330672) US, EU | IBAT inhibitor | Cholestatic pruritus in primary biliary cholangitis |

5

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

Qualified Infectious Disease Product Designation

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

2

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



*In-licence or other alliance relationship with third party ^ In registration
9. 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 | <p>Arm A: 1 dose of a combination of the RSVPreF3 antigen Lot 1 and AS01E adjuvant Lot A at day 1</p> <p>Arm B: 1 dose of a combination of the RSVPreF3 antigen Lot 2 and AS01E adjuvant Lot B at day 1</p> <p>Arm C: 1 dose of a combination of the RSVPreF3 antigen Lot 3 and AS01E adjuvant Lot C at Day 1</p> |
| Description | A randomised, double-blind, multi-country trial to evaluate consistency, safety and reactogenicity of 3 lots of RSVPreF3 OA investigational vaccine administered as a single dose in adults aged 60 years and above |
| Timeline | <p>Trial start: Q4 2021</p> <p>Trial end: Q2 2022</p> |
| Key end points | RSVPreF3-binding IgG concentrations at 1 month post vaccination for three lots of RSVPreF3 OA investigational vaccine |
| Clinicaltrials.gov | Link |

NCT05568797 - RSV OA=ADJ-017

| | |
|---------------------------|---|
| Phase | III |
| Patient | Adults aged 65 years and above |
| Subjects | 880 |
| Treatment arms | <p>Arm A: 1 dose RSVPreF3 OA investigational vaccine and 1 dose of FLU aQIV vaccine on Day 1</p> <p>Arm B: one dose of Flu aQIV on day 1 and 1 dose of RSVPreF3 OA on day 31</p> |
| 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 | <p>Trial start: Q4 2022</p> <p>Primary data reported: Q2 2023</p> |
| 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 | <p>Arm A: adults HA-RSVPreF3 OA Group</p> <p>Arm B: adults HA-Placebo Group</p> <p>Arm C: adults AIR-RSVPreF3 OA Group</p> <p>Arm D: adults AIR-Placebo Group</p> <p>Arm E: OA-RSVPreF3 OA Group ≥ 60 years of age</p> |
| 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 | <p>Trial start: Q4 2022</p> <p>Primary data reported: Q4 2023</p> |
| 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 | <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> |
| Description | An open-label, randomised, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with PCV20 in adults aged 60 years and older |
| Timeline | Trial start: Q2 2023 |
| Key end points | Opsonophagocytic antibody titers for each of the pneumococcal vaccine serotypes and RSV-A & RSV-B serum neutralizing titers |
| Clinicaltrials.gov | Link |

Infectious diseases

Arexvy (RSV Older Adults)

NCT05966090 - RSV OA=ADJ-020

| | |
|---------------------------|--|
| Phase | III |
| Patient | Adults aged 50 years and older |
| Subjects | 530 |
| Treatment arms | <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> |
| Description | A phase III, open-label, randomised, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with Herpes Zoster recombinant subunit (HZ/su) vaccine in adults aged 50 years and older |
| Timeline | <p>Trial start: Q3 2023</p> <p>Data anticipated: H2 2024</p> |
| Key end points | <p>Anti-gE antibody concentrations expressed as group geometric mean concentration ratio</p> <p>RSV-A & -B serum neutralizing titers expressed as group geometric mean titer</p> |
| Clinicaltrials.gov | Link |

NCT05921903 - RSV OA=ADJ-023

| | |
|---------------------------|---|
| Phase | IIb |
| Patient | Immunocompromised (IC) adults 50 years of age and above |
| Subjects | 375 |
| Treatment arms | <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> |
| Description | A randomised, controlled, open-label trial to evaluate the immune response and safety of the RSVPreF3 OA investigational vaccine in adults (≥50 years of age) when administered to lung and renal transplant recipients comparing one versus two doses and compared to healthy controls (≥50 years of age) receiving one dose |
| Timeline | Trial start: Q3 2023 |
| 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 gonorrhoea caused by <i>Neisseria gonorrhoeae</i> |
| 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 <i>Neisseria gonorrhoeae</i> |
| 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 gepotidacin + placebo x 5 days Arm B: 100 mg BID nitrofurantoin + placebo x 5 days |
| Description | A randomised, multicentre, parallel-group, double-blind, double-dummy trial in adolescent and adult female participants comparing the efficacy and safety of gepotidacin to nitrofurantoin in the treatment of uncomplicated urinary tract infection (acute cystitis) |
| Timeline | Trial start: Q4 2019 Data reported: Q2 2023 |
| Key end points | Number of participants with therapeutic response (combined per participant clinical and microbiological response) |
| Clinicaltrials.gov | Link |

