27 July 2022

Innovation: Clinical trials summary

Q2 2022

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R&D pipeline
68 potential vaccines and medicines

Phase I

- **2904545*** (recombinant protein)ǂ *C. difficile*
- **4429016*** (bioconjugated, recombinant protein)ǂ *K. pneumoniae*
- **3993129** (recombinant subunit)ǂ CMV
- **4382276*** (mRNA) flu
- **4396687*** (mRNA) COVID-19
- **4077164*** (bivalent GMMA) iNTS (*Typhimurium + Enteritidis*)
- **3943104*** (recombinant protein)ǂ Therapeutic HSV
- **BVL-GSK098*** (ethionamide booster) tuberculosis
- **VIR-2482*** (neutralizing monoclonal antibody)^ influenza
- **2556286*** (Mtb inhibitor) tuberculosis
- **3186899*** (CRK-12 inhibitor) visceral leishmaniasis[2]
- **3494245*** (proteasome inhibitor) visceral leishmaniasis
- **3882347*** (FimH antagonist) uUTI
- **3923868** (PI4kβ inhibitor) viral COPD exacerbations
- **4182137*** (VIR-7832 monoclonal antibody) COVID-19[1]
- **3965193** (PAPD 5/7 inhibitor) HBV
- **3739937** (maturation inhibitor) HIV
- **cabotegravir** (400 mg/ml formulation) HIV
- **4004280** (capsid protein inhibitor) HIV
- **4011499** (capsid protein inhibitor) HIV
- **3745417** (STING agonist) cancer
- **3845097*** (NY-ESO-1/dnTGFb TCR T) cancer
- **3901961*** (NY-ESO-1/CD8a TCR T) cancer
- **4074386*** (LAG3 antagonist) cancer
- **4362676*** (Mat2A inhibitor) cancer
- **4428859*** (TIGIT antagonist) cancer
- **6097608** (CD96 antagonist) cancer
- **4381562*** (PVRIG antagonist) cancer
- **4527226*** (AL101, anti-sortilin) neurodegenerative diseases
- **3858279*** (anti-CCL17) osteoarthritis pain
- **3915393*** (TG2 inhibitor) celiac disease
- **1070806** (anti-IL18) atopic dermatitis
- **3888130*** (anti-IL7) multiple sclerosis
- **4532990*** (ARO-HSD siRNA) non-alcoholic steatohepatitis
- **3884464*** heart failure

Phase II

- **3437949*** (recombinant protein)ǂ Malaria fractional dose
- **3878858*** (bioconjugated, recombinant protein)ǂ *S. aureus*[1]
- **4069327*** (bioconjugated, tetravalent) *Shigella***
- **3528869*** (viral vector with recombinant protein)ǂ Therapeutic HBV[1]
- **4023393** (conjugated, recombinant protein) MenABCWY 2nd gen[1]
- **4178116** (live, attenuated) Varicella new strain
- **bepirovirsen*** (HBV ASO) HBV
- **3036656*** (leucyl t-RNA inhibitor) tuberculosis
- **sanfetrinem cilexetil*** (serine beta lactamase inhibitor) tuberculosis
- **3640254** (maturation inhibitor) HIV
- **3810109*** (broadly neutralizing antibody) HIV
- **cobolimab*** (TIM-3 antagonist) NSCLC

Phase III/Registration

- **Bexsero infants US** (recombinant protein) MenB
- **Covifenz** (Medicago)* COVID-19ǂǂ
- **4353001** (Sanofi)* COVID-19ǂǂ
- **SKYCovione** (SK Bioscience)* COVID-19ǂǂ
- **3536819** (conjugated, recombinant protein) MenABCWY 1st gen
- **Menveo** (conjugated liquid formulation) MenACWY
- **Rotarix liquid US** (live attenuated, PCV free) rotavirus
- **3844766*** (recombinant protein)ǂ RSV older adults
- **gepotidacin*** (BTI inhibitor) uUTI and GC
- **Xevudy*** (sotrovimab/VIR-7831 monoclonal antibody) COVID-19
- **Blenrep*** (anti-BCMA ADC) multiple myeloma
- **Jemperli*** (PD-1 antagonist) 1L endometrial cancer**
- **letetresgene-autoleucel*** (NY-ESO-1 TCR) SS/MRCLS[3]
- **Zejula*** (PARP inhibitor) ovarian, lung and breast cancer
- **momelotinib*** (JAK1/2 and ACVR1/ALK2 inhibitor) myelofibrosis
- **latozinemab* (AL001, anti-sortilin)** frontotemporal dementia[4]**
- **depemokimab* (LA IL5 antagonist)** asthma**
- **Nucala (IL5 antagonist)** COPD
- **otilimab* (aGM-CSF inhibitor)** rheumatoid arthritis
- **daprodustat (HIF-PHI)** anaemia of chronic kidney disease
- **linerixibat (IBATi)** cholestatic pruritus in primary biliary cholangitis

- Infectious Diseases
- HIV (ViiV)
- Oncology
- Immunology/Respiratory
- Opportunity Driven

Note: Only the most advanced indications are shown for each asset

*In-license or other alliance relationship with third party; **Additional indications or candidates also under investigation; ǂ adjuvanted; ǂǂ GSK contributing pandemic adjuvant ^GSK has exclusive option to co-develop post Ph2

1. In Phase 1/2 study 2. Transition activities underway to enable further progression by partner 3. In potentially registrational Ph2 trial 4. Ph3 trial in patients with progranulin gene mutation

CMV: Cytomegalovirus; GMMA: Generalized Modules for Membrane Antigens; iNTS: invasive non-typhoidal salmonella; HSV: Herpes simplex virus; uUTI: uncomplicated urinary tract infection; COPD: chronic obstructive pulmonary disease; siRNA: small interfering RNA; HBV: Hepatitis B virus; ASO: antisense oligonucleotide; TCR T: T-cell receptor therapy; NSCLC: non-small cell lung cancer; MenB: Meningitis B; PCV: Porcine circovirus; RSV: Respiratory syncytial virus; GC: gonorrhea; ADC: antibody drug conjugate; SS: synovial sarcoma ; MRCLS: myxoid/round cell liposarcoma

