JUNE 2021

Clinical trials summary

Our R&D pipeline

20 vaccines and 42 medicines in 77 different programs

Phase I

- C. Difficile*^ vaccine
- Men ABCWY (2nd Gen)^ vaccine
- SAM (COVID-19 model)^ vaccine
- SAM (rabies model)^ vaccine
- BVL-GSK098* (ethionamide booster) – tuberculosis
- 2556286* (Mtb cholesterol dependent inhibitor) – tuberculosis
- 3186899*[6] (CRK-12 inhibitor) - visceral leishmaniasis
- 3494245* (proteasome inhibitor) - visceral leishmaniasis
- 3882347* (FimH antagonist) - uncomplicated urinary tract infection
- 3923868 (PI4 kinase beta inhibitor) – viral COPD exacerbations
- 4182137*^ (VIR-7832) – COVID-19
- VIR-2482*^ (neutralizing monoclonal antibody) – influenza
- *cabotegravir (1265744) - 400 mg/ml formulation- HIV*
- 3739937 (HIV maturation inhibitor) – HIV
- *Blenrep*^ (belantamab mafodotin)- 1L multiple myeloma combination with Velcade, Revlimid and dexamethasone*
- *Blenrep* ^(belantamab mafodotin)- multiple myeloma in combination with anti-cancer treatments (platform study)*
- 3326595*^ (PRMT5 inhibitor) - cancer
- 3368715*^ (Type 1 PRMT inhibitor) – cancer
- 3745417^ (STING agonist) – cancer
- 3845097*^ (NY-ESO-1/TGFbR2 TCR T) – cancer
- 3901961*^ (NY-ESO-1/CD8a TCR T) – cancer
- 4074386*^ (LAG3 antagonist) – cancer
- 4362676*^ (Mat2A inhibitor) – cancer
- 6097608*^ (CD96 pathway antagonist) – cancer
- EOS-448*^[8] (TIGIT antagonist) – cancer
- 2982772^ (RIP1-k) – psoriasis
- 3858279*^ (CCL17 inhibitor) - osteoarthritis pain
- 3915393*^ (TG2 inhibitor) - celiac disease
- 2798745* (TRPV4 channel blocker) - diabetic macular edema

Phase II

- COVID-19 (SK Bioscience)*^[1,2] vaccine
- Malaria*^ (Fractional Dose) vaccine
- RSV^ paediatric vaccine
- S. aureus*^[1] vaccine
- Shigella*^ vaccine
- Therapeutic HBV*^[1] vaccine
- 3036656* (leucyl t-RNA synthetase inhibitor) – tuberculosis
- 3228836* (HBV antisense oligonucleotide) – HBV
- 3640254 (HIV maturation inhibitor) – HIV
- 3810109*[7] (broadly neutralizing antibody) - HIV
- bintrafusp alfa*^ (4045154, TGFß trap/anti-PDL1) – 1L biliary tract cancer
- Cobolimab*^ (4069889, TIM-3 antagonist) non-small cell lung cancer combination with docetaxel and Jemperli (dostarlimab, PD-1)
- feladilimab*^ (3359609, ICOS agonist) - solid tumours
- *Jemperli*^ (dostarlimab, PD-1) - non-small cell lung cancer*
- *letetresgene-autoleucel*^ (3377794, NY-ESO-1) - 2L+ non-small cell lung cancer*
- *Zejula* (niraparib, PARP inhibitor) - 2L+ Platinum resistant ovarian cancer combination with Jemperli (dostarlimab, PD-1)*
- linerixibat (IBATi) - cholestatic pruritus in primary biliary cholangitis

