

Antibody News You Should Know

January 1 - 15, 2022

"Antibodies to Watch in 2022" is now online!

In this 13th installment of the article series, we discuss key events in commercial antibody therapeutics development that occurred in 2021 (~January through October) and forecast events that might occur in 2022. Which antibodies in late-stage clinical studies might enter regulatory review in 2022? [Read this article](#) to find out.

COVID-19 intervention news

Primary endpoint met in Phase 2/3 study of ensovibep

On January 10, 2022, [Molecular Partners AG and Novartis announced](#) that Part A of the Phase 2/3 EMPATHY clinical trial comparing single intravenous doses of ensovibep vs. placebo to treat COVID-19 met the primary endpoint of viral load reduction over eight days. EMPATHY Part A enrolled 407 patients to identify a dose of ensovibep (75mg, 225mg or 600mg) with optimal safety and efficacy; the primary endpoint was met for all three dosing arms. Novartis has confirmed it will now exercise its option to in-license ensovibep from Molecular Partners and, following exercise of the option, will seek expedited access globally, first via the FDA's Emergency Use Authorization (EUA) process.

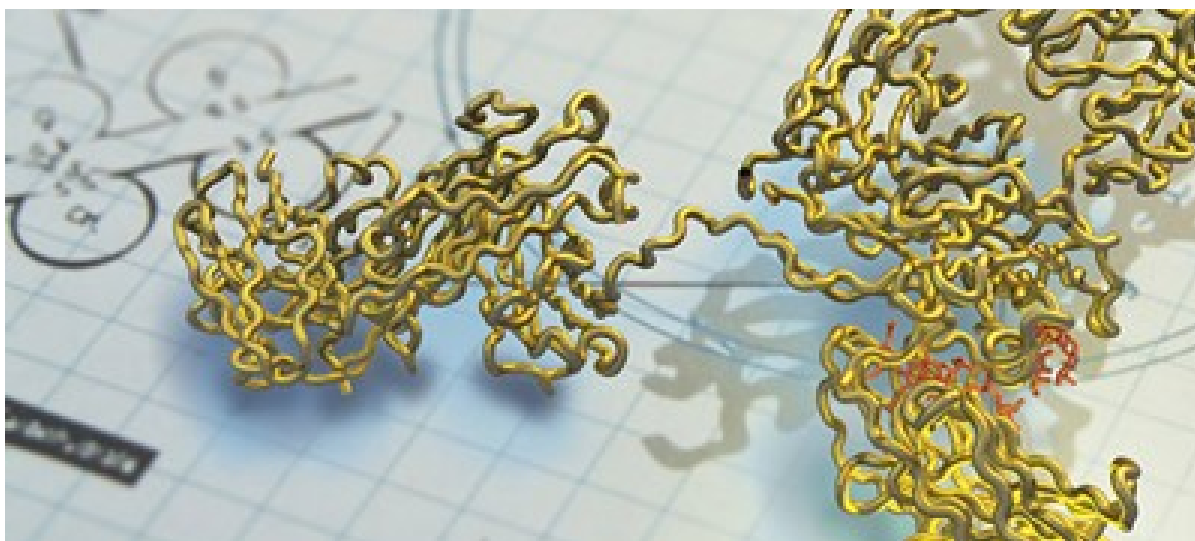
- Ensovibep is a trispecific DARPIn® that targets 3 parts of the spike protein of virus.

EUA for IM-administered sotrovimab requested

On January 13, 2022, [GlaxoSmithKline plc and Vir Biotechnology, Inc. announced](#) the submission of an application to the US Food and Drug Administration (FDA) requesting an amendment to the Emergency Use Authorization (EUA) for sotrovimab to include intramuscular

(IM) administration. This submission is based on the Phase 3, randomized, open-label, non-inferiority COMET-TAIL trial, which achieved its primary endpoint, demonstrating that 500mg IM administration of sotrovimab (n=376) was non-inferior and offered similar efficacy to 500 mg intravenous (IV) administration (n=378) for the early treatment of mild-to-moderate COVID-19 in high-risk, non-hospitalized adults and adolescents.

- Sotrovimab is a human anti-SARS-CoV-2 monoclonal antibody.



[Updates on non-COVID-19 interventions](#)

INDs for new mAb therapeutics filed or cleared with FDA

On January 4, 2022, [Viridian Therapeutics, Inc. announced](#) the submission of an investigational new drug (IND) application to the FDA for VRDN-002, a monoclonal antibody that incorporates half-life extension technology and is designed to support administration as a convenient, low-volume, subcutaneous injection for the treatment of thyroid eye disease. The company submitted the IND for VRDN-002 in December 2021.

- VRDN-002 is a humanized anti-IGF-1R monoclonal antibody.

On January 4, 2022, [Verseau Therapeutics, Inc. announced](#) that the FDA has cleared the company's IND application for its lead investigational product candidate, VTX-0811. The VTX-

0811 two-part Phase 1 clinical trial will initially evaluate the safety profile of the drug administered IV to individuals with select solid tumor types that are predicted to have the highest probability of responding to treatment. The Phase 1b expansion portion of the trial will further evaluate VTX-0811 as a monotherapy and in combination with PD-1 therapy in select tumor types.

- VTX-0811 is a humanized IgG4 monoclonal antibody that binds to P-selectin glycoprotein ligand-1.

On January 3, 2022, [CStone Pharmaceuticals announced](#) that the company will transition CS5001 into clinical studies soon, following FDA's acknowledgement that the study may proceed. This antibody-drug conjugate (ADC) was originally generated by collaboration of LegoChem Biosciences and ABL Bio. CS5001 uses LCB's proprietary tumor-cleavable linker and a pyrrolobenzodiazepine prodrug payload, and has a DAR of 2 achieved via site-specific conjugation.

- CS5001 is an ADC targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1).

Phase 1 studies of ALE.F02, 23ME-00610, and GEN1047 started

On January 4, 2022, [Alentis Therapeutics, AG announced](#) it dosed the first cohort of healthy participants in a first-in-human Phase 1 clinical trial of ALE.F02, which is currently being developed for the treatment of advanced unmet liver and kidney fibrosis. In preclinical studies, ALE.F02 modulates the function of non-junctional Claudin-1, preventing, and possibly reversing, the growth of fibrotic tissue within the liver and kidney by changing the plasticity of key cell types mediating fibrosis.

- ALE.F02 is a monoclonal antibody highly selective for Claudin-1.

On January 6, 2022, [23andMe Holding Co. announced](#) the first participant has been dosed in a Phase 1 clinical trial evaluating 23ME-00610 for the treatment of advanced solid tumors. 23ME-00610 is 23andMe's first wholly owned immuno-oncology antibody to enter clinical studies. The company previously collaborated with GlaxoSmithKline to discover and develop anti-CD96 antibody GSK6097608, which is being evaluated in a Phase 1 study of patients with solid tumors.