Infectious diseases

gepotidacin

NCT04187144 - EAGLE 3

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

Infectious diseases

bepirovirsen

NCT05630807 - B-WELL 1

| | |
|---------------------------|--|
| Phase | III |
| Patient | Non-cirrhotic nucleos(t)ide analogue treated patients with chronic hepatitis B virus |
| Subjects | 900 |
| 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 \leq 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 | 900 |
| 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 \leq 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 | 108 |
| 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 | HBV suppressed subjects under nucleo(s)tide treatment |
| Subjects | 184 |
| Treatment arms | ASO24-targeted immunotherapy group (GSK3228836 (24-week treatment) followed by GSK3528869A) ASO24 group (GSK3228836 (24-week treatment) followed by non-active control) ASO12-targeted immunotherapy group (GSK3228836 (12-week treatment) followed by GSK3528869A) ASO12 group (GSK3228836 (12-week treatment) followed by non-active control) |
| 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 | Number of subjects reporting local and general AEs and percentage of participants with sustained virologic response |
| 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 Data anticipated: H2 2023 |
| Key end points | hSBA titers |
| 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 \geq LLOQ of each <i>N. meningitidis</i> serogroup B indicator strain |
| Clinicaltrials.gov | Link |

Infectious diseases

GSK3437949

NCT03276962

| | |
|---------------------------|---|
| Phase | IIb |
| Patient | Children aged 5-17 months |
| Subjects | 1498 |
| Treatment arms | <p>R012-20 Group: a full dose of RTS,S/AS01E at Month 0, Month 1, Month 2 and Month 20</p> <p>R012-14-mD Group: a full dose of RTS,S/AS01E at Month 0, Month 1, Month 2 Month 14, Month 26, Month 38</p> <p>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</p> <p>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</p> <p>Control Group: Subjects will receive rabies vaccine at Month 0, Month 1, Month 2</p> |
| 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 | <p>Trial start: Q3 2017</p> <p>Data anticipated: H2 2023</p> |
| 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

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: H2 2024 |
| Key end points | Anti-measles, anti-mumps, anti-rubella, and anti-glycoprotein H antibodies geometric mean concentrations |
| 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 | <p>Drug: altSonflex Placebo (adults stage 1 in Europe)</p> <p>Biological: altSonflex1-2-3 High Dose C (adults stage 1 in Europe, adults, children and infants stage 2 in Africa)</p> <p>Biological: altSonflex1-2-3 Medium Dose B (children and infants stage 2 in Africa)</p> <p>Biological: altSonflex1-2-3 Low Dose A (infants stage 2 in Africa)</p> <p>Comparators: Menveo and Boostrix (adults stage 2 in Africa)</p> <p>Comparators: Menveo and Typhim Vi (children stage 2 in Africa)</p> <p>Comparators: Menveo and Infanrix (infants stage 2 in Africa)</p> |
| 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 <i>S. sonnei</i> and <i>S. flexneri</i> 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 | <p>Trial start: Q4 2021</p> <p>Data anticipated: 2025+</p> |
| 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