Phase III/Registration

- *Bexsero Infants^ (US) vaccine*
- COVID-19 (Medicago)*^[2] vaccine
- COVID-19 (Sanofi)*^[2] vaccine
- MenABCWY^ (1st Gen) vaccine
- *Menveo Liquid^[5] vaccine*
- *MMR^ (US) vaccine*
- RSV Maternal*^ vaccine
- RSV Older Adults*^ vaccine
- *Rotarix liquid^ (US) vaccine*
- *Shingrix Immuno-compromised*^ vaccine*
- gepotidacin* (2140944) – uncomplicated urinary tract infection
- *gepotidacin* (2140944) – urogenital gonorrhea (GC)*
- sotrovimab*^[3] (4182136/ VIR-7831)- COVID-19
- *cabotegravir long acting (1265744) - HIV pre-exposure prophylaxis*
- *Blenrep*^ (belantamab mafodotin)- 3L+ multiple myeloma*
- *Blenrep*^ (belantamab mafodotin) - 2L+ multiple myeloma combination with Pomalyst and dexamethasone*
- *Blenrep*^ (belantamab mafodotin) - 2L+ multiple myeloma combination with Velcade and dexamethasone*
- *Jemperli*^(dostarlimab) - recurrent or advanced dMMR/MSI-H solid tumors*
- *Jemperli*^ (dostarlimab) - 1L endometrial cancer*
- *Jemperli*^ (dostarlimab) - 1L endometrial cancer combination with niraparib*
- letetresgene-autoleucel*^[5] (3377794) - 2L+ synovial sarcoma & myxoid/round cell liposarcoma
- *Zejula* (niraparib) - 1L maintenance ovarian cancer combination with Jemperli (dostarlimab)*
- *Zejula* (niraparib)- 1L maintenance non-small cell lung cancer combination with pembrolizumab*
- *Zejula*[4] (niraparib)- pre-metastatic, select biomarker population breast cancer*
- *Benlysta^ (belimumab) + rituximab - systemic lupus erythematosus*
- depemokimab *^ (3511294, long acting IL-5 antagonist) – asthma
- *Nucala^ (mepolizumab) - COPD*
- *Nucala^ (mepolizumab) - nasal polyposis*
- otilimab*^ (3196165, aGM-CSF) - rheumatoid arthritis
- *otilimab*^[5](3196165, aGM-CSF) - COVID-19 related acute pulmonary disease*
- daprodustat (HIF-PHI) - anemia associated with chronic kidney disease

Lead indication
Follow-on indication

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

*In-license or other alliance relationship with third party
^Immunomodulator

1. In Phase 1/2 study
2. GSK is contributing pandemic adjuvant to COVID-19 vaccines collaborations
3. sotrovimab US emergency use authorization approved 26May21
4. Ph3 study expected to start in 2H2021
5. In potentially registrational Phase 2 trial
6. transition activities underway to enable further progression by external partner
7. Study start imminent (Jun/Jul21)
8. Subject to regulatory clearance of iTeos Therapeutics collaboration

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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, Randomized, 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 po BID x 5 days	2000	Therapeutic response/Cure	Start Oct 2019	NCT04020341	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)
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	2000	Therapeutic response/Cure	Start Oct 2019	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

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
sotrovimab / VIR 7831	Phase III **COMET-ICE**	SARS-CoV-2 positive adults who are not hospitalised	**Arm 1:** sotrovimab **Arm 2:** placebo	1360	Progression of Covid-19	Start Aug 2020	NCT04545060	A Randomized, Multi-center, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of Monoclonal Antibody VIR-7831 for the Early Treatment of Coronavirus Disease 2019 (COVID-19) in Non-hospitalized Patients
sotrovimab / VIR 7831	Phase III **COMET-TAIL**	12yrs and high risk of progression of COVID-19 or >65yo	**Arm 1:** sotrovimab 500mg iv infusion **Arm 2:** sotrovimab 500mg im injection **Arm3:** sotrovimab 250mg im injection	1020	Progression of Covid-19	Start Jun 2021	NCT04913675	A Phase 3 Randomized, Multi-center, Open Label Study to Assess the Efficacy, Safety, and Tolerability of Monoclonal Antibody VIR-7831 (Sotrovimab) Given Intramuscularly Versus Intravenously for the Treatment of Mild/Moderate Coronavirus Disease 2019 (COVID-19) in High-risk Non-hospitalized Patients.