- 23ME-00610 is a humanized monoclonal antibody that targets CD200R1, which is part of an immunological checkpoint that plays a pivotal role in maintenance of immune tolerance.

On January 6, 2021, details were posted on clinicaltrials.gov for a first-in-human study ([NCT05180474](#)) to evaluate the safety of GEN1047 in subjects with malignant solid tumors. Sponsored by Genmab, the study will enroll an estimated 220 patients. The study started in December 2021 and has an estimated primary completion date in January 2025.

- GEN1047 is an Fc-silenced DuoBody® targeting B7H4 and CD3.

Phase 3 program for vilobelimab starts

On January 5, 2022, [InflaRx N.V. announced](#) the initiation of the Phase 3 program with vilobelimab in hidradenitis suppurativa patients with active draining tunnels. Enrollment is slated to start in Q2 2022.

Vilobelimab is an IgG4 monoclonal antibody that targets human complement factor C5a.

- Telisotuzumab vedotin receives FDA's Breakthrough Therapy designation

Telisotuzumab vedotin granted Breakthrough Therapy designation

On January 4, 2022, [AbbVie announced](#) the FDA granted Breakthrough Therapy Designation to their anti-cMet antibody-drug conjugate telisotuzumab vedotin for the treatment of patients with advanced/metastatic epidermal growth factor receptor wild type, nonsquamous non-small cell lung cancer with high levels of c-Met overexpression whose disease has progressed on or after platinum-based therapy. The Phase 3 study TeliMET NSCLC-01 (M18-868) is planned to begin in the first half of 2022.

- Telisotuzumab vedotin (ABBV-399) is an ADC composed of a humanized IgG1 antibody targeting cMet conjugated to the cytotoxic drug MMAE.

FDA grants its first approval for a veterinary mAb

On January 13, 2022, the [FDA approved Solensia \(frunevetmab\)](#), the first monoclonal antibody new animal drug approved by the FDA for use in any animal species. Solensia™ is approved for the control of pain associated with osteoarthritis in cats. Substantial evidence of effectiveness was demonstrated by the results of two field studies in cats with naturally occurring osteoarthritis. The endpoints used to evaluate the effectiveness of Solensia™ were observer-reported measures conducted by either owners (assessment of the cat's activities before

development of osteoarthritis, as well as before and after treatment) or veterinarians (orthopedic examinations before and after treatment).

- Developed by Zoetis Inc., frunevetmab is a felinized immunoglobulin G mAb that targets nerve growth factor.

Attending a meeting soon?

The Antibody Society members save up to 20% on registration fees to attend:

PepTalk, January 17-19, 2022

- Use code TAS20 for a 20% discount

LAG-3 Targeted Drug Development Summit, January 25-27, 2022

- Use code 24181ABS for a 10% discount

World ADC, March 29 – April 1, 2022

- Use code TABS10 for a 10% discount

Novel Format Conjugates Summit, April 25-27, 2022

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Anti-SARS-CoV-2 antibodies queue for clinical study

On January 21, 2022, [Sorrento Therapeutics, Inc. announced](#) the release of new data on the Omicron variant neutralizing antibody STI-9167, discovered and developed for clinical trials in an ongoing collaboration between Sorrento and the Icahn School of Medicine at Mount Sinai.

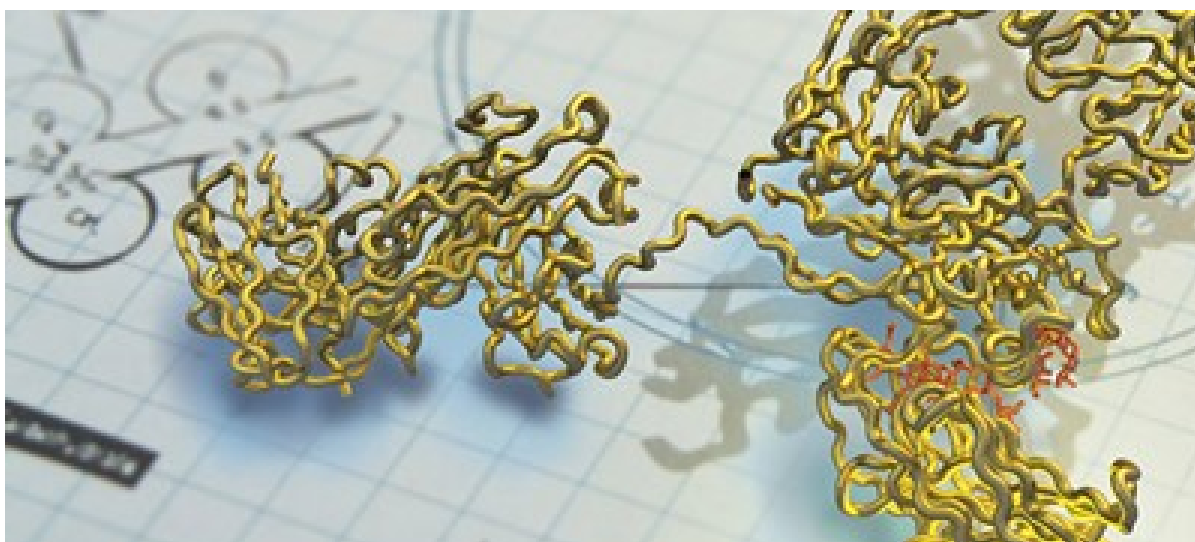
Sorrento is evaluating in-house GMP manufacturing and is in negotiations with major global CMOs for commercial scale manufacturing to secure capacity to manufacture and supply tens of millions of doses. Sorrento currently has sufficient cGMP drug substance for 100,000s of doses at the projected intranasal dose of STI-9199, the intranasal formulation of STI-9167.

Investigational New Drug (IND) applications are to be submitted in the US, UK and Mexico within a month for use as either a small volume intravenous push or intranasal instillation.

On January 31, 2022, [IMMUNOPRECISE ANTIBODIES LTD. announced](#) the release of data demonstrating strong neutralizing potency of its PolyTope® TATX-03 antibody cocktail towards the SARS-CoV-2 Omicron variant in in vitro pseudovirus assays. This first-generation 4 antibody cocktail against SARS-CoV-2 was rationally designed to sustain efficacy against all SARS-CoV-2 strains and variants with the goal of protecting and treating all individuals. PolyTope TATX-03 can engage multiple modes of action, facilitated through simultaneously targeting various non-overlapping epitopes on the spike trimer. The company expects that, upon completion of ongoing studies, the preclinical data will enable the company to file an IND application.