Infectious diseases

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
gepotidacin	Phase III **EAGLE 1**	Uncomplicated urogenital gonorrhea patients	**Arm A:** 8x 750mg gepotidacin for one day **Arm B:** ceftriaxone (500mg IM), 1g azithromycin)	600	Bacterial eradication/ cure; 4-8 days post treatment	Start Oct 2019	NCT04010539	A Phase III, Randomised, Multicenter, Open-Label Study in Adolescent and Adult Participants Comparing the Efficacy and Safety of Gepotidacin to Ceftriaxone Plus Azithromycin in the Treatment of Uncomplicated Urogenital Gonorrhea Caused by Neisseria gonorrhoeae
gepotidacin	Phase III **EAGLE 2**	Females with uUTI / acute cystitis	**Arm A:** 1500mg BID gepotidacin x 5 days **Arm B:** nitrofurantoin100mg plus placebo po BID x 5 days	2500	Therapeutic response/ Cure	Start Oct 2019	NCT04020341	A Phase III, Randomised, Multicenter, Parallel-Group, Double-Blind, Double-Dummy Study 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)
gepotidacin	Phase III **EAGLE 3**	Females with uUTI / acute cystitis	**Arm A:** 1500mg BID gepotidacin x 5 days **Arm B:** nitrofurantoin100mg po BID x 5 days	2500	Therapeutic response/ Cure	Start Apr 2020	NCT04187144	A Phase III, Randomized, Multicenter, Parallel-Group, Double-Blind, Double-Dummy Study 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)

Infectious diseases

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
bepirovirsen/ GSK3228836	Phase II **B-Together**	Patients with Chronic Hepatitis B (CHB)	**Arm 1:** bepirovirsen for 12 wks + PegIFN for =< 24 wks **Arm 2:** bepirovirsen for 24 weeks + PegIFN =< 24 wks	100	Sustained virologic response for 24 weeks post treatment	Start Jan 2021	NCT04676724	A Phase IIb Multi-Center, Randomised, Open Label Study to Assess the Efficacy and Safety of Sequential Treatment with GSK3228836 followed by Pegylated Interferon Alpha 2a in Participants with Chronic Hepatitis B Virus
bepirovirsen	Phase II **B-Clear**	Patients with Chronic Hepatitis B (CHB)	**Treatment Naiive** **Arm 1:** bepi 300 mg w/LD **Arm 2:** bepi 300mg w/LD, Bepi 150mg **Arm 3:** bepi 300 mg, Pbo **Arm 4:** Pbo, bepi 300 mg **Receiving stable nucleos(t)ide treatment** **Arm 1:** bepi 300 mg **Arm 2:** bepi 300mg, bepi 150 mg **Arm 3:** bepi 300 mg, Pbo **Arm 4:** Pbo, bepi 300 mg	457	Sustained virologic response for 48 weeks post treatment	Start Jul 2020; Interim end of treatment data reported	NCT04449029	Phase IIb Multi-Center, Randomised, Partial-Blind Parallel Cohort Study to Assess the Efficacy and Safety of Treatment with GSK3228836 in Participants with Chronic Hepatitis B Virus (B-Clear)

Pbo: Placebo,
LD loading dose

Infectious diseases

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
Shingrix	Phase III **ZOSTER-059**	*Shingrix* co-administered with Prevnar13 in adults aged 50 years and older	Control Group; Co-Ad Group	913	Anti-pneumococcal Antibodies; Anti-gE Antibody; Anti-pneumococcal Antibody Titers, Anti-gE Antibody Concentrations; safety	Complete	NCT03439657	A Phase IIIB, randomised, open-label, multicenter clinical trial to assess the immunogenicity and safety of GSK Biologicals' Herpes Zoster vaccine GSK1437173A when co-administered with Prevenar13™ in adults aged 50 years and older.
Shingrix	Phase III **ZOSTER-062**	*Shingrix* two-dose schedule in adults ≥ 50 years of age with a prior episode of Herpes Zoster	Shingrix, Placebo	1426	Number of confirmed Herpes Zoster (HZ) cases	Start Sep 2019	NCT04091451	A study to evaluate the safety and immunogenicity of GSK's Herpes Zoster subunit vaccine (HZ/su) when given on a two-dose schedule to adults at least 5 years of age (YOA) who had prior episode of shingles

Infectious diseases

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
RSV OA	Phase III **RSV OA-004**	Adults >60 yo	**Arm 1:** RSV vaccine administered Day 1, and at 12 months and 24 months **Arm 2:** RSV vaccine administered Day 1; revaccination may be given whenever needed **Arm 3:** RSV vaccine administered Day 1	1717	RSV-A neutralising antibody titres	Start Feb 2021	NCT04732871	A Phase 3, Randomised, Open-label, Multi-country Study 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
RSV OA	Phase III **RSV OA-007**	Adults >60 yo	**Arm 1;** RSV OA + FLU-QIV on Day 1 **Arm 2:** FLU-QIV on Day 1, RSV OA on Day 31	880	RSV-A neutralising antibody titres 1 month after vaccination	Start Apr 2021	NCT04841577	A Phase 3, Open-label, Randomised, Controlled, Multi-country Study 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
RSV OA	Phase III **RSV OA-006**	Adults >60	RSVPre F3 OA Lot 1 RSVPre F3 OA Lot 2 RSVPre F3 OA Lot 3 RSVPre F3 OA Lot 4 Placebo	26,665	RSV associated LRTD	Start May 2021	NCT04886596	A Phase 3, Randomised, Placebo-controlled, Observer-blind, Multi-country Study to Demonstrate the Efficacy of a Single Dose of GSK's RSVPreF3 OA Investigational Vaccine in Adults Aged 60 Years and Above