GSK3528869

NCT03866187

| | | |
|---------------------------|---|--|
| Phase | I/II | |
| Patient | HBV suppressed subjects under nucleo(s)tide treatment | |
| Subjects | 148 | |
| Treatment arms | ChAd155-hli-HBV low dose formulation ChAd155-hli-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 2019 Data anticipated: 2025+ | |
| Key end points | Safety and reactogenicity, as well as percentage of patients with >1 log decline of HBsAg | |
| 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 | <p>Combination Product: MenABCWY-2Gen low dose vaccine</p> <p>Combination Product: MenABCWY-2Gen high dose vaccine</p> <p>Combination Product: Placebo</p> <p>Combination Product: MenB vaccine</p> <p>Biological: MenACWY vaccine</p> |
| 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 | <p>Trial start: Q2 2021</p> <p>Data anticipated: H1 2024</p> |
| Key end points | <p>AEs, including all SAEs, AEs leading to withdrawal and AEs of special interest (AESIs)</p> <p>Immunological vaccine effectiveness by enc-hSBA and immunogenicity by hSBA on indicator strains</p> |
| Clinicaltrials.gov | Link |



NCT05082285

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

Infectious diseases

GSK4178116

NCT05084508

| | |
|---------------------------|---|
| Phase | II |
| Patient | Healthy children between 12-15 months |
| Subjects | 800 |
| Treatment arms | <p>Arm A: low potency varicella NS vaccine, plus routine schedule</p> <p>Arm B: medium potency varicella NS vaccine, plus routine schedule</p> <p>Arm C: high potency varicella NS vaccine, plus routine schedule</p> <p>Arm D: marketed varicella vaccine lot 1, plus routine schedule</p> <p>Arm E: marketed varicella vaccine lot 2, plus routine schedule</p> |
| 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 | <p>Trial start: Q4 2021</p> <p>Data anticipated: H1 2024</p> |
| 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 | <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 administered intramuscularly 4 times within 12 months</p> |
| 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 | <p>Trial start: Q2 2022</p> <p>Data anticipated: 2025+</p> |
| 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 | <p>Arm A: HPV9 High formulation</p> <p>Arm B: HPV9 Medium formulation</p> <p>Arm C: HPV9 Low formulation</p> <p>Arm D: Gardasil 9</p> |
| 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 | <p>Trial start: Q3 2022</p> <p>Data anticipated: H1 2024</p> |
| Key end points | AEs, SAEs, anti-HPV IgG 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 <i>Neisseria gonorrhoeae</i> 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 gonorrhoea in trial phase II | |
| Clinicaltrials.gov | Link | |

Infectious diseases

GSK4396687

NCT05960097

| | |
|---------------------------|--|
| Phase | II |
| Patient | Adults at least 18 years old |
| Subjects | 415 |
| Treatment arms | <p>Arm A: CV0701 bivalent high dose</p> <p>Arm B: CV0701 bivalent medium dose</p> <p>Arm C: CV0701 bivalent low dose</p> <p>Arm D: CV0601 monovalent high dose</p> <p>Arm E: Control vaccine</p> |
| Description | A randomized, active-controlled, observer-blind study to assess the safety, reactogenicity, and immunogenicity of a booster dose of investigational COVID-19 mRNA vaccines in healthy adults who previously received a complete primary vaccination series with or without booster dose(s) |
| Timeline | <p>Trial start: Q3 2023</p> <p>Data anticipated: H1 2024</p> |
| Key end points | <p>Serum neutralizing titers against pseudoviruses bearing SARS-CoV-2 spike proteins at Day 29</p> <p>Percentage of participants with solicited local AE during 7 days after vaccination</p> |
| Clinicaltrials.gov | Link |

Infectious diseases

GSK3993129

NCT05089630

| | |
|---------------------------|---|
| Phase | I/II |
| Patient | Healthy adults 18 to 50 years of age |
| Subjects | 329 |
| Treatment arms | <p>Arm A: pentamer (low)/gB(low)/adjuvant vaccine</p> <p>Arm B: pentamer (med)/gB(low)/adjuvant vaccine</p> <p>Arm C: pentamer (med)/gB(med)/adjuvant vaccine</p> <p>Arm D: pentamer (high)/gB(med)/adjuvant vaccine</p> <p>Arm F: placebo (saline)</p> |
| 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 | <p>Trial start: Q4 2021</p> <p>Data anticipated: H2 2024</p> |
| Key end points | Safety, reactogenicity and immunogenicity |
| Clinicaltrials.gov | Link |