FDA limits use of two anti-SARS-CoV-2 antibody products

On January 24, 2022, the US [Food and Drug Administration \(FDA\)](#) revised the [authorizations](#) for two monoclonal antibody treatments – bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab). Because data show these treatments are highly unlikely to be active against the omicron variant, which is circulating at a very high frequency throughout the United States, these treatments are not authorized for use in any U.S. states, territories, and jurisdictions at this time.



[Updates on non-COVID-19 interventions](#)

CR9114 antibody to be developed for influenza

On January 18, 2022, [Leyden Laboratories announced](#) that they had entered into an exclusive licensing agreement with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize CR9114 for mucosal administration. Leyden Labs will develop an intranasal spray protecting against influenza A and influenza B based on CR9114, which was derived from work done by Crucell Holland B.V. and The Scripps Research Institute.

- CR9114 is a human monoclonal antibody protecting against influenza A and influenza B in preclinical models.

CytomX Therapeutics' CX-904 to enter clinical study soon

On January 19, 2022, [CytomX Therapeutics, Inc. announced](#) that the FDA has cleared the company's IND application for CX-904, a conditionally activated bispecific antibody being co-developed by CytomX and Amgen. CytomX's Probody therapeutics are "masked" to reduce binding to antigen in healthy tissue, but can become "unmasked" by proteases that are preferentially activated in the tumor microenvironment.

- CX-904 is a conditionally activated EGFRxCD3 T-cell-engaging bispecific antibody.

Seagen queues 2 antibody therapeutics for clinical study

On January 18 and 26, 2022, Seagen Inc. posted details on clinicaltrials.gov for Phase 1 studies of SGN-B7H4V and SGN-PDL1V, respectively. The Phase 1 [NCT05194072](#) study will evaluate the effects of SGN-B7H4V in patients with advanced solid tumors. The Phase 1 [NCT05208762](#) study will evaluate the effects of SGN-PDL1V in patients with advanced solid tumors. Both studies are not yet recruiting patients as of February 1, 2022.

- SGN-B7H4V is composed of a human IgG1 anti-B7-H4 monoclonal antibody conjugated to the microtubule disrupting agent monomethyl auristatin E (MMAE) via a protease-cleavable peptide linker.
- SGN-PDL1V is an MMAE antibody-drug conjugate directed to the T cell checkpoint ligand, PD-(L)1.

Marketing authorisation application submitted to EMA for teclistamab

On January 31, 2022, The [Janssen Pharmaceutical Companies of Johnson & Johnson announced](#) the submission of a marketing authorisation application (MAA) to the European Medicines Agency (EMA) seeking approval of teclistamab for the treatment of patients with relapsed or refractory multiple myeloma (RRMM). Janssen announced in December 2021 that a biologics license application had been submitted to the FDA seeking approval of teclistamab for the treatment of RRMM. Teclistamab received a PRiority MEdicines designation by the EMA and Breakthrough Therapy Designation by the FDA.

- Teclistamab is a T-cell redirecting, bispecific antibody targeting both B-cell maturation antigen and CD3.

European Commission approves Vyepti® (eptinezumab)

On January 24, 2022, [H. Lundbeck A/S announced](#) that the European Commission has granted marketing authorization for Vyepti® (eptinezumab) in the European Union for the

prophylactic treatment of migraine in adults who have at least four migraine days per month. The marketing authorization is based on the efficacy and safety of Vyepti, which has been investigated in two phase III clinical trials (PROMISE-1 in episodic migraine and PROMISE-2 in chronic migraine). In February 2020, FDA approved eptinezumab-jjmr for the preventive treatment of migraine in adults.

- Eptinezumab-jjmr is a humanized immunoglobulin G1 (IgG1) monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand.

FDA approves tebentafusp-tebn and faricimab-svoa

On January 26, 2022, [Immunocore Holdings plc announced](#) the approval from the FDA of KIMMTRAK® (tebentafusp-tebn) for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (mUM). Developed by Immunocore, this molecule creates a bridge between tumor cells and immune cells, and thus facilitates tumor-cell killing by T cells. As the TCR domain recognizes a peptide presented on HLA-A*02:01, tebentafusp can only be used to treated patients expressing this HLA type. The EMA, the United Kingdom's Medicines and Healthcare Regulatory Agency, Health Canada, and the Australian Government Department of Health Therapeutic Goods Administration have accepted the submission of MAAs for tebentafusp.

- Tebentafusp (IMCgp100) is a bispecific fusion protein composed of: 1) a T cell receptor (TCR) recognizing a human leukocyte antigen (HLA)-A*02:01 complexed with a peptide derived from gp100 antigen expressed by melanoma cells, and 2) an antibody single-chain variable fragment that binds CD3 present on T cells.

On January 28, 2022, [Genentech announced](#) that the FDA has approved Vabysmo™ (faricimab-svoa) for the treatment of wet, or neovascular, age-related macular degeneration (AMD) and diabetic macular edema (DME). The approval was based in part on results from four Phase 3 studies in wet AMD and DME. Results from these studies were recently reported in The Lancet. The EMA has accepted the submission of an MAA for faricimab.

- Faricimab (RO6867461, RG7716) is an anti-vascular endothelial growth factor-A and anti-angiopoietin-2 bispecific antibody derived from Roche's CrossMab technology.

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Novartis requests Emergency Use Authorization for ensovibep

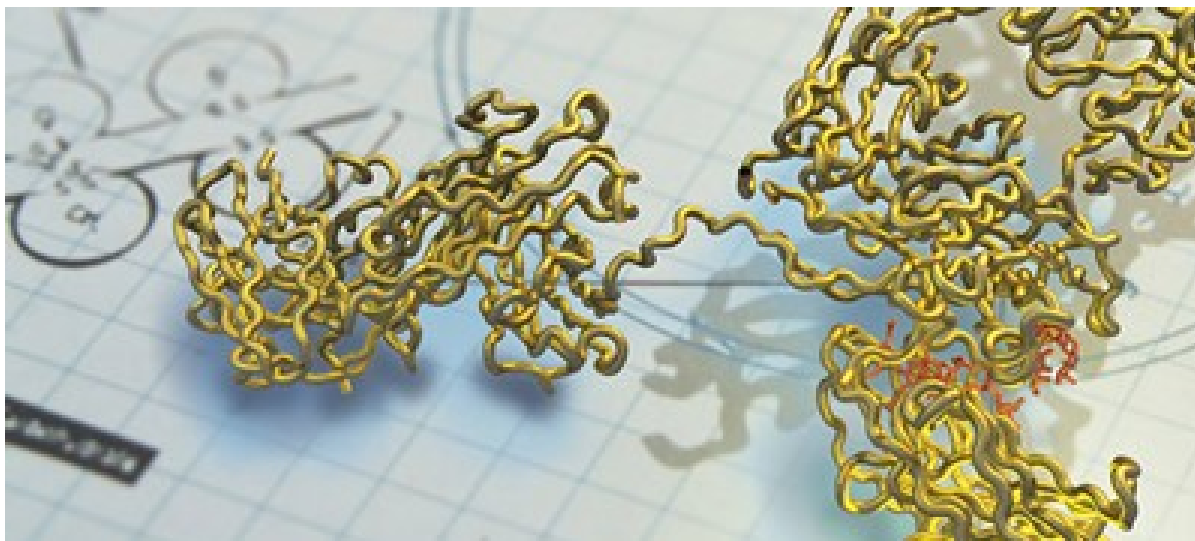
On February 10, 2022, [Molecular Partners AG was informed by its partner Novartis](#) that the company has requested Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for ensovibep to treat COVID-19. This submission is based on the totality of the data from clinical and preclinical studies including the positive results of the Phase 2 portion of the EMPATHY study, a randomized, placebo-controlled study which enrolled 407 symptomatic patients infected with SARS-CoV-2.