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
sotrovimab / VIR 7831 **VIR 7832**	Phase I **AGILE**	Adults with confirmed SARS-CoV-2 infection	**Arm 1:** MK-4482 **Arm 2:** control **Arm 3:** placebo **Arm 4:** nitazoxanide **Arm 5:** VIR-7832 **Arm 6:** sotrovimab	600	Safety, progression of COVID-19	Start Jul 2020	NCT04746183	AGILE: Seamless Phase I/IIa Platform for the Rapid Evaluation of Candidates for COVID-19 Treatment
sotrovimab / VIR 7831	Phase II **COMET-PEAK**	SARS-CoV-2 positive adults who are not hospitalised	**Part 1:** sotrovimab **Part 2: Arm 1:** sotrovimab 500mg IV **Part 2: Arm 2:** sotrovimab 500mg IM **Part 3: Arm 1:** sotrovimab 500mg IV **Part 3: Arm 2:** sotrovimab 250mg IM	**Part 1:** 40 **Part 2:** 166 **Part 3:** 160	Safety, virology and clinical outcomes	Start Feb 2021	NCT04779879	A Multicenter, Randomized, Double-Blind, Parallel Group Phase II Study to Evaluate the Safety, Tolerability and Pharmacokinetics of a Second Generation VIR-7831 Material in Non-Hospitalized Participants With Mild to Moderate Coronavirus Disease 2019 (COVID-19)

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
GSK3228836 / HBV ASO	Phase II **B-Together**	Patients with Chronic Hepatitis B (CHB)	**Arm 1:** GSK3228836 for 12 wks + PegIFN for =< 24 wks **Arm 2:** GSK3228836 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

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
GSK3228836 / HBV ASO	Phase II **B-Clear**	Patients with Chronic Hepatitis B (CHB)	Treatment Naiive **Cohort 1:** GSK3228836 300 mg + LD/ GSK3228836 150 mg + Placebo **Cohort 1:** GSK3228836 300 mg + LD **Cohort 1:** Placebo/ GSK3228836 300 mg + Placebo LD **Cohort 1:** GSK3228836 300 mg + LD/ Placebo Receiving stable nucleos(t)ide treatment **Cohort 2:** GSK3228836 300 mg + LD **Cohort 2:** GSK3228836 300 mg + LD/ GSK3228836 150 mg + Placebo **Cohort 2:** GSK3228836 300 mg + LD/ Placebo **Cohort 2:** Placebo/ GSK3228836 300 mg + Placebo LD	440	Sustained virologic response for 48 weeks post treatment	Start Jul 2020	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)

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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	**Recruitment complete**	NCT03439657	A Phase IIIB, randomized, 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	Placebo Group Shingrix Group	1426	Number of confirmed Herpes Zoster (HZ) cases	Start Sep 2019	NCT04091451	A study to evaluate the safety and immunogenicity of GlaxoSmithKline'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

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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 on Day 1	1650	RSV-A neutralising antibody titres	Start Feb 2021	NCT04732871	A Phase 3, Randomized, 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, Randomized, 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

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
RSV OA	Phase III **RSV OA-006**	Adults > 60	**Arm 1:** RSVPre F3 OA Lot 1 **Arm 2:** RSVPre F3 OA Lot 2 **Arm 3:** RSVPre F3 OA Lot 3 **Arm 4:** RSVPre F3 OA Lot 4 **Arm 5:** Placebo	25000	RSV infection	Start May 2021	NCT04886596	A Phase 3, Randomized, 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

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
RSV Maternal	Phase III **GRACE**	Pregnant women aged 18-49 yo	**Arm 1:** single dose of RSV MAT on day 1 **Arm 2:** placebo	20000 (10000 women + 10000 infants)	Infant participants with RSV-associated LRTI up to 6 months of age	Start Nov 2020	NCT04605159	A Phase III, Randomized, Double-blind, Placebo-controlled Multi-country Study to Demonstrate Efficacy of a Single Dose of Unadjuvanted RSV Maternal Vaccine, Administered IM to Pregnant Women 18 to 49 Years of Age, for Prevention of RSV Associated LRTIs in Their Infants up to 6 Months of Age