Infectious diseases

GSK3036656

NCT05382312

| | |
|---------------------------|--|
| Phase | Ila |
| Patient | Males and females aged 18 to 65 years inclusive with drug-sensitive (rifampicin-susceptible) pulmonary tuberculosis |
| Subjects | 55 |
| Treatment arms | <p>Arm A: Participants receiving GSK3036656+bedaquiline</p> <p>Arm B: Participants receiving GSK3036656+delamanid</p> <p>Arm C: Participants receiving bedaquiline+delamanid</p> <p>Arm D: Participants receiving RIFAFOUR e-275</p> |
| 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 | <p>Trial start: Q3 2022</p> <p>Data anticipated: H1 2024</p> |
| Key end points | Change from baseline in log ₁₀ CFU of <i>Mycobacterium tuberculosis</i> |
| Clinicaltrials.gov | Link |

Infectious diseases

GSK4429016

NCT04959344

| | |
|--------------------|---|
| Phase | I/II |
| Patient | Healthy adults |
| Subjects | 166 |
| Treatment arms | <p>Arm A: Kleb4V target dose</p> <p>Arm B: Kleb4V target dose + AS03</p> <p>Arm C: Kleb4V low dose</p> <p>Arm D: Kleb4V low dose + AS03</p> <p>Arm F: placebo (diluent)</p> |
| Description | Safety and immunogenicity of a <i>Klebsiella pneumoniae</i> tetravalent bioconjugate vaccine (Kleb4V) |
| Timeline | <p>Study start: Q3 2021</p> <p>Study end: Q2 2022</p> |
| Key end points | Occurrence, severity and relationship of solicited local and general AEs |
| Clinicaltrials.gov | Link |

Infectious diseases

GSK4382276

NCT05446740

| | | | | | | | | | | | |
|---------------------------|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------------|--------------------------|--------------------------------|
| Phase | I | | | | | | | | | | |
| Patient | Healthy younger and older adults | | | | | | | | | | |
| Subjects | 324 | | | | | | | | | | |
| Treatment arms | <table border="0"> <tr> <td>GSK4382276A Dose level 1</td> <td>GSK4382276A Dose level 7</td> </tr> <tr> <td>GSK4382276A Dose level 2</td> <td>GSK4382276A Dose level 8</td> </tr> <tr> <td>GSK4382276A Dose level 3</td> <td>GSK4382276A Dose level 9</td> </tr> <tr> <td>GSK4382276A Dose level 4</td> <td>Combination Product: FDQ21A-NH</td> </tr> <tr> <td>GSK4382276A Dose level 6</td> <td>Combination Product: FDQ22A-NH</td> </tr> </table> | 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 |
| 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 | <p>Trial start: Q3 2022</p> <p>Final data anticipated: H1 2024</p> | | | | | | | | | | |
| Key end points | <p>Safety and reactogenicity, including number of participants reporting systemic and solicited administration site events</p> <p>Serum anti-influenza seroconversion rates and geometric mean titers</p> | | | | | | | | | | |
| Clinicaltrials.gov | Link | | | | | | | | | | |

NCT05823974

| | |
|---------------------------|---|
| Phase | I/II |
| Patient | Healthy younger and older adults |
| Subjects | 1512 |
| Treatment arms | <p>Biological: Flu mRNA</p> <p>Combination Product: Control 1</p> <p>Combination Product: Control 2</p> |
| Description | A randomized, dose-finding/dose-confirmation study to evaluate the reactogenicity, safety and immunogenicity of mRNA-based multivalent seasonal influenza vaccine candidates administered in healthy younger and older adults |
| Timeline | <p>Trial start: Q2 2023</p> <p>Final data anticipated: H2 2024</p> |
| Key end points | <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> |
| 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 B: iNTS-GMMA and TCV low doses group - Europe Arm C: Step 1 group (placebo) - Europe Arm D: iNTS-TCV full dose_1 group - Europe Arm E: iNTS-GMMA and TCV full doses_1 group - Europe | Arm F: Step 2 group (placebo) - Europe Arm G: iNTS-TCV full dose_2 group - Africa Arm H: iNTS-GMMA and TCV full doses_2 group - Africa Arm I: Stage 2 group (control) - Africa |
| 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