Infectious diseases

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
MenABCWY	Phase III **MenABCWY – 019**	Participants aged 15- 25 years	**Arm 1:** 2 doses of MenABCWY days 1, 181 + placebo day 211 **Arm 2:** 1 dose MenABCWY day 1; 2 doses of MenB on Day 181 and Day 211	1206	hSBA titres	Start 1Q 2021	NCT04707391	A Phase IIIB, Randomised, Controlled, Observer-blind Study to Evaluate Safety and Immunogenicity of GSK's Meningococcal ABCWY Vaccine When Administered in Healthy Adolescents and Adults, Previously Primed With Meningococcal ACWY Vaccine
MenABCWY	Phase III **MenABCWY 2Gen-038**	Participants aged 10- 25 years	**Arm 1:** rMenB+OMV NZ (2/3 dose schedule) plus MenACWY **Arm 2:** rMenB+OMV NZ (2 dose schedule) plus MenACWY plus placebo **Arm 3:** placebo + MenABCWY-1 **Arm 4:** placebo + MenABCWY-2 **Arm 5:** placebo + MenABCWY-3 **Arm 6:** rMenB+OMV NZ + MenACWY + placebo	3651	Bactericidal activity	Start Aug 2020	NCT04502693	Effectiveness of GSK Biologicals S.A.'s Meningococcal Group B and Combined ABCWY Vaccines in Healthy Adolescents and Young Adults

Infectious diseases

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
MenABCWY	Phase II	Participants aged 55- 89 days	**Arm 1:** MenABCWY-2Gen low dose IM **Arm 2:** MenB+MenACWY-TT **Arm 3:** MenABCWY-2Gen high dose IM **Arm 4:** MenABCWY-1Gen IM	688	Safety hSBA titres	Start Nov 2021	NCT05082285	A Phase II, Randomized, Partially Blinded Study to Assess the Safety, Tolerability and Immunogenicity of Meningococcal Combined ABCWY Vaccine When Administered to Healthy Infants

Infectious diseases

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
MenABCWY -2Gen	Phase II	Healthy Participants aged between 10 to 50 years	**Phase I:** Arm 1: MenABCWY-2Gen low dose Arm 2: NaCl control Arm 3 MenABCWY-2Gen high dose Arm 4: NaCl control **Phase II** Arm 5: MenABCWY-2Gen low dose Day 1, 6 months + NaCl Arm 6: MenABCWY-2Gen low dose Day 1, 2 months, + NaCl Arm 7 MenABCWY-2Gen high dose Day1, 6 months + NaCl Arm 8 MenABCWY-2Gen high dose Day 1, 2months + NaCl Arm9: 2 doses Bexsero (Men B) + one dose Menveo (MenABCWY) control Arm 10: MenABCWY-2Gen low dose Day 1 and month 1 Arm 11: MenABCWY-2Gen high dose Day 1 and month 1	1258	Safety, Antibody Titres	Start Jun 2021	NCT04886154	A Phase I/II, Randomised, Controlled Study 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)

Infectious diseases

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
GSK4178116	Phase II	Healthy children aged 12-15 months	**Arm 1:** low potency ‘816, plus routine schedule **Arm 2:** medium potency ‘816 plus routine schedule **Arm 3:** high potency ‘816 plus routine schedule **Arm 4:** marketed varicella vaccine Lot 1 plus routine schedule **Arm 5:** marketed varicella vaccine Lot 2 plus routine schedule Routine schedule: measles, mumps, rubella vaccine, hepatitis A vaccine, 13-valent pneumococcal conjugate vaccine	800	anti-glycoprotein-E antibodies at day 43	Start Oct 21	NCT05084508	A Phase II, Observer-blind, Randomised, Controlled Study 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

HIV

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
cabotegravir	Phase III	HIV uninfected cisgender men and transgender women who have sex with men	**Arm A:** – **Step 1:** cabotegravir + TDF/FTC daily for 5 weeks – **Step 2:** CAB LA + placebo daily to week 153 – **Step 3:** oral TDF/FTC daily from week 153 for 48weeks **Arm B:** – **Step 1:** oral TDF/FTC + oral CAB placebo for 5 weeks – **Step 2:** oral TDF/FTC + CAB LA placebo to week 153 – **Step 3:** oral TDF/FTC	4570	HIV infections	Start Dec 2016	NCT02720094	A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), For Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women Who Have Sex With Men

Check footnotes

HIV

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
Cabotegravir	Phase III	HIV uninfected women who are at high risk of acquiring HIV	**Arm A:** Step 1: oral cabotegravir + oral TDF/FTC for 5 weeks Step 2: two CAB injections four weeks apart and every 8 weeks and oral placebo from week 5 Step 3: daily TDF/FTC for up to 48 weeks, starting within 8 weeks of the last injection **Arm B:** Step 1: daily TDF/FTC and oral placebo for 5 weeks Step 2: daily TDF/FTC + placebo injections four weeks apart and every 8 weeks Step 3: daily TDF/FTC up to 48 weeks starting within 8 weeks of the last injection	3200	HIV infections	Start Nov 2017	NCT03164564	A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women

HIV

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
GSK3810109	Phase II	Anti-retroviral naiive HIV-1 infected adults	**Part 1:** Cohort 1: '109A infusion (40mg/kg) Cohort 2: '109A infusion (280 mg/kg) **Part 2** Cohort 3: '109A IV or SC – dosing determined from part 1 Cohort 4: '109A IV or SC – dosing determined from part 1 Cohort 5: '109A IV or SC – dosing determined from part 1	50	Plasma HIV-1 levels; safety	Start Jun 21	NCT04871113	A phase IIa Multicentre, Randomised, Open-Label, Two-Part Adaptive Design Study to Evaluate the Antiviral Effect, Safety and Tolerability of GSK3810109A, an HIV-1 Specific Broadly Neutralising Human Monoclonal Antibody in Antiretroviral-naïve HIV-1-Infected Adults

