

Antibody News You Should Know

April 1 - 15, 2022

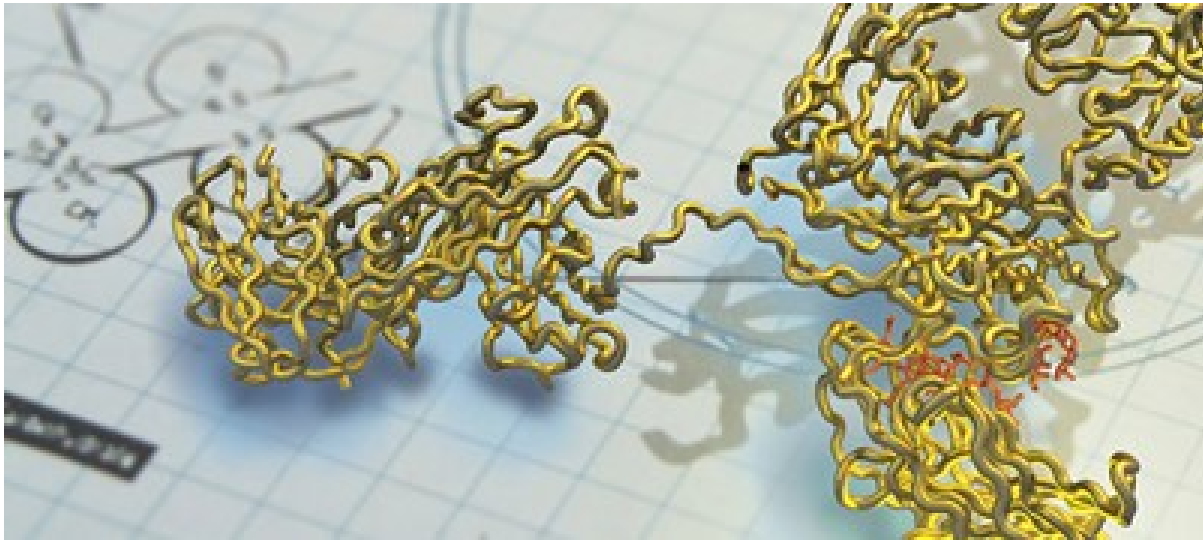
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FDA's decision on REGEN-COV is delayed

On April 14, 2022, [Regeneron Pharmaceuticals, Inc. announced](#) that the U.S. Food and Drug Administration (FDA) has extended by three months its review of the Biologics License Application (BLA) for REGEN-COV® (casirivimab and imdevimab) to treat COVID-19 in non-hospitalized patients and as prophylaxis in certain individuals. The extension is due to ongoing discussions with the FDA on pre-exposure prophylactic use, for which Regeneron has submitted additional data from its completed prophylaxis trial that the FDA has accepted for review. The FDA considers the submission of these additional data to be a Major Amendment to the BLA and has provided a new target action date of July 13, 2022.

- REGEN-COV is a cocktail of two anti-SARS-CoV-2 monoclonal antibodies derived from Regeneron's proprietary VelocImmune® and VelociSuite® technologies.
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[Updates on non-COVID-19 interventions](#)

New antibodies queued for first-in-human studies

On April 4, 2022, [Aqualung Therapeutics Corporation announced](#) their plans for submission of an investigational new drug (IND) application for ALT-100 in May 2022, followed by initiation of clinical study in June 2022. [A study recently published](#) in the American Journal of Respiratory and Cell Molecular Biology reported the capacity of the ALT-100 to reduce ionizing radiation-induced murine lung fibrosis. The lead indication is acute respiratory distress syndrome and ventilator-induced lung injury, and development in chronic indications such as pulmonary fibrosis will occur in parallel.

- ALT-100 is a humanized therapeutic antibody that targets extracellular nicotinamide phosphoribosyltransferase, a highly novel potent driver of innate immunity and inflammation.

On April 7, 2022, Amgen posted details on [clinicaltrials.gov](#) for a first-in-human Phase 1 study ([NCT05317078](#)) of AMG 794 in subjects with Claudin 6-positive advanced/metastatic non-squamous non-small cell lung cancer or epithelial ovarian cancer. The estimated enrollment is 98 participants, and the study is due to start in May 2022. Preclinical data for AMG794 were presented on April 10, 2022, at the American Association for Cancer Research (AACR) Annual Meeting in New Orleans, Louisiana.

- AMG 794 is a Claudin 6-targeted half-life extended bispecific T-cell engager (HLE BITE®) molecule.