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 Data anticipated: H2 2024 | |
| 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

GSK3536867

NCT05613205

| | |
|---------------------------|--|
| Phase | I |
| Patient | Healthy adults aged 18-50 years in Europe |
| Subjects | 96 |
| Treatment arms | <p>Arm A: Step 1a low dose without adjuvant group</p> <p>Arm B: Step 1a control group</p> <p>Arm C: Step 1b low dose with adjuvant group</p> <p>Arm D: Step 1b control group</p> <p>Arm E: Step 2 full dose without adjuvant group</p> <p>Arm F: Step 2 full dose with adjuvant group</p> <p>Arm G: Step 2 control group</p> |
| 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 | <p>Trial start: Q4 2022</p> <p>Data anticipated: H1 2024</p> |
| 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 | <p>Arm A: Part A - GSK2556286 with up to 11 cohorts</p> <p>Arm B: Part A - placebo</p> <p>Arm C: Part B - GSK2556286 with up to 4 cohorts</p> <p>Arm D: Part B - placebo</p> |
| 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 | <p>Trial start: Q4 2020</p> <p>Data anticipated: H1 2024</p> |
| Key end points | SAEs and non-SAEs |
| Clinicaltrials.gov | Link |

Infectious diseases

GSK3494245

NCT04504435

| | |
|---------------------------|--|
| Phase | I |
| Patient | Healthy adult males |
| Subjects | 54 |
| Treatment arms | <p>Cohort 1: maximum of 3 ascending doses GSK3494245 starting at 20 mg and placebo (fasted)</p> <p>Cohort 2: maximum of 3 ascending doses GSK3494245 starting at dose level 5 and placebo (fasted)</p> <p>Cohort 3: Participants receiving GSK3494245 (fasted then fed)</p> <p>Cohort 3: Participants receiving GSK3494245 (fed then fasted)</p> |
| 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 | <p>Trial start: Q3 2020</p> <p>Data anticipated: H2 2024</p> |
| Key end points | Number of participants with AEs and SAEs |
| Clinicaltrials.gov | Link |

Infectious diseases

GSK3882347

NCT05138822

| | |
|---------------------------|--|
| Phase | 1b |
| 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 | 1b |
| 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 |

HIV

HIV

VH3810109

NCT04871113 - B-NAB

| | |
|---------------------------|---|
| Phase | II |
| Patient | Anti-retroviral naïve HIV-1 infected adults |
| Subjects | 62 |
| Treatment arms | <p>Part 1</p> <p>Cohort 1: '109A infusion (40mg/kg)</p> <p>Cohort 2: '109A infusion (280 mg/kg)</p> <p>Part 2</p> <p>Cohort 3: '109A IV or SC – dosing determined from part 1</p> <p>Cohort 4: '109A IV or SC – dosing determined from part 1</p> <p>Cohort 5: '109A IV or SC – dosing determined from part 1</p> |
| 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 | <p>Trial start: Q2 2021</p> <p>Data anticipated: H2 2023</p> |
| Key end points | Safety, plasma HIV-1 levels |
| Clinicaltrials.gov | Link |



NCT05996471

| | |
|---------------------------|--|
| Phase | IIb |
| Patient | Antiretroviral therapy (ART)-experienced adults living with HIV |
| Subjects | 150 |
| Treatment arms | <p>Group 1: VH3810109 + cabotegravir</p> <p>Group 2: VH3810109 + rHuPH20 + cabotegravir</p> <p>Group 3: Active comparator - Participants receiving standard of care (SOC) antiretroviral therapy (ART)</p> |
| Description | A multicentre, randomised, open-label, trial comparing the efficacy, safety, PK, and tolerability of VH3810109, administered either intravenously or as a subcutaneous infusion with rHuPH20, in combination with cabotegravir given intramuscularly, to standard of care in virologically suppressed, antiretroviral therapy (ART)-experienced adults living with HIV |
| Timeline | <p>Trial start: Q3 2023</p> <p>Data anticipated: H2 2024</p> |
| Key end points | Safety, plasma HIV-1 levels |
| Clinicaltrials.gov | Link |