- Ensovibep is a Designed Ankyrin Repeat Protein (DARPin) therapeutic candidate that targets 3 parts of the spike protein of SARS-CoV-2.

FDA issues an EUA for bebtelovimab

On February 11, 2022, the [FDA issued an EUA for bebtelovimab](#), an anti-SARS-CoV-2 monoclonal antibody. The EUA was issued to Eli Lilly and Co. The EUA for bebtelovimab is supported by clinical from a Phase 2, randomized, single-dose clinical trial (NCT04634409) evaluating the efficacy of bebtelovimab alone and bebtelovimab combined with other monoclonal antibodies for treating mild to moderate COVID-19. Bebtelovimab is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

- Bebtelovimab (LY-CoV1404) targets the SARS-CoV-2 spike glycoprotein receptor binding domain and has been shown to neutralize the Omicron variant.



[Updates on non-COVID-19 interventions](#)

Clinical study for drug-Fc conjugate may proceed

On February 14, 2022, [Cidara Therapeutics, Inc. announced](#) that the FDA accepted the company's Investigational New Drug (IND) application for its drug-Fc conjugate CD388, a highly potent, long-acting antiviral immunotherapy designed to deliver universal prevention and treatment of seasonal and pandemic influenza. Cidara intends to initiate a Phase 1 study in healthy volunteers before the end of the current quarter.

- CD388 is composed of the Fc domain of a human IgG1 conjugated to a neuraminidase inhibitor.

New antibody therapeutics queue for first-in-human studies

On February 2, 2022, Takeda posted details for a Phase 1/2 study of TAK-280. The [NCT05220098](#) study will evaluate the effects of TAK-280 in patients with unresectable locally advanced or metastatic cancer. The study will enroll an estimated 186 patients and has an estimated start date of March 1, 2022.

- TAK-280 (MVC-280) is a conditionally active bispecific T cell targeted immunotherapy.

On February 8, 2022, Seagen, Inc. posted details for a Phase 1 study of SGN-ALPV. The [NCT05229900](#) study will evaluate the effects of SGN-ALPV in patients with advanced solid tumors. The study will enroll an estimated 285 patients and has an estimated start date of March 31, 2022.

- SGN-ALPV is an antibody-drug conjugate.

On February 10, 2022, Silverback Therapeutics posted details for a Phase 1/2 first-in-human study ([NCT05234606](#)) of SBT6290 alone and in combination with PD-(L)1 inhibitors in subjects with advanced solid tumors associated with Nectin-4 expression. The study will enroll an estimated 225 patients and has an estimated start date in February 2022.

- SBT6290 is an anti-Nectin4 IgG1 with a TLR8 agonist payload.

Phase 2 asset licensed

On February 3, 2022, [Regio Biosciences announced](#) it entered into an exclusive license agreement with AstraZeneca to further develop REG-101, a novel therapeutic acting on reverse cholesterol transport (RCT). Regio expects to initiate a Phase 2a clinical program evaluating REG-101 in peripheral artery disease during the second half of 2022.

- REG-101, previously known as MEDI5884, is a humanized IgG4P kappa monoclonal antibody that targets human endothelial lipase.

Phase 2 asset NGM621 granted Fast Track designation

On February 7, 2022, [NGM Biopharmaceuticals announced](#) that NGM621 was granted FDA's Fast Track designation for the treatment of patients with geographic atrophy secondary to age-related macular degeneration. NGM621 is in a Phase 2 study for this indication (CATALINA clinical trial, clinicaltrials.gov identifier: NCT04465955).

- NGM621 is a humanized IgG1 antibody targeting complement C3.

First Phase 2 study of argenx's ARX-117 starts

On February 4, 2022, details were posted for the first Phase 2 study ([NCT05225675](#)) of ARGX-117, which is designed with an Fc backbone equipped with the proprietary NHance™ mutation that is intended to enhance the binding of the antibody to FcRn in the endosome and prevent the

antibody going into the lysosome for degradation. The study will evaluate the effects of ARGX-117 in patients with multifocal motor neuropathy.

- ARGX-117 is a human IgG1 anti-C2 “sweeping” antibody.

FDA's advisory committee recommends bridging study for sintilimab

On February 10, 2022, FDA's Oncologic Drugs Advisory Committee indicated that at least one **bridging study for sintilimab** should be required before the mAb can be considered for approval in the US. To date, all clinical data were collected from sites in China. On the single voting question, the advisory committee voted that additional clinical trial(s) should be required to demonstrate applicability to the U.S. population and U.S. medical practice prior to a final regulatory decision.

- Sintilimab is a novel PD-1 inhibitor being developed and commercialized under a collaboration agreement between Innovent and Lilly.

FDA approves Enjaymo

On February 4, 2022, the **FDA approved Enjaymo (sutimlimab-jome)** infusion to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease (CAD). This rare autoimmune disorder is characterized by hemolysis caused by activation of the classic complement pathway. Sutimlimab received FDA's Breakthrough Therapy and Orphan Drug designations for CAD, and Orphan Drug designation in the EU for this indication. The BLA was based on data from the CARDINAL open-label, single-arm study (NCT03347396), which enrolled 24 adult patients with CAD who received a recent blood transfusion. In this study, sutimlimab administration rapidly halted hemolysis, increased hemoglobin levels, and reduced fatigue. The European Medicines Agency has accepted the submission of a Marketing Authorisation Application for sutimlimab.

- Sutimlimab is a hinge-stabilized, humanized IgG4k antibody that targets and inhibits complement component 1s (C1s). A mutation in the Fc region (L235E) reduces the effector functions of the antibody.

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New anti-SARS-CoV-2 antibody queues to enter clinical study

On February 22, 2022, [Sorrento Therapeutics, Inc. announced](#) that additional preclinical results demonstrate broad spectrum COVISHIELD (STI-9167) neutralizing activity against Omicron BA.1, Omicron BA.1+R346K, and the increasingly prevalent sublineage, Omicron BA.2. An investigational new drug (IND) application for COVISHIELD™ IN (STI-9199), formulated for intranasal administration for clinical use in the context of early symptomatic and asymptomatic infections, was submitted to the Food and Drug Administration (FDA) on February 1, 2022.