On April 8, 2022, [Agenus Inc. announced](#) that an IND application for AGEN1571 was cleared by the FDA and a clinical trial will commence. Agenus presented preclinical data for AGEN1571 on April 12, 2022, at AACR. The abstract title was “AGEN1571 is a novel high-affinity ILT2 antagonist antibody that promotes adaptive and innate immune responses”.

- AGEN1571 is a novel anti-ILT2 antibody designed to modulate tumor-associated macrophages, as well as T, natural killer (NK) and NKT cells.

On April 11, 2022, [APRINOIA Therapeutics announced](#) that the FDA has granted a may proceed authorization for its novel therapeutic anti-tau monoclonal antibody, APNmAb005, allowing the company to test and evaluate its safety in healthy subjects in a Phase 1 single ascending dose study. The company intends to evaluate APNmAb005 in patients with tau-related diseases including Alzheimer's disease, progressive supranuclear palsy, corticobasal degeneration, and other forms of frontotemporal lobar degeneration in the future.

- APNmAb005 is a humanized anti-tau antibody specifically targeting human tau aggregates.

On April 12, 2022, Capella Bioscience, a subsidiary of Centessa Pharmaceuticals, posted details on [clinicaltrials.gov](#) for a first-in-human, dose escalating Phase 1 study ([NCT05323110](#)) of CBS001 in healthy volunteers. The estimated enrollment is 88 participants, and the study is due to start in April 2022. In future studies, the company plans to evaluate CBS001 as a treatment of idiopathic pulmonary fibrosis.

- CBS001 is a humanized, neutralizing therapeutic monoclonal antibody that targets the inflammatory membrane form of LIGHT (known as TNFSF14).

Phase 1 study of an ADC starts

On April , Byondis posted details on [clinicaltrials.gov](#) for their first-in-human study ([NCT05323045](#)) of antibody-drug conjugate (ADC) BYON3521. Initiated on March 21, 2022, this dose-escalation and expansion trial will evaluate the safety, pharmacokinetics and efficacy of BYON3521 in patients with c-MET expressing locally advanced or metastatic solid tumors. The estimated enrollment is 120 participants.

- BYON3521 is composed of a humanized IgG1 monoclonal antibody directed against the c-MET receptor covalently conjugated to a duocarmycin-containing linker-drug.

Phase 1 studies for 2 ADCs are terminated

On April 2, 2022, [Silverback Therapeutics announced](#) they discontinued the development of ADCs SBT6050 and SBT6290. In the Phase 1/1b trial of SBT6050, a total of 58 patients were enrolled and received SBT6050 as monotherapy and in combination with a checkpoint inhibitor at dose levels ranging from 0.15 mg/kg through 1.2 mg/kg with the length of patient experience ranging from 2 weeks through 41 weeks. Further development was discontinued based on limited monotherapy anti-tumor activity and cytokine-related adverse events that limited the dose in combination with pembrolizumab. SBT6290 was expected to show a similar clinical profile and, therefore, this development program was also discontinued.

- SBT6050 (pertuzumab zuvotolimod) is composed of a novel, potent TLR8 agonist conjugated to a HER2-directed monoclonal antibody.
- SBT6290 is composed of the same linker payload (TLR 8 agonist) conjugated to a Nectin4 antibody.

Regulatory review news

On April 1, 2022, **Y-mAbs Therapeutics, Inc. announced** that the company completed the resubmission of its BLA to FDA for 131I-omburtamab. The omburtamab BLA is for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. In Oct 2020, FDA had issued a Refusal to File letter regarding the original BLA.

- Omburtamab is a monoclonal antibody that targets B7-H3.

On April 6, 2022, **Novartis announced** that the European Medicines Agency (EMA) validated marketing authorization applications for anti-PD-1 tislelizumab for adults with: 1) Locally advanced or metastatic, squamous or non-squamous non-small cell lung cancer (NSCLC) as first-line treatment in combination with chemotherapy; 2) Locally advanced or metastatic NSCLC as monotherapy after prior chemotherapy; and 3) Unresectable, recurrent, locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) as monotherapy after prior chemotherapy. The EMA filings follow FDA filing acceptance for tislelizumab in esophageal cancer. Tislelizumab was first approved in China in 2019.

- Tislelizumab is a hinge-stabilized, humanized anti-PD-1 IgG4 antibody that was engineered with additional mutations (E233P/F234V/L235A/D265A/R409K) to more fully abrogate FcγR interactions.