HIV

VH3739937

NCT06061081

| | |
|---------------------------|--|
| Phase | II |
| Patient | Treatment-naïve adults living with HIV-1 |
| Subjects | 26 |
| Treatment arms | Arm A: VH3738837 Arm B: placebo |
| Description | A randomized, double-blind (sponsor-unblinded), placebo-controlled, adaptive study to investigate the antiviral effect, safety, tolerability and pharmacokinetics of VH3739937 in treatment-naïve adults living with HIV-1 |
| Timeline | Trial start anticipated: H2 2023 Data anticipated: H1 2024 |
| Key end points | AEs and SAEs, concentrations of VH3738837 |
| Clinicaltrials.gov | Link |

HIV

VH4004280 & VH4011499

NCT06012136

| | |
|---------------------------|--|
| Phase | I |
| Patient | Healthy adults |
| Subjects | 160 |
| Treatment arms | Arm A: VH4004280 Arm B: Placebo Arm C: VH4011499 |
| Description | A double-blind (sponsor-unblinded), placebo-controlled, randomized, single dose escalation study to evaluate the safety, tolerability, and pharmacokinetics of a parenterally administered suspension of investigational capsid inhibitors in healthy adults |
| Timeline | Trial start: Q3 2023 Data anticipated: 2025+ |
| Key end points | AEs, PK |
| Clinicaltrials.gov | Link |

NCT06039579

| | |
|---------------------------|--|
| Phase | II |
| Patient | HIV-1 infected treatment-naïve adults |
| Subjects | 42 |
| Treatment arms | Arm A: VH4004280 Arm B: VH4011499 Arm C: VH4004280-matching placebo Arm D: VH4011499-matching placebo |
| Description | A randomized, double-blind (sponsor-unblinded), placebo-controlled trial to investigate the antiviral effect, safety, tolerability and pharmacokinetics of orally administered investigational capsid inhibitor monotherapy in HIV-1 infected treatment-naïve adults |
| Timeline | Trial start anticipated: H2 2023 Data anticipated: H1 2024 |
| Key end points | Maximum change from baseline (Day 1) in plasma HIV-1 RNA |
| 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

VH4524184

NCT05631704

| | |
|---------------------------|---|
| Phase | I |
| Patient | Healthy participants |
| Subjects | 84 |
| Treatment arms | <p>Arm A: Part 1 cohort 1 - VH4524184 DL1</p> <p>Arm B: Part 1 cohort 1 - placebo</p> <p>Arm C: Part 1 cohort 2 - VH4524184 DL2</p> <p>Arm D: Part 1 cohort 2 - placebo</p> <p>Arm E: Part 1 cohort 3 - VH4524184 DL3</p> <p>Arm F: Part 1 cohort 3 - placebo</p> <p>Arm G: Part 1 cohort 4 - VH4524184 DL4</p> <p>Arm H: Part 1 cohort 4 - placebo</p> <p>Arm I: Part 1 cohort 5 - VH4524184 DL5</p> <p>Arm J: Part 1 cohort 5 - placebo</p> <p>Arm K: Part 2 cohort 7 - VH4524184 RL1</p> <p>Arm L: Part 2 cohort 7 - placebo</p> <p>Arm M: Part 2 cohort 8 - VH4524184 RL2</p> <p>Arm N: Part 2 cohort 8 - placebo</p> <p>Arm O: Part 3 cohort 10 - VH4524184 fasted / VH4524184 fed</p> |
| 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 | <p>Trial start: Q4 2022</p> <p>Data anticipated: H2 2023</p> |
| 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 | 806 |
| Treatment arms | Arm A: placebo Arm B: mepolizumab |
| Description | A multicentre randomised, double-blind, parallel-group, placebo-controlled trial of mepolizumab 100 mg subcutaneously as add-on treatment in participants with COPD experiencing frequent exacerbations and characterised by eosinophil levels |
| Timeline | Trial start: Q4 2019 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: H1 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: H1 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 verbal response scale (VRS) score from Week 49 through to Week 52 |
| Clinicaltrials.gov | Link |