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
RSV Maternal	Phase II	Healthy pregnant women aged 18-40	**Arm 1:** RSV MAT formulation 2 single dose **Arm 2:** RSV MAT formulation 3 single dose **Arm 3:** Placebo	420	Safety, RSV antibodies	Start Nov 2019	NCT04126213	A Phase II, Randomised, Observer-blind, Placebo Controlled Multi-country Study to Assess the Safety, Reactogenicity and Immunogenicity of a Single Intramuscular Dose of GSK Biologicals' Investigational RSV Maternal Unadjuvanted Vaccine (GSK3888550A), in Healthy Pregnant Women Aged 18 to 40 Years and Infants Born to Vaccinated Mothers

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
RSV Maternal	Phase II	Healthy non-pregnant women aged 18-45	**Arm 1:** RSVPreF3 formulation 3 + (exUS) dTpa **Arm 2:** RSVPreF3 formulation 3 + placebo **Arm 3:** RSVPreF3 formulation 3 + RSVPreF3 formulation 2 + (exUS) dTpa **Arm 4:** RSVPreF3 formulation 3 + RSVPreF3 formulation 2 + placebo **Arm 5:** RSVPreF3 formulation 3 + dTpa + placebo **Arm 6:** RSVPreF3 formulation 3 + dTpa (US) **Arm 7:** RSVPreF3 formulation 3 + placebo **Arm 8:** RSVPreF3 formulation 3 + RSVPreF3 formulation 2 + dTpa (US) **Arm9 :** RSVPreF3 formulation 3 + RSVPreF3 formulation 2 + placebo **Arm 10:** RSVPreF3 formulation 3 + dTpa (US) + placebo	509	Safety, RSV neutralising antibody titres	Start Nov 2019	NCT04138056	A Phase II Study of a Primary Dose of Investigational RSV Maternal Vaccine, Given Alone or With Boostrix, With a 2nd Dose Investigational RSV Maternal Vaccine

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
RSV Ped GSK3389245A	RSV PED-011	Infants aged 6 and 7 months likely to be unexposed to RSV	Synflorix Group 2 Dose GSK3389245A + Bexsero Group 2 dose GSK3389245A + Synflorix Group Placebo Group 1 dose GSK3389245A + Placebo 1 Dose GSK3389245A + Bexsero Group 2 dose GSK3389245A + Placebo Bexsero Group 2 Dose GSK3389245A + Nimenrix Group Nimenrix Group 1 Dose GSK3389245A + Menveo Group 2 Dose GSK3389245A + Menveo Group Menveo Group 1 Dose GSK3389245A + Nimenrix Group 1 dose GSK3389245A + Synflorix Group	150	Safety; RTI, LRTI	Start Apr 2019	NCT03636906	A study to evaluate safety, reactogenicity and immunogenicity of GSK Biologicals' RSV investigational vaccine based on viral proteins encoded by chimpanzee-derived adenovector (ChAd155-RSV) (GSK3389245A) in infants.

Infectious Diseases

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
MenABCWY	Phase IIIb	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, Randomized, 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	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 GlaxoSmithKline Biologicals S.A.'s Meningococcal Group B and Combined ABCWY Vaccines in Healthy Adolescents and Young Adults

HIV

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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

HIV

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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

Infectious Diseases | HIV | Oncology | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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	Not yet recruiting	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	1L HIV+	GSK3640254 200 mg + ABC/3TC or FTC/TAF GSK3640254 150 mg + ABC/3TC or FTC/TAF GSK3640254 100 mg + ABC/3TC or FTC/TAF DTG + ABC/3TC or FTC/TAF	240	Plasma HIV-1 RNA <50 c/mL at Wks 48 and 96 CD4+ cell counts at Weeks 24, 48 and 96	Start Nov 2020	NCT04493216	A Phase IIb, randomized, 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