- STI-9167/ STI-9199 is an anti-SARS-CoV-2 antibody that was optimized to maximize protein stability and minimize interactions with host Fc gamma receptors.

FDA revises EUAs for Xevudy and EVUSHELD

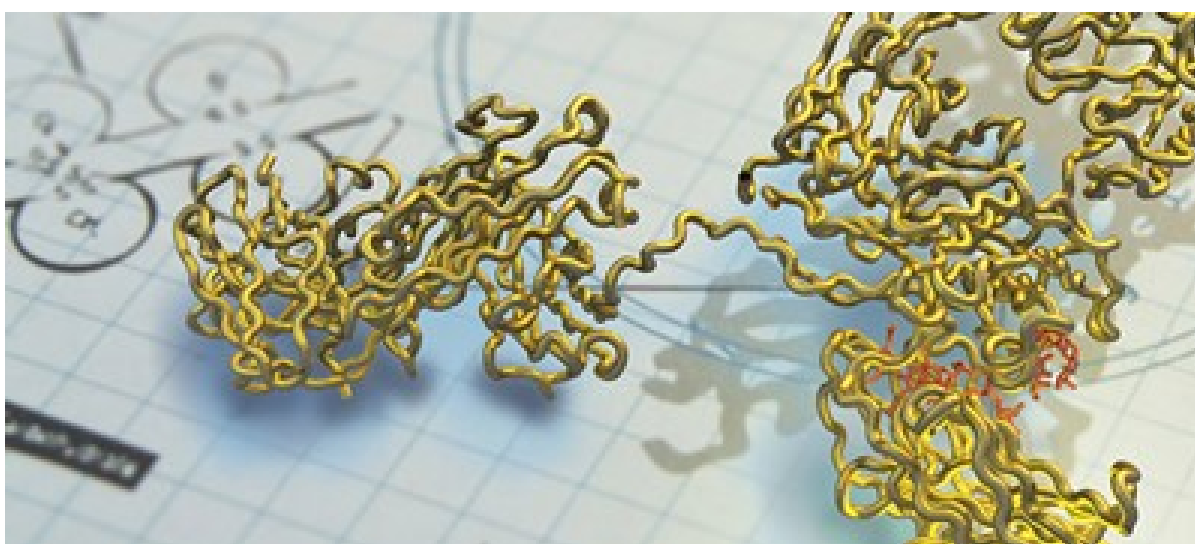
On February 23, 2022, the [FDA released a new fact sheet](#) for healthcare providers with revisions to the EUA for sotrovimab (Xevudy), manufactured by GlaxoSmithKline. The FDA updated authorization for those likely to have been infected with or have been exposed to a susceptible SARS-CoV-2 variant, as well as the intravenous infusion time. They also added COMET-TAIL safety, PK, and efficacy data and information on susceptibility of SARSCoV-2 variants to sotrovimab.

- Sotrovimab is a human IgG1 antibody that targets the receptor binding domain of the spike protein of SARS-CoV-2.

On February 24, 2022, the [FDA revised the emergency use authorization](#) of AstraZeneca's anti-SARS-CoV-2 antibody combination (tixagevimab/ cilgavimab; EVUSHELD) to increase the initial authorized dose to 300 mg of each antibody. Patients who have already received the previously authorized dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive an additional dose of 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible to raise

their monoclonal antibody levels to those expected for patients receiving the higher dose. FDA first issued an emergency use authorization for EVUSHELD in December 2021.

- Tixagevimab and cilgavimab, the active components of EVUSHELD, are neutralizing IgG1 monoclonal antibodies that bind to distinct, non-overlapping epitopes within the receptor binding domain of the spike protein of SARS-CoV-2.



[Updates on non-COVID-19 interventions](#)

INDs for new antibody therapeutics submitted or cleared

On February 15, 2022, [Ambrx Biopharma Inc. announced](#) it received a “Study May Proceed” letter from the FDA related to an IND application for ARX305 to treat a broad range of solid and hematologic tumors such as renal cell carcinoma. ARX305 will be evaluated in a Phase 1, multicenter, open-label, dose-escalation, and dose-expansion study that will assess the safety, pharmacokinetics and preliminary anti-tumor activity of ARX305 in adults with clear cell renal cell carcinoma who are resistant or refractory to prior standard therapies. Ambrx has licensed the rights to develop and commercialize ARX305 in China to NovoCodex Pharmaceuticals Ltd.

- ARX305 is an antibody-drug conjugate designed to target CD70.

On February 15, 2022, [AffaMed Therapeutics announced](#) that the FDA has cleared its IND application for the clinical development of AM712 (ASKG712) for the treatment of retinal vascular diseases. AffaMed Therapeutics recently entered into a licensing agreement with AskGene Pharma Inc. for the exclusive rights to develop, manufacture and commercialize AM712 in ex-Asia plus Japan territories globally. AskGene received China CTA clearance for AM712(ASKG712) in January 2022.

- AM712 is a bispecific, antibody-peptide fusion molecule that targets VEGF and Ang-2.

On February 21, 2022, [Harbour BioMed announced](#) that China National Medical Products Administration had approved its IND application for HBM9378 for the treatment of moderate-to-severe asthma. HBM9378 is also known as SKB378 by Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd., a subsidiary of Sichuan Kelun Pharmaceutical Co., Ltd, which has partnered with Harbour BioMed in the development of the antibody therapeutic.

- HBM9378/ SKB378 is a human antibody targeting thymic stromal lymphopoietin.

On February 28, 2022, [Harbour BioMed announced](#) that it has been approved by the Institutional Review Boards to commence a Phase 1 trial of HBM7008 in Australia. This study will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary anti-tumor activity of HBM7008 in patients with solid tumors. HBM7008 was developed from the HBICE® platform, i.e., heavy chain only (HCAb)-based immune cell engagers (HBICE®).

- HBM7008 is a human bispecific antibody targeting B7H4 and 4-1BB.

Fast track designation granted for IO-202

On February 17, 2022, [Immune-Onc Therapeutics, Inc. announced](#) that the FDA has granted Fast Track designation for IO-202 for the treatment of patients with relapsed or refractory acute myeloid leukemia (AML). The company received Orphan Drug Designation for IO-202 for the treatment of AML in 2020. IO-202 is currently in Phase 1 clinical development for the treatment of AML and chronic myelomonocytic leukemia.

- IO-202 is a monoclonal antibody that targets leukocyte immunoglobulin-like receptor B4 (LILRB4), which suppresses T-cell activation and supports tissue infiltration of AML cells.