NCT05281523 - ANCHOR-2

| | |
|---------------------------|---|
| Phase | III |
| Patient | Adults with chronic rhinosinusitis with nasal polyps (CRSwNP) |
| Subjects | 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 verbal response scale (VRS) score from Week 49 through to Week 52 |
| 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 2022 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 | 825 |
| Treatment arms | Arm A: camlipixant 25 mg twice a day Arm B: camlipixant 50 mg twice a day Placebo twice a day |
| Description | A 52-week, randomised, double-blind, placebo-controlled, parallel-arm efficacy and safety study with open-label extension of camlipixant in adult participants with refractory chronic cough, including unexplained chronic cough |
| Timeline | Trial start: Q4 2022 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 | 825 |
| Treatment arms | Arm A: camlipixant 25 mg twice a day Arm B: camlipixant 50 mg twice a day Placebo twice a day |
| Description | A 24-week, randomised, double-blind, placebo-controlled, parallel-arm efficacy and safety study with open-label extension of camlipixant in adult participants with refractory chronic cough, including unexplained chronic cough |
| Timeline | Trial start: Q1 2023 Data anticipated: 2025+ |
| Key end points | 24-hour cough frequency |
| Clinicaltrials.gov | Link |

Respiratory/Immunology

Benlysta (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: Q4 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: 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: H2 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

GSK1070806

NCT05999799

| | |
|---------------------------|---|
| Phase | IIb |
| Patient | Patients with moderate to severe atopic dermatitis |
| Subjects | 175 |
| Treatment arms | <p>Arm A: GSK1070806 dose 1</p> <p>Arm B: GSK1070806 dose 2</p> <p>Arm C: GSK1070806 dose 3</p> <p>Arm D: GSK1070806 dose 4</p> <p>placebo</p> |
| Description | A randomized, double-blind, parallel group, placebo-controlled dose finding study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of GSK1070806 SC injection |
| Timeline | <p>Trial start anticipated: H2 2023</p> <p>Data anticipated: 2025+</p> |
| Key end points | Percent change from baseline in eczema area and severity index (EASI) at Week 16 |
| Clinicaltrials.gov | Link |

Respiratory/Immunology

GSK3888130

NCT05131971

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

Oncology

Oncology

Ojjaara (mometotinib)

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 | 150 |
| 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: Q3 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 | <p>Substudy 1: belantamab mafodotin + OX40 (GSK3174998)</p> <p>Substudy 2: belantamab mafodotin + feladilimab</p> <p>Substudy 3: belantamab mafodotin + nirogacestat (GSI)</p> <p>Substudy 4: belantamab mafodotin + dostarlimab</p> <p>Substudy 5: belantamab mafodotin + isatuximab</p> <p>Substudy 6: belantamab mafodotin + nirogacestat + lenalidomide + dexamethasone</p> <p>Substudy 7: belantamab mafodotin + nirogacestat + pomalidomide + dexamethasone</p> |
| 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 | <p>Trial start: Q4 2019</p> <p>Data anticipated: 2025+</p> |
| Key end points | <p>Dose escalation phase: DLT, safety, ORR</p> <p>Cohort expansion phase: ORR, CBR, safety</p> |
| Clinicaltrials.gov | Link |

NCT03544281 - DREAMM-6

| | |
|---------------------------|--|
| Phase | I/II |
| Patient | Participants with relapsed/refractory multiple myeloma (RRMM) |
| Subjects | 152 |
| Treatment arms | <p>Arm A: belantamab mafodotin + lenalidomide + dexamethasone</p> <p>Arm B: belantamab mafodotin + bortezomib + dexamethasone</p> |
| 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 | <p>Trial start: Q3 2018</p> <p>Data anticipated: H1 2024</p> |
| Key end points | DLT, safety, ORR, PK |
| Clinicaltrials.gov | Link |