HIV

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
GSK 3640254	Phase II DYNAMIC	Treatment naiive HIV infected adults	**Arm 1:** blinded '254 100mg + unblinded DTG to week 24. '254 + DTG from week 24 to 52 **Arm 2:** blinded '254 (150mg) + unblinded DTG to wk 24. '254 + DTG week 24 to 52 **Arm 3:** blinded '254 (200mg) + unblinded DTG to wk 24. '254 + DTG week 24 to 52 **Arm 4:** blinded 3TC (300mg) + unblinded DTG to wk 24. 3TC 300mg + DTG unblinded week 24 to 52	80	HIV RNA	Start Aug 21	NCT04900038	A Phase IIb, Randomized, Double-blind, Parallel-group Study to Assess the Efficacy, Safety, Tolerability, and Resistance Profile of GSK3640254 in Combination With Dolutegravir Compared to Dolutegravir Plus Lamivudine in HIV-1 Infected, Treatment-naïve Adults
GSK 3640254	Phase II DOMINO	Treatment naiive HIV infected adults	Arm 1: GSK3640254 100 mg + ABC/3TC or FTC/TAF Arm 2: GSK3640254 150 mg + ABC/3TC or FTC/TAF Arm 3: GSK3640254 200 mg + ABC/3TC or FTC/TAF Arm 4: DTG + ABC/3TC or FTC/TAF	150	Plasma HIV-1 RNA <50 c/mL at Wks 48 and 96 CD4+ cell counts at Weeks 24, 48 and 96	Start Nov 20	NCT04493216	A Phase IIb, randomised, partially blind, active controlled, dose-range finding study of GSK364254 compared to a reference arm of dolutegravir, each in combination with nucleoside reverse transcriptase inhibitors, in HIV-1 infected antiretroviral treatment-naive adults

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
belantamab mafodotin	Phase III **DREAMM-3**	3L/4L+ MM pts who have failed Len + PI	**Arm 1:** belantamab **Arm 2:** pomalidomide plus dexamethasone	320 for main study 380 with China expansion	PFS OS, CBR, DoR, ORR	Start Apr 2020	NCT04162210	A Phase III, Open-Label, Randomised Study to Evaluate the Efficacy and Safety of Single Agent Belantamab Mafodotin Compared to Pomalidomide plus Lowdose Dexamethasone (pom/dex) in Participants with Relapsed/Refractory Multiple Myeloma (RRMM) DREAMM-3
belantamab mafodotin	Phase II **DREAMM-2**	4L+ MM pts who have failed antiCD38, PI and immunomodulator	belantamab mafodotin 2.5 or 3.4 mg/kg frozen, or 3.4 mg/kg lyophilized	221	ORR, CBR, TTR, TTP PFS, OS, DoR	Primary analysis complete,	NCT03525678	A Phase II, Open Label, Randomised, Two-Arm Study to Investigate the Efficacy and Safety of Two Doses of the Antibody Drug Conjugate GSK2857916 in Participants with Multiple Myeloma Who Had 3 or More Prior Lines of Treatment, Are Refractory to a Proteasome Inhibitor and an Immunomodulatory Agent and Have Failed an Anti-CD38 Antibody (DREAMM 2)
belantamab mafodotin	Phase II **DREAMM-4 / KEYNOTE PN489**	4L+ refractory MM patients	**Part 1:** Dose escalation (2.5-3.4 mg/kg) belanatamab + pembrolizumablizumab **Part 2:** Dose expansion: belantamab + pembrolizumab	41	**Part 1**: DLT **Part 2**: ORR	Start Mar 2019 Recruitment complete	NCT03848845	A Phase I/II Single Arm Open-Label Study to Explore Safety and Clinical Activity of GSK2857916 Administered in Combination with Pembrolizumab in Subjects with Relapsed/Refractory Multiple Myeloma (DREAMM 4)

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
belantamab mafodotin	Phase I **DREAMM-5**	4L+ refractory MM patients	**Sub study 1:** belantamab + OX40 (GSK3174998) **Sub study 2:** belanatamab + feladilimab **Sub-study 3:** belantamab + nirogacestat (GSI) **Sub-study 4:** belantamab + dostarlimab **Sub-study 5:** belanatamab + isatuximab **Sub-study 6:** belanatamab + nirogacestat + lenalidomide + dexamethasone **Sub-study 7:** belanatamab + nirogacestat + pomalidomide + dexamethasone	>464	Dose escalation phase: Safety, DLT Cohort expansion phase: ORR, CBR	Active, recruiting. Start Oct 19	NCT04126200	A Phase I/II, Randomised, Open-label Platform Study Utilizing a Master Protocol to Study belantamab mafodotin (GSK2857916) as monotherapy and in Combination with Anti-Cancer Treatments in Participants with Relapsed/Refractory Multiple Myeloma (RRMM) – DREAMM 5.
belantamab mafodotin	Phase II **DREAMM-6**	2L+ MM pts	**Arm A:** belantamab + lenalidomide + dexamethasone **Arm B:** belantamab + bortezomib + dexamethasone	152	Safety, DLT; ORR PK	Start Sep 2018	NCT03544281	A Phase I/II, Open-label, Dose Escalation and Expansion Study to Evaluate Safety, Tolerability, and Clinical Activity of the Antibody-Drug Conjugate GSK2857916 Administered in Combination with Lenalidomide Plus Dexamethasone (Arm A), or Bortezomib Plus Dexamethasone (Arm B) in Participants with Relapsed / Refractory Multiple Myeloma – DREAMM-6

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
belantamab mafodotin	Phase III **DREAMM-7**	2L+ MM pts	**Arm A**: belantamab + bortezomib + dexamethasone (B-Vd) **Arm B:** daratumumab, bortezomib + dexamethasone (D-Vd)	478	PFS CRR, ORR, DoR, TTR, TTP, OS	Start May 2020	NCT04246047	DREAMM 7: A Multicenter, Open-Label, Randomised Phase III Study 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) in Participants With Relapsed/Refractory Multiple Myeloma
belantamab mafodotin	Phase III **DREAMM-8**	2L+ MM	**Arm A:** belantamab + pomalidomide + dexamethasone (B-Pd) **Arm B:** pomalidomide + bortezomib + dexamethasone (PVd)	450	PFS, MRD, OS, ORR, CRR, VGPR or better rate, DoR, TTBR, TTR, TTP, PFS2	Start Oct 2020	NCT04484623	A Phase III, Multicenter, Open-Label, Randomised Study to Evaluate the Efficacy and Safety of Belantamab Mafodotin in Combination with Pomalidomide and Dexamethasone (B-Pd) versus Pomalidomide plus Bortezomib and Dexamethasone (PVd) in Participants with Relapsed/Refractory Multiple Myeloma (DREAMM 8)