BLA for mirikizumab is planned

On February 18, 2022, [Eli Lilly and Company announced](#) that patients with moderately-to-severely active ulcerative colitis (UC) who took mirikizumab achieved statistically superior rates

of clinical remission at 12 weeks compared to patients taking placebo in the pivotal LUCENT-1 Phase 3 study. Lilly plans to submit a Biologics License Application (BLA) to the FDA for approval of mirikizumab in UC, followed by submissions to other regulatory agencies around the world, in the first half of 2022.

- Mirikizumab is a humanized IgG4 antibody that targets IL-23p19.

Marketing application for nirsevimab under evaluation by EMA

On February 17, 2022, [Sanofi announced](#) that the European Medicines Agency has accepted the Marketing Authorization Application for nirsevimab under an accelerated assessment procedure. Developed by Sanofi and AstraZeneca, nirsevimab is the first investigational long-acting antibody designed to protect all infants for the respiratory syncytial virus (RSV) season with a single dose. Nirsevimab is not yet approved in any country; additional regulatory submissions are planned to take place in 2022.

- Nirsevimab is a human anti-RSV antibody with an extended half-life derived from YTE (M252Y, S254T, T256E) mutations in the Fc.

BLA for teplizumab resubmitted to FDA

On February 22, 2022, [Provention Bio, Inc. announced](#) it has resubmitted the BLA for teplizumab for the delay of clinical type 1 diabetes in at-risk individuals. The resubmission addressed the FDA's pharmacokinetic comparability considerations contained in the complete response letter issued in July 2021, as well as Chemical, Manufacturing, and Controls (CMC) and product quality considerations. Within 30 days of the resubmission, FDA will review the documents provided, determine whether the resubmission is complete and acceptable for review, and give the company a review goal date for the application.

- Teplizumab, also called MGA031 and hOKT31(Ala-Ala), is a humanized, non-Fc receptor binding, anti-CD3 monoclonal antibody.

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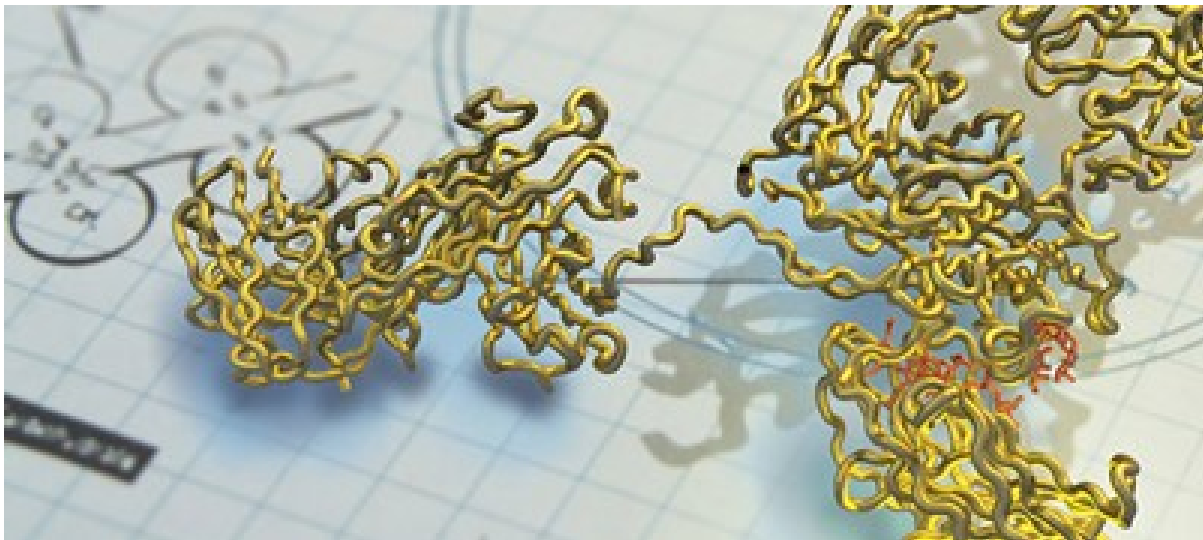
High-concentration formulation of TATX-03 to be explored

On March 14, 2022, [Elektrofi and ImmunoPrecise Antibodies Ltd. \(IPA\)](#) announced that they are entering into a collaboration to explore a high-concentration formulation of IPA's COVID-19 antibody cocktail, PolyTope® TATX-03. This collaboration aims to generate an Investigational New Drug (IND)-enabling data package for the U.S. Food and Drug Administration (FDA) for an alternatively formulated version of TATX-03, named TATX-03E, that could be easily self-administered in a non-healthcare setting. The collaboration will be supported by Elektrofi's contract with the Defense Health Agency's Small Business Innovation Research Program within the Department of Defense.

Clinical hold on IMM-BCP-01 lifted

On March 11, 2022, [Immunome, Inc.](#) announced that the FDA lifted the clinical hold on its IND application for its antibody cocktail (IMM-BCP-01), for the treatment of SARS-CoV-2 infection. FDA had placed the company's IND application on clinical hold and requested further information related to the preparation and administration of IMM-BCP-01 at clinical sites. In response, Immunome provided the FDA with a comprehensive report detailing the necessary information.

- IMM-BCP-01 is a three-antibody cocktail targeting non-overlapping regions of the Spike protein of SARS-CoV-2, including highly conserved, subdominant epitopes.



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Twist Bioscience and Kriya Therapeutics announce discovery agreement

On March 9, 2022, [Twist Bioscience Corporation and Kriya Therapeutics, Inc. announced](#) an antibody discovery agreement for antibodies delivered using adeno-associated viral gene therapy in therapeutic oncology applications. Twist Biopharma, a division of Twist Bioscience, expects to leverage its antibody discovery and optimization platform to discover novel antibodies against specific targets of interest that will be engineered into Kriya Therapeutics's proprietary gene therapy technology platform for durable and targeted delivery.

Nectin Therapeutics receives funding to support clinical study of NTX1088

On March 8, 2022, [Nectin Therapeutics announced](#) a \$5.4 million investment from Cancer Focus Fund, which will support Phase 1 study of their first-in-class monoclonal antibody NTX1088. The Cancer Focus Fund investment will support a Phase 1 clinical study assessing NTX1088 in the treatment of locally advanced and metastatic solid tumors. The Phase 1 trial is expected to begin enrolling patients around mid-year of 2022.

- NTX1088 targets PVR (also known as CD155) with high affinity and blocks its interactions with TIGIT and CD96, preventing their immune inhibitory signaling. and it

blocks the interaction between PVR and DNAM1, also known as CD226, a molecule involved in the activation of anti-cancer T cells and natural killer cells.