Infectious Diseases | HIV | **Oncology** | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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 1H 2020	NCT04162210	A Phase III, Open-Label, Randomized 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)
belantamab mafodotin	Phase II **DREAMM-2**	3L/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 PFS, OS, DoR	Primary analysis complete, active not recruiting	NCT03525678	A Phase II, Open Label, Randomized, 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**	3L/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

Infectious Diseases | HIV | **Oncology** | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
belantamab mafodotin	Phase I **DREAMM-5**	3L/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 belantamab monotherapy	>464	Safety, DLT (for the dose escalation phase) ; Cohort expansion phase: ORR, CBR	OX40 Start Oct 2019 - closed 3Q2020 feladilimab Start Nov 2020 nirogacestat Start Jun 2020 dostarlimab Start Apr 2021	NCT04126200	A Phase I/II, Randomized, 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 Oct 2018 Arm B data ASH2020	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 Name	Trial phase and Name	Population description	Treatment arms	No of patients	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	A Multicenter, Open-Label, Randomized 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, Randomized 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

Oncology

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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	Start Jan 2020	NCT04091126	A Phase 1, Randomized, 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 Name	Trial phase and Name	Population description	Treatment arms	No of patients	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 Randomized, 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

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
cobolimab	Phase I **AMBER**	Advanced solid tumours	**Part 1d:** cobolimab + dostarlimab + TSR-033 **Part 1a:** cobolimab monotherapy **Part 1b:** cobolimab + nivolumab **Part 1c:** cobolimab + dostarlimab **Part 2:** CohortB Non-small cell lung cancer(cobolimab + dostarlimab) **Part 1e:** cobolimab + dostarlimab **Part 1f:** cobolimab + dostarlimab + Docetaxel **Part 2:** Cohort A (Melanoma) (cobolimab monotherapy) **Part 2:** Cohort A (Melanoma) (cobolimab + dostarlimab) **Part2:**CohortB Non-small cell lung cancer (cobolimab-monotherapy) **Part2:** CohortC Colorectal cancer (cobolimab monotherapy) **Part2:** CohortC Colorectal cancer (cobolimab + dostarlimab) **Part 2:** Cohort D (TIM-3 selected NSCLC) (cobolimab + dostarlimab)	369	Safety - DLT ORR	Start Jul 2016	NCT02817633	A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-022, an Anti-TIM-3 Monoclonal Antibody, in Patients With Advanced Solid Tumors (AMBER)

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Infectious Diseases | HIV | **Oncology** | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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 Randomized, 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 (1-20 mg/kg) **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

Oncology

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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, Randomized, 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

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
feladilimab	Phase I **INDUCE-1**	Dose escalation and expansion study of GSK335969 in participants with selected advanced solid tumors	**Part 1:** feladilimab **Part 2:** feladilimab + pembrolizumab **Part 2:** feladilimab + chemotherapy +/- pembrolizumab **Part 2:** feladilimab + GSK3174998 **Part 2:** feladilimab+ dostarlimab **Part 2:** feladilimab + dostarlimab + cobolimab **Part 2:** feladilimab + bintrafusp alfa	873	Safety, DLT, DCR, OS, PFS.	Start Jun 2016	NCT02723955	A Phase I Open Label Study of GSK335969 Administered Alone and in Combination with Anticancer Agents in Subjects with Selected Advanced Solid Tumors
feladilimab	Phase II; platform trial **ENTRÉE**	2L/3L NSCLC	**Part 1:** feladilimab + Ipilimumab **Part 2:** docetaxel **Part 2:** feladilimab + docetaxel **Part 2:** feladilimab + Ipilimumab	341	Safety, OS ORR DCR	Start Jan 2019	NCT03739710	A Phase II, Randomized, Open-label Platform Trial Utilizing a Master Protocol to Study Novel Regimens Versus Standard of Care Treatment in NSCLC Participants

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Infectious Diseases | HIV | **Oncology** | Immunology / Respiratory | Opportunity Driven

Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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 Randomized, 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
niraparib + dostarlimab	Phase II **MOONSTONE**	Pt resistant 2L ovarian cancer	Single arm niraparib+ dostarlimab	41	ORR DoR, PFS, OS	Not recruiting	NCT03955471	A Phase 2 Open-Label, Single-Arm Study to Evaluate the Efficacy and Safety of the Combination of Niraparib and Dostarlimab (TSR-042) in Patients With Platinum-Resistant Ovarian Cancer (MOONSTONE)

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
niraparib	Phase III **ZEAL-1L**	Maintenance for 1L advanced NSCLC	**Arm1:** niraparib + pembrolizumab **Arm 2:** placebo + pembrolizumab	650	PFS, OS TTP (in the CNS)	Start Nov 2020	NCT04475939	A Phase 3, Randomized, 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 II **OPAL**	>2L recurrent Ovarian cancer; resistant to prior Pt threapy	**Cohort A:** dostarlimab + bevacizumab + niraparib	40	ORR PFS, OS	Start Nov 2018	NCT03574779	Phase 2 Multicohort Study to Evaluate the Safety and Efficacy of Novel Treatment Combinations in Patients With Recurrent Ovarian Cancer
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)	Not yet recruiting	NCT04915755	A Randomized 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)

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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	80	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	54	Safety, ORR		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

Immunology / Respiratory

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
depemokimab/ GSK3511294	Phase III **SWIFT-1**	SEA patients	**Arm 1:** GSK3511294 plus SoC **Arm 2:** placebo plus SoC	375	Annualized rate of clinically significant exacerbations over 52 weeks	Start Feb 2021 Data 2024	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/ GSK3511294	Phase III **SWIFT-2**	SEA patients	**Arm 1:** GSK3511294 plus SoC **Arm 2:** placebo plus SoC	375	Annualized rate of clinically significant exacerbations over 52 weeks	Start Feb 2021 Data 2024	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

Immunology / Respiratory

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
depemokimab/ GSK3511294	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	Annualized rate of clinically significant exacerbations over 52 weeks	Start Feb 2021 Data 2024	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
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, Randomized, Double-blind, Parallel-group, Placebo-controlled Study of Mepolizumab 100 mg SC as add-on Treatment in Participants With COPD Experiencing Frequent Exacerbations and Characterized by Eosinophil Levels

Immunology / Respiratory

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
otilimab - COVID	Phase IIa **OSCAR**	Patients with severe pulmonary COVID-19	**Arm 1:** otilimab iv **Arm 2:** placebo iv	1150	Mortality and proportion of patients requiring respiratory support	OSCAR part 1 reported Feb 2021 OSCAR part 2 PoC data 2H2021	NCT04376684	Investigating otilimab in patients with severe pulmonary COVID-19 related disease; PH 2, otilimab(90 mg IV) Vs placebo, randomized, double-blind, efficacy and safety study in pts with severe pulmonary COVID-19 related disease-OSCAR
otilimab - RA	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	1500	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

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
otilimab - RA	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	1500	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 - RA	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	525	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

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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)	Fully recruited Data - 2H2021	NCT02879305	A phase 3 randomized, 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)	Start May 2017 Completion Sep 2020	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

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	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)	Start Sep 2018 Completion Jun 2020	NCT03400033	A Phase 3 Randomized, 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:** dabopoeitin 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)	Fully recruited Data - 2H2021	NCT02876835	A 28-week, randomized, 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

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Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
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)	Start Mar 2018 Completion Oct 2020	NCT03409107	A 28-week, randomized, 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