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
belantamab mafodotin	Phase I **DREAMM-12**	3L+ MM (normal and impaired renal function)	belantamab monotherapy	36	PK, renal function, safety	Start Oct 2020	NCT04398745	A Phase I Study to Evaluate the Pharmacokinetics and Safety of Belantamab Mafodotin Monotherapy in Participants With Relapsed and/or Refractory Multiple Myeloma (RRMM) Who Have Normal and Varying Degrees of Impaired Renal Function (DREAMM 12)
belantamab mafodotin	Phase I **DREAMM-9**	1L MM	**Cohort 1:** belantamab 1.9 mg/kg Q3/4W + VRd/Rd **Cohort 2:** belantamab 1.4 mg/kg Q6/8W + VRd/Rd **Cohort 3:** belantamab 1.9 mg/kg Q6/8W + VRd/Rd **Cohort 4:** belantamab 1 mg/kg Q3/4W + VRd/Rd **Cohort 5:** belantamab 1.4 mg/kg Q3/4W + VRd/Rd **Cohort 6:** belantamab 1.9 or 2.5 mg/kg Q9/12W+VRd/Rd **Cohort 7:** belantamab 1.9/2.5mg/kg Q6/8W (split)+VRd/Rd **Cohort 8:** belantamab 2.5 mg/kg Q6/8W + VRd/Rd	144	Safety; DLT, ORR, CRR VGPR or better	Start Dec 2019	NCT04091126	A Phase 1, Randomised, Dose and Schedule Evaluation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of Belantamab Mafodotin Administered in Combination With Standard of Care in Participants With Newly Diagnosed Multiple Myeloma

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
belantamab mafodotin	Phase II **DREAMM-14**	RR MM	belantamab	180	Safety; ORR % of patients with >= Gr 2 ocular events	Recruiting	NCT05064358	A Phase 2, Randomized, Parallel, Open-label Study to Investigate the Safety, Efficacy, and Pharmacokinetics of Various Dosing Regimens of Single-agent Belantamab Mafodotin (GSK2857916) in Participants With Relapsed or Refractory Multiple Myeloma (DREAMM-14). This study aims to evaluate alternative dosing regimens of single-agent belantamab mafodotin in participants with relapsed or refractory multiple myeloma (RRMM) to determine if an improved overall benefit/risk profile can be achieved by modifying the belantamab mafodotin dose, schedule, or both.

Check footnotes

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
cobolimab	Phase II **COSTAR LUNG**	Advanced NSCLC pts who have progressed on prior PD(L)1 and chemotherapy	**Arm A**: Experimental; cobolimab+dostarlimab+ docetaxel **Arm B:** Experimental; dostarlimab+docetaxel **Arm C:** Active comparator; docetaxel	250	OS ORR	Start Dec 2020	NCT04655976	A Randomised, Open Label Phase 2/3 Study Comparing Cobolimab + Dostarlimab + Docetaxel To Dostarlimab + Docetaxel To Docetaxel Alone In Participants With Advanced Nonsmall Cell Lung Cancer Who Have Progressed On Prior Anti-PD-(L)1 Therapy And Chemotherapy (COSTAR Lung)

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
dostarlimab	Phase II **PERLA**	1L Metastatic NSCLC pts	**Arm 1:** dostarlimab + chemo **Arm 2 :** pembrolizumab + chemo	240	ORR, OS, PFS	Start Nov 2020	NCT04581824	A Randomised, Phase 2, Double-blind Study to Evaluate the Efficacy of Dostarlimab Plus Chemotherapy Versus Pembrolizumab Plus Chemotherapy in Metastatic Non-Squamous Non-Small Cell Lung Cancer
dostarlimab	Phase I **GARNET**	Late stage NSCLC, endometrial (MSS and MSI-high) MSI-H solid tumours Advanced solid tumours	**Part 1:** dostarlimab **Part 2A**: dostarlimab **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 ca **Part 2B:** Cohort G PROC without known BRCA **Part 2B:** Cohort E NSCLC **Part 2B:** Cohort F non-endometrial dMMR/MSI-H & POLE-Mut cancers	740	Safety, ORR, DoR	Start Mar 2016	NCT02715284	A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an Anti-PD-1 Monoclonal Antibody, in Patients With Advanced Solid Tumors

Check footnotes

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
Dostarlimab	Phase III **RUBY** ENGOT-EN6 GOG-3031	1L Stage III or IV endometrial cancer (recurrent or advanced disease)	**Arm 1**: dostarlimab + SoC followed by dostarlimab **Arm 2:** placebo + SoC followed by placebo **Arm 3:** dostarlimab + SoC followed by dostarlimab+niraparib **Arm 4:** placebo + SoC followed by placebo SoC = carboplatin-paclitaxel	740	PFS, DCR, OS	Start Jul 2019	NCT03981796	A Phase 3, Randomised, Double-blind, Multicenter Study of Dostarlimab (TSR-042) Plus Carboplatin-paclitaxel Versus Placebo Plus Carboplatin-paclitaxel in Patients With Recurrent or Primary Advanced Endometrial Cancer (RUBY)

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
niraparib + dostarlimab	Phase III **FIRST**	1L Ovarian maintenance	**Arm 1**: treatment: cycle 1 SoC cycles 2-6 SoC + placebo; **Arm 1:** maintenance: placebo + beva **Arm 2:** treatment: cycle 1 SoC; cycles 2-6 SoC + placebo **Arm 2:** maintenance: niraparib + placebo +/- beva **Arm 3:** treatment Cycle 1 SoC; cycles 2-6 SoC + dostar **Arm 3:** maintenance: niraparib + dostar +/- beva SoC = carboplatin + paclitaxel +/- bevacizumab)	1405	PFS, OS, ORR	Start Oct 2018	NCT03602859	ENGOT-0V44 The FIRST (First-line Ovarian Cancer Treatment With Niraparib Plus TSR-042) Study: A Randomised, Double-blind, Phase 3 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