Epsilogen receives funding to support further clinical studies of IgE therapeutic

On March 2, 2022, [Epsilogen Ltd. announced](#) it has secured £30.75 million (\$41.20 million) in an oversubscribed Series B financing round led by new investor Novartis Venture Fund and joined by new investors 3B Future Health Fund and British Patient Capital, Schroders Capital and Caribou Property. The proceeds from the financing will enable Epsilogen to establish clinical proof of concept for lead drug candidate MOv18 IgE in a phase Ib trial in platinum-resistant ovarian cancer, an aggressive cancer with poor treatment alternatives.

- MOv18 IgE targets the folate receptor alpha (FR alpha) antigen and is the world's first IgE antibody to enter the clinic.

DF6002/BMS-9896415 achieves Phase 1-related milestone

On March 1, 2022, [Dragonfly Therapeutics, Inc. announced](#) the achievement of a Phase 1 clinical development milestone from Bristol Myers Squibb (BMS) for progression of its Phase 1 DF6002-001 study with a pharmacokinetic profile and peripheral pharmacodynamics consistent with preclinical models. Dragonfly received IND approval for DF6002 from the U.S. Food and Drug Administration in May 2020, its Phase 1/2 clinical trial began in July 2020, and BMS signed an exclusive worldwide license agreement that includes this asset in August 2020. BMS intends to advance the research and development of DF6002 in oncology and hematology.

- DF6002/BMS-9896415 is a monovalent IL-12 immunoglobulin Fc fusion protein (i.e., a half-life extended IL-12) proposed to achieve strong anti-tumor efficacy by establishing an inflammatory tumor microenvironment necessary for productive anti-tumor responses.

FDA designations granted for HPN217, HPN328, and epcoritamab

On March 2, 2022, [Harpoon Therapeutics, Inc. announced](#) that the FDA has granted Fast Track designation to HPN217, a Tri-specific T cell Activating Construct (TriTAC®), for the treatment of patients with relapsed, refractory multiple myeloma (RRMM) who have received at least four lines of therapy. HPN217 had previously received Orphan Drug designation for this multiple myeloma. AbbVie has an exclusive global licensing option to HPN217 for this indication. A Phase 1/2 clinical trial is currently ongoing for HPN217 in the RRMM patient population.

- HPN217 is composed of three antigen-binding domains: 1) anti-BCMA single domain antibody; 2) anti-albumin single domain antibody; and 3) anti-CD3 ϵ scFv.

On March 7, 2022, [Harpoon Therapeutics, Inc. announced](#) that the FDA has granted Orphan Drug designation for TriTAC® HPN328 for the treatment of small cell lung cancer (SCLC). A Phase 1/2 clinical trial is currently ongoing for HPN328 in the SCLC patient population.

- HPN328 is composed of three domains targeting DLL3, CD3, and albumin.

On March 8, 2022, [Genmab A/S announced](#) that the FDA has granted Orphan Drug designation to the epcoritamab for the treatment of follicular lymphoma (FL). Epcoritamab is being co-developed by Genmab and AbbVie. Epcoritamab is currently being evaluated as a treatment option for patients with FL in several clinical trials, including the phase 1/2 EPCORE™ NHL-1 evaluating the efficacy and safety of subcutaneous epcoritamab in patients with relapsed or refractory B-cell non-Hodgkin's lymphoma

- Epcoritamab (DuoBody®-CD3xCD20) is an investigational IgG1 bispecific antibody created using Genmab's proprietary DuoBody technology.

New antibody therapeutics enter clinical study

On March 2, 2022, information was posted on clinicaltrials.gov for a first-in-human study ([NCT05263479](#)) of the antibody-drug conjugate (ADC) HS-20089. Sponsored by Shanghai Hansoh Biomedical Co., Ltd, this study will evaluate safety, tolerability, pharmacokinetics, and efficacy of HS-20089 in patients with advanced solid tumors. Initiated in January 2022, the study has a primary completion date in December 2023.

- HS-20089 is a novel DAR-6 ADC targeting B7-H4.

On March 9, 2022, [Denali Therapeutics announced](#) the start of a Phase 1/2 clinical study of (PTV):PGRN (DNL593), which starts in healthy participants but then will include participants with frontotemporal dementia caused by mutations in the granulin gene. Denali and Takeda have a strategic collaboration to co-develop and co-commercialize DNL593, which derives from Fstar's Fcab (constant Fc-domains with antigen-binding activity) technology.

- DNL593 is a recombinant protein linking progranulin to a modified Fc domain that binds human transferrin receptor for enhanced CNS biodistribution

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EUA planned for adintrevimab

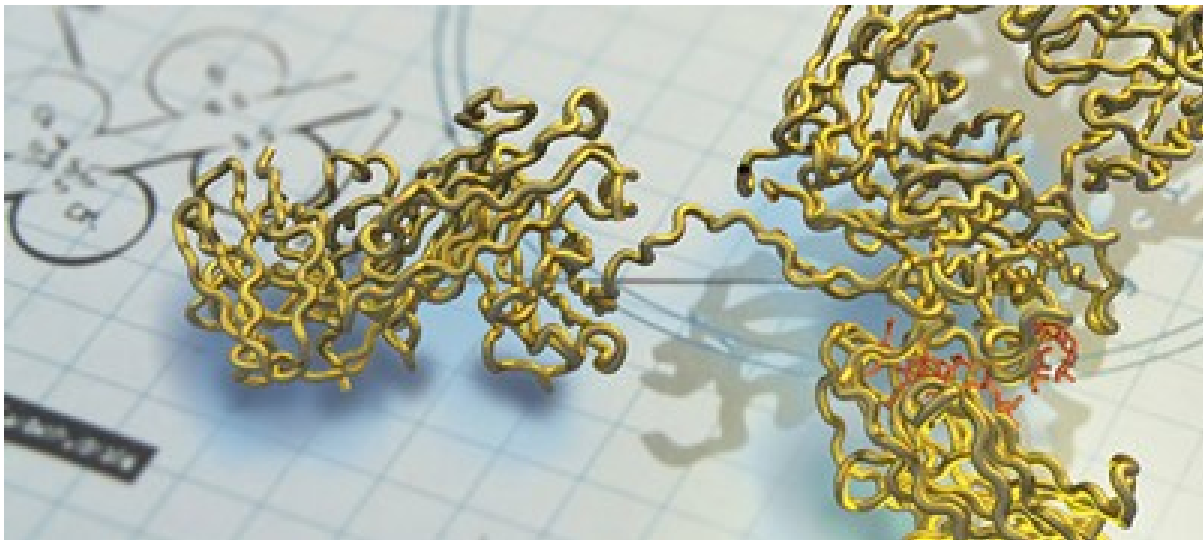
On March 30, 2022, [Adagio Therapeutics, Inc. announced](#) positive results from clinical studies of adintrevimab (ADG20). The company reported that the primary endpoints were met with statistical significance for all three indications in the company's ongoing global Phase 2/3 clinical trials evaluating adintrevimab as a pre-and-post-exposure prophylaxis (EVADE) and treatment (STAMP) for COVID-19. EVADE and STAMP were primarily conducted during a time when pre-Omicron SARS-CoV-2 variants were dominant. Following the emergence of the Omicron variant, in a pre-specified exploratory analysis in a subset of the pre-exposure cohort, a clinically meaningful reduction in cases of symptomatic COVID-19 was observed with adintrevimab compared to placebo. Based on clinical study data, Adagio plans to submit an Emergency Use Authorization (EUA) application in the US in the second quarter of 2022 for adintrevimab for both the prevention and treatment of COVID-19.