Oncology

Blenrep (belantamab mafodotin)

NCT04246047 - DREAMM-7

| | |
|---------------------------|---|
| Phase | III |
| Patient | Participants with relapsed/refractory multiple myeloma (RRMM) |
| Subjects | 571 |
| Treatment arms | Arm A: belantamab mafodotin + bortezomib + dexamethasone (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: H1 2024 |
| Key end points | PFS, CRR, ORR, DoR, TTR, TTP, OS, PFS2, MRD negativity rate, safety |
| Clinicaltrials.gov | Link |

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 2024 |
| Key end points | PFS, MRD negativity rate, ORR, CRR, VGPR or better rate, DoR, TTBR, TTR, TTP, OS, PFS2, safety |
| Clinicaltrials.gov | Link |

Oncology

Blenrep (belantamab mafodotin)

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 |

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 |

Oncology

Blenrep (belantamab mafodotin)

NCT04398680 - DREAMM-13

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

NCT05064358 - DREAMM-14

| | |
|--------------------|--|
| Phase | II |
| Patient | Participants with relapsed/refractory multiple myeloma (RRMM) |
| Subjects | 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 \geq 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 |

NCT06062420 - GALAXIES H&N-202

| | |
|---------------------------|---|
| Phase | II |
| Patient | Participants with recurrent/metastatic PD-L1 positive squamous cell carcinoma of the head and neck |
| Subjects | 360 |
| Treatment arms | Arm A: dostarlimab monotherapy Arm B: dostarlimab and belrestotug Arm C: dostarlimab and GSK6097608 Arm D: dosarlimab and belrestotug and GSK6097608 |
| Description | A randomized, open-label, platform study using a master protocol to evaluate novel immunotherapy combinations as first-line treatment in participants with recurrent/metastatic PD-L1 positive squamous cell carcinoma of the head and neck |
| Timeline | Trial start anticipated: H2 2023 Data anticipated: 2025+ |
| Key end points | ORR |
| Clinicaltrials.gov | Link |

Oncology

belrestotug

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

GSK6097608

NCT04446351

| | |
|---------------------------|--|
| Phase | I |
| Patient | Participants with advanced solid tumours |
| Subjects | 184 |
| Treatment arms | <p>Arm A: GSK6097608</p> <p>Arm B: GSK6097608 + dostarlimab</p> <p>Arm C: dostarlimab</p> <p>Arm D: dostarlimab + belrestotug</p> <p>Arm E: dostarlimab + belrestotug + GSK6097608</p> <p>Arm D: dostarlimab + cobolimab</p> |
| Description | A first time in human, open-label trial of GSK6097608 administered as monotherapy and in combination with anticancer agents |
| Timeline | <p>Trial start: Q1 2020</p> <p>Data anticipated: 2025+</p> |
| 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 |

Oncology

GSK4524101

NCT06077877

| | |
|---------------------------|---|
| Phase | I/II |
| Patient | Adult participants with solid tumors |
| Subjects | 112 |
| Treatment arms | <p>Arm A, Part 1: GSK4524101 monotherapy</p> <p>Arm B, Part 1: GSK4524101 plus Niraparib</p> <p>Arm C, Part 1: GSK4524101 food effect cohort</p> <p>Arm D, Part 2: GSK4524101 plus Niraparib</p> <p>Arm E, Part 2: Niraparib</p> |
| Description | A first-time-in-human, open-label, multicentre, dose escalation and expansion study of the oral DNA Polymerase Theta inhibitor (POLQi) GSK4524101 and the PARP inhibitor (PARPi) <i>Niraparib</i> in adult participants with solid tumors |
| Timeline | <p>Trial start anticipated: H2 2023</p> <p>Data anticipated: 2025+</p> |
| Key end points | DLTs, AEs, SAEs, ORR |
| 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 - HORIZON

| | |
|---------------------------|--|
| 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: Q3 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-free 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 | Multiple 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 survival |
| PBC | Primary biliary 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 |