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
niraparib	Phase III **ZEAL-1L**	Maintenance for 1L advanced NSCLC	**Arm 1:** niraparib + pembrolizumab **Arm 2:** placebo + pembrolizumab	650	PFS, OS TTP (in the CNS)	Start Nov 2020	NCT04475939	A Phase 3, Randomised, Double-Blind, Placebo-Controlled, Multicenter Study Comparing Niraparib Plus Pembrolizumab Versus Placebo Plus Pembrolizumab as Maintenance Therapy in Participants Whose Disease Has Remained Stable or Responded to First-Line Platinum Based Chemotherapy With Pembrolizumab for Stage IIIB/IIIC or IV Non-Small Cell Lung Cancer (ZEAL-1L)
niraparib	Phase III **ZEST**	Her2- with BRCA-mutation, or TNBC	**Cohort 1**: tBRCAmut Her2- breast cancer **Cohort 2**: tBRCAwt TNBC **Arm 1:** niraparib **Arm 2:** placebo	800	DFS OS, TTP (on next anti cancer therapy)	Start June 2021	NCT04915755	A Randomised Phase 3 Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants With Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer With Molecular Disease Based on Presence of Circulating Tumor DNA After Definitive Therapy (ZEST)

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
momelitinib	Phase III **MOMENTUM**	Adults with symptomatic anaemic myelofibrosis	**Arm 1:** momelotinib **Arm 2:** danazol	195	Total Symptom Score at week 24 using Myelofibrosis Symptom Assessment Form; Transfusion independence, Splenic Response Rate	Reported	NCT04173494	A Randomised, Double-blind, Phase 3 Study to Evaluate the Activity of Momelotinib (MMB) Versus Danazol (DAN) in Symptomatic, Anemic Subjects With Primary Myelofibrosis (PMF), Post-polycythemia Vera (PV) Myelofibrosis, or Post-essential Thrombocythemia (ET) Myelofibrosis Who Were Previously Treated With JAK Inhibitor Therapy

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
letetresgene-autoleucel **NY-ESO-1**	Phase II **IGNYTE-ESO**	1L or 2L+ advanced synovial sarcoma and MRCLS	**Substudy 1:** lete-cel in 1L advanced (metastatic or unresectable) SS or MRCLS **Substudy 2:** lete-cel in advanced (metastatic or unresectable) SS or MRCLS post anthracycline chemo	97	ORR, PFS, TTR	Start Dec 2019	NCT03967223	Master Protocol to Assess the Safety and Antitumor Activity of Genetically Engineered NY-ESO-1-Specific (c259) T Cells, alone or in combination with other agents, in HLA-A2+ Participants with NY-ESO-1 and/or LAGE-1a Positive Solid Tumors (IGNYTE-ESO)
letetresgene-autoleucel **NY-ESO-1**	Phase I **NY-ESO Lung**	2L+ NSCLC	**Arm A:** letetresgene autoleucel monotherapy **Arm B**: letetresgene autoleucel plus pembrolizumab **Arm C:** letetresgene autoleucel plus pembrolizumab	38	Safety, ORR	Start Dec 2020	NCT03709706	A Phase 1b/2a Pilot Study to Evaluate the Safety and Tolerability of Autologous T-Cells Expressing Enhanced TCRs (T Cell Receptors) Specific for NY-ESO-1/LAGE-1a (GSK3377794) Alone, or in Combination with Pembrolizumab in HLA-A2+ Participants with NY-ESO-1- or LAGE-1a-Positive Advanced or Recurrent Non-Small Cell Lung Cancer

Oncology

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
GSK3901961 GSK3845097 GSK4427296	Phase I	Advanced solid tumours	**Substudy 1:** previously treated advanced SS; GSK3901961 iv **Substudy 1:** previously treated metastatic NSCLC: GSK3901961 iv **Substudy 2:** previously treated advanced SS GSK3845097 iv **Substudy 3:** Previously treated SS/MRCLS GSK4427296	50	Safety, ORR	Start Dec 2020	NCT04526509	Master Protocol to Assess the Safety and Recommended Phase 2 Dose of Next Generations of Autologous Enhanced NY-ESO-1/ LAGE-1a TCR Engineered T-cells, Alone or in Combination With Other Agents, in Participants With Advanced Tumors

Immunology/respiratory

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
depemokimab	Phase III **SWIFT-1**	Severe Asthma with an Eosinophilic phenotype (SEA) patients	**Arm 1:** depemokimab plus SoC **Arm 2:** placebo plus SoC	375	Annualised rate of clinically significant exacerbations over 52 weeks	Start Feb 2021	NCT04719832	A 52-week, randomised, double-blind, placebo-controlled, parallel-group, multi-centre study of the efficacy and safety of GSK3511294 adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype.
depemokimab	Phase III **SWIFT-2**	SEA patients	**Arm 1:** depemokimab plus SoC **Arm 2:** placebo plus SoC	375	Annualised rate of clinically significant exacerbations over 52 weeks	Start Feb 2021	NCT04718103	A 52-week, randomised, double-blind, placebo-controlled, parallel-group, multi-centre study of the efficacy and safety of GSK3511294 adjunctive therapy in adult and adolescent participants with severe uncontrolled asthma with an eosinophilic phenotype
depemokimab	Phase III **NIMBLE**	SEA patients	**Arm 1:** GSK3511294 plus placebo matching prior anti-IL-5/5R treatment **Arm 2:** prior anti-IL-5/5R treatment plus placebo matching GSK3511294	1700	Annualised rate of clinically significant exacerbations over 52 weeks	Start Feb 2021	NCT04718389	A 52-week, randomised, double-blind, double-dummy, parallel group, multi-centre, non-inferiority study assessing exacerbation rate, additional measures of asthma control and safety in adult and adolescent severe asthmatic participants with an eosinophilic phenotype treated with GSK3511294 compared with mepolizumab or benralizumab