- Adintrevimab is a half-life engineered human anti-SARS-CoV-2 antibody.

Evusheld approved in the European Union

On March 28, 2022, [AstraZeneca announced](#) that Evusheld (tixagevimab co-packaged with cilgavimab) was granted marketing authorisation in the European Union for the pre-exposure prophylaxis (prevention) of COVID-19 in a broad population of adults and adolescents aged 12 years and older weighing at least 40 kg. Evusheld was previously granted an EUA for pre-exposure prophylaxis of COVID-19 in the US and has been granted conditional marketing authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain for pre-exposure prophylaxis of COVID-19.

- Tixagevimab and cilgavimab are half-life engineered human anti-SARS-CoV-2 antibodies.
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New spin-off announced

On March 23, 2022, [Ligand Pharmaceuticals Incorporated announced](#) the signing of a definitive merger agreement with Avista Public Acquisition Corp. II, a publicly traded special purpose acquisition company, providing for the spin-off of OmniAb, Inc., Ligand's antibody discovery business, immediately followed by a merger with a newly formed subsidiary of APAC. The combined company will be led by Ligand's President, Matt Foehr, and will be renamed "OmniAb, Inc."

Sanofi partners with Seagen and IGM Biosciences

On March 16, 2022, [Sanofi and Seagen Inc. announced](#) an exclusive collaboration agreement to design, develop, and commercialize antibody-drug conjugates (ADCs) for up to three cancer targets. The collaboration will utilize Sanofi's proprietary monoclonal antibody technology and Seagen's proprietary ADC technology.

On March 29, 2022, Sanofi and IGM Biosciences, Inc. announced the signing of an exclusive worldwide collaboration agreement to create, develop, manufacture, and commercialize IgM antibody agonists against three oncology targets and three immunology/inflammation targets. Engineered IgM antibodies represent a new class of potential therapeutics that combine the multi-valency of IgM antibodies possessing 10 binding sites compared to conventional IgG antibodies, which have only 2 target binding sites.

Numab Therapeutics AG partners with Ono Pharmaceutical Co

On March 31, 2022, [Numab Therapeutics AG announced](#) that Ono Pharmaceutical Co., Ltd. has exercised its option to enter into a development and license agreement for a multispecific antibody candidate that was generated through a research collaboration between the two companies initiated in 2017. Under the terms of the license agreement, Ono acquires intellectual

property rights and exclusive global development and commercialization rights for a multispecific antibody targeting a novel immuno-oncology target. In consideration for the discovery work and the license, Numab will receive up to CHF 258 million in research funding, upfront and milestone payments plus tiered single to double digit royalties on future sales.

Two antibody therapeutics queued for first clinical study

On March 24, 2022, [Celsius Therapeutics announced](#) its first clinical candidate, anti-TREM1 antibody CEL383, for the treatment of inflammatory bowel disease. TREM1, a myeloid target with a central role in IBD, was identified through single cell analysis of hundreds of clinical samples using machine learning algorithms via the company’s SCOPE platform. The company anticipates filing an investigational new drug application with the U.S. Food and Drug Administration (FDA) within the next year, with a Phase 1 study expected to commence in early 2023.

On March 24, 2022, [details were posted on clinicaltrials.gov](#) for a first-in-human study of SG2501. Sponsored by Hangzhou Sumgen Biotech Co., Ltd., the Phase 1 study will evaluate the effects of SG2501 in subjects with relapsed or refractory hematological malignancies and lymphoma. The study aims to recruit 72 participants and has an estimated start date of April 1, 2022.

- SG2501 is a bispecific antibody targeting CD38 and CD47.

Biologics License Application submitted for mirvetuximab soravtansine

On March 29, 2022, [ImmunoGen, Inc. announced](#) that they submitted a Biologics License Application (BLA) under the accelerated approval pathway to the FDA for mirvetuximab soravtansine monotherapy in patients with folate receptor alpha (FR α)-high platinum-resistant ovarian cancer who have been previously treated with 1 to 3 prior systemic treatments. The FDA granted Orphan Drug Designation to mirvetuximab soravtansine for the treatment of ovarian cancer and Fast Track Designation for the treatment of patients with medium to high FR α -positive platinum-resistant ovarian cancer who received at least one, but no more than three, prior systemic treatment regimens, and for whom single-agent chemotherapy is appropriate as the next line of therapy.

- Mirvetuximab soravtansine (IMGN853) is an ADC comprising a folate receptor alpha-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin-targeting agent.

Relatlimab / nivolumab combo approved in the US

On March 18, 2022, [Bristol Myers Squibb announced](#) that FDA has approved Opdualag (nivolumab and relatlimab-rmbw), as a fixed-dose combination administered as a single intravenous infusion, for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. The combination of nivolumab (anti-PD-1) and relatlimab (anti-LAG-3) results in increased T-cell activation compared to the activity of either antibody alone. This approval is the first for relatlimab; nivolumab was first approved by FDA in 2014.

- Relatlimab is a human IgG4 anti-LAG-3 antibody.

Serplulimab approved in China

On March 25, 2022, [Shanghai Henlius Biotech, Inc announced](#) that HANSIZHUANG (serplulimab injection) has been approved by China's National Medical Products Administration for the treatment of adult patients with advanced unresectable or metastatic MSI-H (Microsatellite Instability-High) solid tumors that have failed to respond to previous standard treatments, providing an alternative treatment option for patients.

- Serplulimab is a humanized IgG4 antibody that targets PD-1.

Nemolizumab approved in Japan

On March 28, 2022, [Maruho Co., Ltd. announced](#) that it has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare for Mitchga® (nemolizumab) Subcutaneous Injection 60mg Syringes for the treatment of itching associated with atopic dermatitis (only when existing treatment is insufficiently effective) in Japan. Chugai granted Maruho the rights for the development and marketing of nemolizumab (CIM331) in the skin disease area for the Japanese market.

- Nemolizumab is a humanized IgG2 antibody targeting IL-31 receptor alpha.

A banner with a blue geometric background. The text "Antibody Engineering & Therapeutics Europe" is written in white, bold, sans-serif font. The background features various shades of blue triangles and a dark, abstract shape on the right side.

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