Approvals in the European Union

On April 4, 2022, **Immunocore Holdings plc announced** that the European Commission (EC) has approved KIMMTRAK® (tebentafusp). KIMMTRAK was approved for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. FDA granted an approval for KIMMTRAK for the same indication in January 2022.

- KIMMTRAK is a bispecific protein composed of a soluble T cell receptor fused to an anti-CD3 immune-effector function.

On April 13, 2022, **Astellas Pharma Inc. and Seagen Inc. announced** that the EC approved PADCEV™ (enfortumab vedotin) as monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a PD-1/L1 inhibitor. The EC approval is supported by data from the global phase 3 EV-301 trial that demonstrated an overall survival (OS) benefit compared with chemotherapy.

- Enfortumab vedotin is an ADC composed of an anti-Nectin-4 IgG1 antibody conjugated to monomethyl auristatin E.

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April 15 - May 1, 2022

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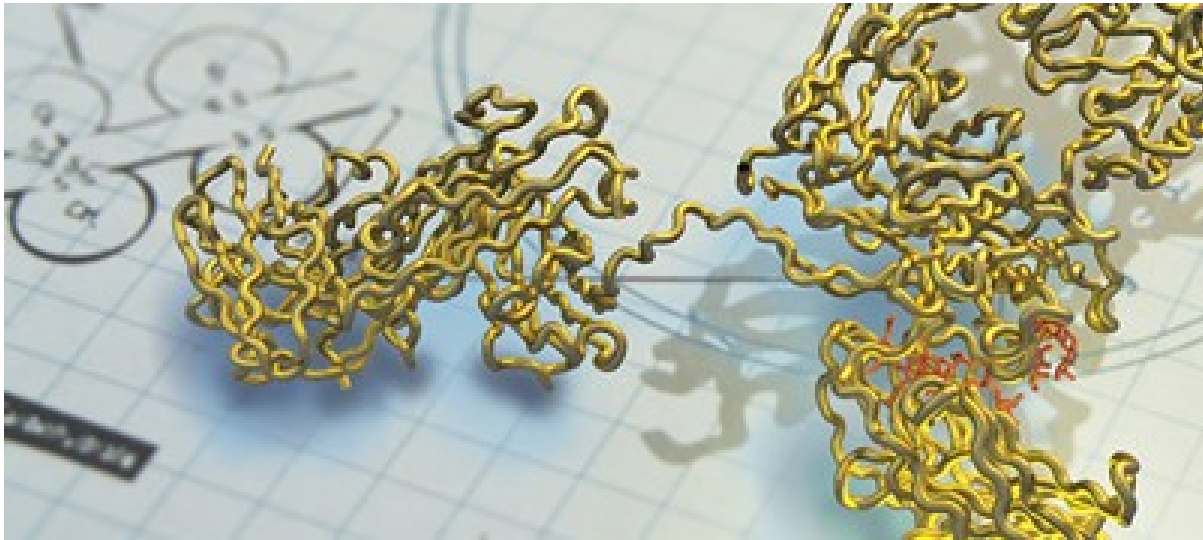
New anti-SARS-CoV-2 antibodies queued for first-in-human studies

On April 25, 2022, [Sorrento Therapeutics, Inc. announced](#) that the US Food and Drug Administration (FDA) granted clearance for the first Phase 1 clinical study of STI-9167 (Intravenous COVISHIELD™), which will be a safety and pharmacokinetic study in healthy volunteers. Initial trials are expected to be followed by a multinational Phase 2/3 trial in both mild and moderate COVID-19 patients. STI-9167 has demonstrated in vitro and in vivo activity against all SARS-CoV-2 variants tested, including the Omicron strain BA.1, Omicron BA.1.1 and Omicron BA.2.

- STI-9167 is a human anti-SARS-CoV-2 antibody optimized to maximize protein stability and minimize interactions with host Fc gamma receptors.

On April 28, 2022, details were posted on [clinicaltrials.gov](#) for a first-in-human study ([NCT05351437](#)) of Memo Therapeutics AG's anti-SARS-CoV-2 antibody MTx-COVAB36. The study will evaluate 4 doses of MTx-COVAB36 (100 mg IV, 500 mg IV, 1000 mg IV, 2000 mg IV) in healthy volunteers. The study will enroll an estimated 32 volunteers, and has an estimated start date of May 5, 2022.