Immunology/respiratory

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
depemokimab	Phase III **OCEAN**	Adults with relapsing or refractory Eosinophilic Granulomatosis with Polyangiitis (EGPA)	**Arm 1:** depemokimb **Arm 2:** mepolizumab	160	Remission (Birmingham Vasculitis Activity Score)	Not yet recruiting	NCT05263934	A 52-week, Randomised, Double-blind, Double-dummy, Parallel-group, Multi-centre, Non-inferiority Study to Investigate the Efficacy and Safety of Depemokimab Compared With Mepolizumab in Adults With Relapsing or Refractory Eosinophilic Granulomatosis With Polyangiitis (EGPA) Receiving Standard of Care (SoC) Therapy
depemokimab	Phase III **DESTINY**	Adults with Hypereosinophilic Syndrome (HES)	**Arm 1:** depemokimab **Arm 2:** placebo	120	Frequency of HES flares; time to HES flare	Not yet recruiting	NCT05334368	A Randomised, Double-blind, Placebo-controlled Study to Investigate the Efficacy and Safety of Depemokimab in Adults With Hypereosinophilic Syndrome (HES)
depemokimab	Phase III **ANCHOR-1**	Patients with Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	**Arm 1:** depemokimab **Arm 2:** Placebo	250	Nasal Polyp score at wk 52; Nasal obstruction score	Start Mar 2022	NCT05274750	A Randomised, Double-blind, Parallel Group Phase III Study to Assess the Efficacy and Safety of 100 mg SC Depemokimab in Patients With Chronic Rhinosinusitis With Nasal Polyps (CRSwNP) - ANCHOR-1 (depemokimAb iN CHrOnic Rhinosinusitis)
depemokimab	Phase III **ANCHOR-2**	Patients with Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	**Arm 1:** depemokimab **Arm 2:** Placebo	250	Nasal Polyp score at wk 52; Nasal obstruction score	Start Mar 2022	NCT05281523	A Randomised, Double-blind, Parallel Group Phase III Study to Assess the Efficacy and Safety of 100 mg SC Depemokimab in Patients With Chronic Rhinosinusitis With Nasal Polyps (CRSwNP) - ANCHOR-2 (depemokimAb iN CHrOnic Rhinosinusitis)

Immunology/respiratory

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
mepolizumab	Phase III **MATINEE**	Adults >40 with documented COPD	**Arm 1:** mepolizumab + optimised COPD SoC **Arm 2:** placebo + optimised COPD SoC	800	Exacerbation rate	Start Oct 2019	NCT04133909	A Multi-center, Randomised, Double-blind, Parallel-group, Placebo-controlled Study of Mepolizumab 100 mg SC as add-on Treatment in Participants With COPD Experiencing Frequent Exacerbations and Characterised by Eosinophil Levels
mepolizumab	Phase III **MERIT**	Adults with CRSwNP/ECRS In Japan/China	**Arm 1:** mepolizumab + SoC **Arm 2:** Placebo + SoC	160	Endoscopic NP score at wk52 Nasal obstruction score	Start Feb 2021	NCT04607005	A Randomised, Double-blind, Placebo Controlled, Parallel Group Phase III Study to Assess the Clinical Efficacy and Safety of 100 mg SC Mepolizumab in Adults With Chronic Rhinosinusitis With Nasal Polyps (CRSwNP) / Eosinophilic Chronic Rhinosinusitis (ECRS) MERIT: Mepolizumab in Eosinophilic Chronic RhinosinuslTis Study

Immunology/respiratory

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
otilimab	Phase III **contRAst-1**	Moderate to severe MTX-IR RA patients	**Arm 1:** otilimab (90mg sc weekly) + MTX **Arm 2:** otilimab (150mg sc weekly) + MTX **Arm 3:** tofacitinib (5mg twice daily) + MTX **Arm 4:** placebo sc weekly + twice daily + MTX **Arm 5:** placebo sc weekly + twice daily; from week 12; otilimab sc weekly **Arm 6:** placebo sc weekly + twice daily; from week 12: tofacitinib 5mg twice daily + MTX	1537	ACR20 at Week 12 CDAI, HAQ-DI	Start May 2019	NCT03980483	A 52-week, Phase 3, Multicentre, Randomised, Double Blind, Efficacy and Safety Study Comparing GSK3196165 With Placebo and With Tofacitinib, in Combination With Methotrexate in Participants With Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Methotrexate

Immunology/respiratory

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
otilimab	Phase III **contRAst-2**	Moderate to severe RA DMARD-IR patients	**Arm 1**: otilimab (90mg sc weekly) **Arm 2**: otilimab (150mg sc weekly) **Arm 3**: tofacitinib (5mg twice daily) **Arm 4:** placebo sc weekly + twice daily **Arm 5:** placebo sc weekly + twice daily; from week 12; otilimab 150mg sc weekly **Arm 6:** placebo sc weekly + twice daily; from week 12: tofacitinib 5mg twice daily + MTX	1753	ACR20 at Week 12 CDAI, HAQ-DI	Start Jun 2019	NCT03970837	A 52-week, Phase 3, Multicentre, Randomised, Double Blind, Efficacy and Safety Study, Comparing GSK3196165 With Placebo and With Tofacitinib in Combination With Conventional Synthetic DMARDs, in Participants With Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Conventional Synthetic DMARDs or Biologic
otilimab	Phase III **contRAst-3**	Moderate to severe RA patients IR to biologic DMARD and/or JAKs	**Arm 1:** otilimab 90mg sc weekly **Arm 2:** otilimab 150mg sc weekly **Arm 3**: sarilumab 200mg sc every other week **Arm 4**: placebo; from week 12 otilimab 90mg sc weekly **Arm 5:** placebo from week 12 otilimab 150mg sc weekly **Arm 6**: placebo; from week 12 sarilumab 200mg sc	550	ACR20 at Week 12 CDAI, HAQ-DI	Start Oct 2019	NCT04134728	A 24-week, Phase 3, Multicentre, Randomised, Double-blind, Efficacy and Safety Study, Comparing GSK3196165 With Placebo and With Sarilumab, in Combination With Conventional Synthetic DMARDs, in Participants With Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Biological DMARDs and/or Janus Kinase Inhibitors