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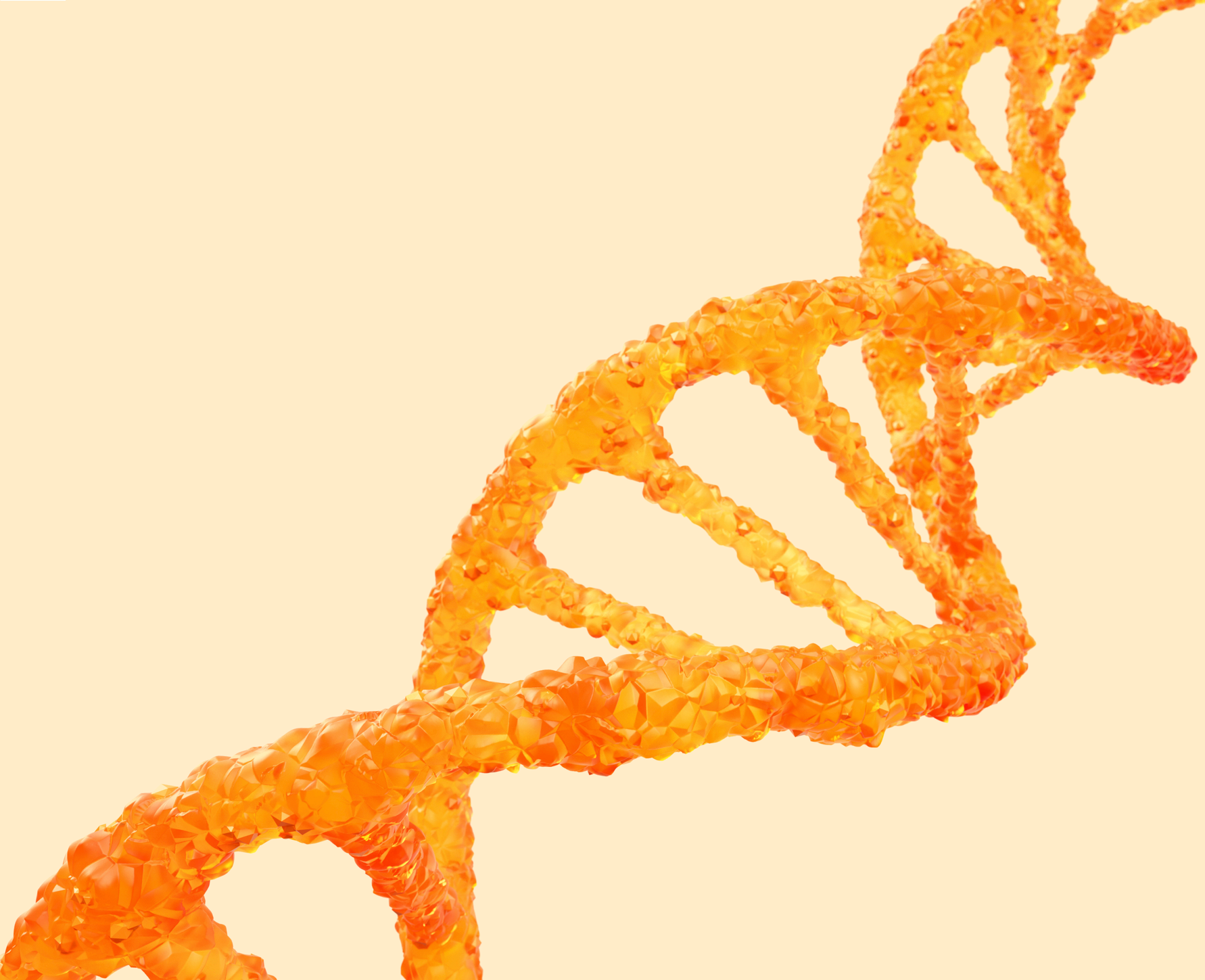
Asset Name	Trial phase and Name	Population description	Treatment arms	No of patients	Key end points	Timing/status	CT identifier	Description
linerixibat	Phase II	Subjects with Primary Biliary Cholangitis	**Arm 1:** linerixibat **Arm 2:** placebo	147	Worse daily itch score; Primary Biliary Cholangitis-40 (PBC-40) Scale	Start Jan 2017	NCT02966834	Dose Response Study of GSK2330672 for the Treatment of Pruritus in Participants With Primary Biliary Cholangitis



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