- MTx-COVAB36 is a human monoclonal IgG1 antibody derived from the memory B cells of convalescent COVID-19 donors and directed against SARS-CoV-2 spike protein.
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[Updates on non-COVID-19 interventions](#)

Business news

On April 19, 2022, [Regeneron Pharmaceuticals, Inc. and Checkmate Pharmaceuticals, Inc. announced](#) a definitive agreement for the acquisition of Checkmate by Regeneron at an all-cash price of \$10.50 per share of Checkmate common stock. The proposed acquisition, which values Checkmate at a total equity value of approximately \$250 million, is intended to strengthen Regeneron's portfolio of diverse and combinable immuno-oncology candidates. Checkmate's lead investigational candidate is vidutolimod, a CpG-A oligodeoxynucleotide Toll-like receptor 9 agonist delivered in a virus-like particle.

On April 20, 2022, [Dragonfly Therapeutics, Inc. announced](#) an expansion of its research collaboration with AbbVie to discover and develop Dragonfly's novel immunotherapies for new targets in autoimmune and fibrotic diseases. Their collaboration involving Dragonfly's proprietary Tri-specific NK cell Engager Therapy (TriNKET™) platform was initiated in November 2019, and AbbVie successfully licensed its first TriNKET™ drug candidate from Dragonfly in January 2021.

First-in-human studies planned or started

On April 26, 2022, [SOTIO Biotech announced](#) that it has dosed the first patient in a first-in-human Phase 1/2 trial of SOT102 in patients with gastric and pancreatic cancer. The Phase 1/2 CLAUDIO-01 trial (EudraCT number: 2021-005873-25) will assess the safety and preliminary efficacy of SOT102 in monotherapy and in combination with established standard of care therapies in up to 109 patients with gastric adenocarcinoma or adenocarcinoma of the gastroesophageal junction and pancreatic adenocarcinoma. SOT102 is being developed in collaboration with NBE-Therapeutics.

- SOT102 is a CLDN18.2-targeting antibody-drug conjugate (ADC).

On April 27, 2021, details were posted on clinical trials.gov for a first-in-human Phase 1/2 study of Chimagen Biosciences' novel trispecific T-cell engager CMG1A46. The [NCT05348889](#) study will evaluate the safety and efficacy of CMG1A46 in adult patients

with advanced CD20 and/or CD19 positive B-cell hematologic malignancies. The study will enroll an estimated 165 patients, and has an estimated start date in April 2022.

- CMG1A46, a 151 KD IgG-like “1:(1+1)” tri-specific antibody constructed on Chimagen’s TRIAD platform, targets CD19, CD20 and CD3.

First Phase 3 studies of 2 ADCs planned or started

On April 15, 2022, details were posted on clinicaltrials.gov for the first Phase 3 study of Mersana Therapeutics’ XMT-1536 (upifitamab rilsodotin). The Phase 3 study ([NCT05329545](https://clinicaltrials.gov/ct2/show/study/NCT05329545)) will evaluate XMT-1536 maintenance in platinum-sensitive recurrent ovarian cancer. The estimated enrollment is 350 patients and the estimated start date is May 26, 2022.

- Upifitamab rilsodotin is composed of an average of 10-15 DolaLock payload molecules conjugated to a humanized anti-[NaPi2b](https://pubmed.ncbi.nlm.nih.gov/34811111/) antibody, via the Dolaflexin ADC platform.

On April 21, 2022, details were posted on clinicaltrials.gov for the first Phase 3 study ([NCT05338970](https://clinicaltrials.gov/ct2/show/study/NCT05338970)) of patritumab deruxtecan. Sponsored by Daiichi Sankyo, the study will evaluate the effects of patritumab deruxtecan versus platinum-based chemotherapy in metastatic or locally advanced epidermal growth factor receptor-mutated non-small cell lung cancer after failure of epidermal growth factor receptor tyrosine kinase inhibitor therapy. The estimated enrollment is 560 patients and the study is recruiting patients.

- Patritumab deruxtecan is composed of an anti-HER3 IgG1 antibody attached by a peptide linker to a novel topoisomerase I inhibitor payload.

Biologics License Application for tremelimumab receives priority review

On April 25, 2022, [AstraZeneca announced](https://www.astrazeneca.com/media-rooms/press-releases/2022/04/25-astrazeneca-announces-fda-acceptance-of-bla-for-tremelimumab) that the Biologics License Application (BLA) for tremelimumab has been accepted for Priority Review in the US, supporting the indication of a single priming dose of the anti-CTLA4 antibody added to Imfinzi (durvalumab) for the treatment of patients with unresectable hepatocellular carcinoma. The FDA's first action date for their regulatory decision is during the fourth quarter of 2022 following the use of a priority review voucher. A marketing application for tremelimumab was submitted to the European Medicines Agency (EMA) in late 2021.