Immunology/respiratory

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
latozinemab GSK 4527223 AL001	Phase II **INFRONT-2**	Heterozygous Carriers of Granulin or C9orf72 Mutations Causative of Frontotemporal Dementia	latozinemab every 4 weeks for up to 96 weeks	40	Safety and tolerability	Start Jun 2019	NCT03987295	A Phase 2, Multicenter, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of AL001 in Heterozygous Carriers of Granulin or C9orf72 Mutations Causative of Frontotemporal Dementia
latozinemab GSK 4527223 AL001	Phase III **INFRONT-3**	Individuals at Risk for or With Frontotemporal Dementia Due to Heterozygous Mutations in the Progranulin Gene	**Arm 1**: latozinemab **Arm 2:** placebo	180	Clinical Dementia Rating: (CDR) plus NACC FTLD-SB scale	Start Jul 2020	NCT04374136	A Phase 3, Multicenter, Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of AL001 in Individuals at Risk for or With Frontotemporal Dementia Due to Heterozygous Mutations in the Progranulin Gene
latozinemab GSK 4527223 AL001	Phase II	Participants with C9orf72-associated Amyotrophic Lateral Sclerosis	**Arm 1:** latozinemab every 4 weeks **Arm 2:** placebo every 4 weeks	45	Safety and tolerability	Start Sep 2021	NCT05053035	A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of AL001 in C9orf72-Associated Amyotrophic Lateral Sclerosis (ALS)

Opportunity driven

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
daprodustat	Phase III **ASCEND-D**	Dialysis subjects with anaemia associated with CKD	**Arm 1:** daprodustat **Arm 2:** rhEPO	2964	Safety: Time to MACE (all cause mortality, non fatal MI and non-fatal stroke) Efficacy: Mean change in Hb from baseline to evaluation period (EP, Weeks 28 to 52)	Reported	NCT02879305	A phase III randomised, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to recombinant human erythropoietin, following a switch from erythropoietin-stimulating agents
daprodustat	Phase III **ASCEND-ID**	Incident Dialysis subjects with anaemia associated with CKD	**Arm 1:** daprodustat **Arm 2:** darbopoetin alfa	312	Efficacy: Mean change in Hb from baseline to evaluation period (EP, Weeks 28 to 52)	Reported	NCT03029208	A 52-week Open-label (Sponsor-blind), Randomized, Active-controlled, Parallel-group, Multi-center Study to Evaluate the Efficacy and Safety of Daprodustat Compared to Recombinant Human Erythropoietin in Subjects With Anemia Associated With Chronic Kidney Disease Who Are Initiating Dialysis
daprodustat	Phase III **ASCEND- NHQ**	Non-dialysis subjects with anaemia related to CKD	**Arm 1:** daprodustat **Arm 2:** Placebo	614	Mean change in Hb from baseline to EP (Weeks 24 to 28)	Reported	NCT03409107	A 28-week, randomised, double-blind, placebo-controlled, parallel-group, multi-center, study in recombinant human erythropoietin (rhEPO) naïve non-dialysis participants with anemia associated with chronic kidney disease to evaluate the efficacy, safety and effects on quality of life of daprodustat compared to placebo

Opportunity driven

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
daprodustat	Phase III **ASCEND-TD**	Dialysis subjects with anaemia associated with CKD	**Arm 1:** daprodustat **Arm 2:** epoetin alfa	407	Mean change in Hb from baseline to evaluation period (EP, Weeks 28 to 52)	Reported	NCT03400033	A phase III Randomised, Double-blind, Active-controlled, Parallel-group, Multi-center Study in Hemodialysis Participants With Anemia of Chronic Kidney Disease to Evaluate the Efficacy, Safety and Pharmacokinetics of Three-times Weekly Dosing of Daprodustat Compared to Recombinant Human Erythropoietin, Following a Switch From Recombinant Human Erythropoietin or Its Analogs
daprodustat	Phase III **ASCEND-ND**	Non-dialysis subjects with anaemia related to CKD	**Arm 1:** daprodustat **Arm 2:** darbopoetin alfa	3872	Safety: Time to MACE (all-cause mortality, non fatal MI and non-fatal stroke); Efficacy: Mean change in Hb from baseline to evaluation period (EP, Weeks 28 to 52)	Reported	NCT02876835	A Phase 3 Randomised, Open-label (Sponsor-blind), Active-controlled, Parallel-group, Multi-center, Event Driven Study in Non-dialysis Subjects With Anaemia Associated With Chronic Kidney Disease to Evaluate the Safety and Efficacy of Daprodustat Compared to Darbepoetin Alfa

Opportunity driven

Asset	Trial Phase and Name	Population description	Treatment Arms	No of subjects	Key End points	Timing/ Status	CT identifier	Description
linerixibat	Phase II **GLIMMER**	Subjects with Primary Biliary Cholangitis	**Arm 1:** linerixibat **Arm 2:** placebo	147	Worst daily itch score; Primary Biliary Cholangitis-40 (PBC-40) Scale	Start Jan 2017	NCT02966834	Dose Response Study of GSK2330672 for the Treatment of Pruritus in Participants With Primary Biliary Cholangitis
linerixibat	Phase III **GLISTEN**	Subjects with Primary Biliary Cholangitis	**Arm 1:** linerixibat **Arm 2:** linerixibat followed by placebo **Arm 3:** placebo **Arm 4:** placebo followed by linerixibat	230	Monthly Itch Scores over 24 weeks Worst daily itch score	Start Aug 2021	NCT04950127	A Two-part, Randomized, Placebo Controlled, Double Blind, Multicenter, Phase 3 Study to Evaluate the Efficacy and Safety of Linerixibat for the Treatment of Cholestatic Pruritus in Participants With Primary Biliary Cholangitis (PBC)

Glossary

ASH	American Society of Haematology
ASO	Anti Sense Oligonucleotide
BID	Twice a day
BRCA	BReast CAncer gene
CDAI	Clinical Disease Activity Index
CHB	Chronic Hepatitis B
CNS	Central Nervous System
DCR	Disease Control Rate
DFS	Disease Free Survival
DLT	Dose Limiting Toxicity
dMMR/MSI-H	Deficient MisMatch Repair/MicroSatellit Instability
DoR	Duration of Response
DTG	Dolutegravir
EP	Evaluation Period
FTC	Emtricitabine
FTLD scale	Frontotemporal lobar degeneration
Gr 2	Grade 2
HAQ-DI	Health assessment Questionnaire Disability Index
Hb	Haemoglobin
Hsba titres	Human Serum Bactericidal Antibody
HZ	Herpes Zoster
IM	Intra-muscular
Iv	Intra-venous