- Tremelimumab is a human IgG2 antibody targeting the immune checkpoint CTLA-4.

Two marketing applications withdrawn

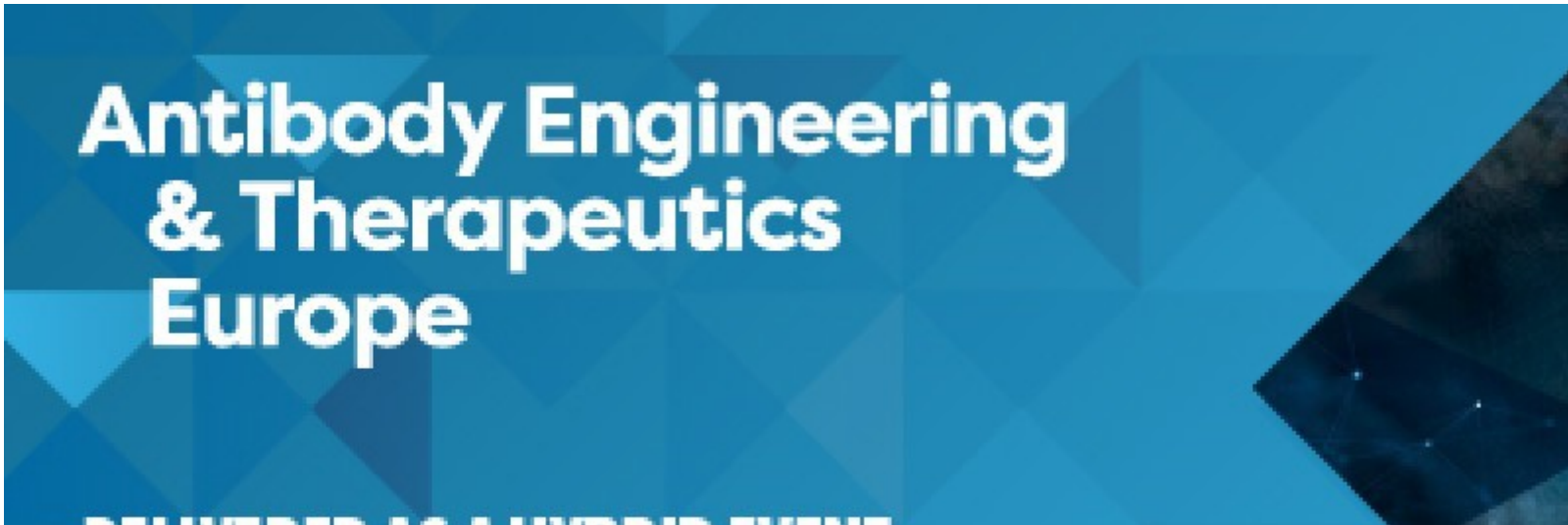
On April 15, 2022, [TG Therapeutics, Inc. announced](https://www.tgtherapeutics.com/newsroom/press-releases/2022/04/15-tg-therapeutics-inc-announces-withdrawal-of-bla-supplemental-new-drug-application) that the company has voluntarily withdrawn the pending BLA/supplemental New Drug Application for the combination of ublituximab and UKONIQ® (umbralisib) for the treatment of adult patients with chronic lymphocytic leukemia and small lymphocytic lymphoma. The decision to withdraw was based on recently updated overall survival (OS) data from the UNITY-CLL Phase 3 trial that showed an increasing imbalance in OS. The company

had also submitted a BLA for ublituximab for patients with relapsing forms of multiple sclerosis; FDA's first action on this BLA is expected by September 28, 2022.

- Ublituximab is a chimeric IgG1 monoclonal antibody that targets CD20. The antibody has reduced fucose content due to its production in YB2/0 cells.

On April 22, 2022, **Biogen Inc. announced** that the company is no longer pursuing an approval for aducanumab for the treatment of the early stages of Alzheimer's disease in the European Union. The company withdrew its application following interactions with the EMA's Committee for Medicinal Products for Human Use (CHMP) indicating that the data provided thus far would not be sufficient to support a positive opinion on the marketing authorization of aducanumab by EMA. Biogen's marketing application had been under review by the CHMP in response to the company's request for a re-examination of the negative opinion the regulatory body issued in December 2021. In June 2021, aducanumab (Aduhelm) was approved by the FDA for treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease.

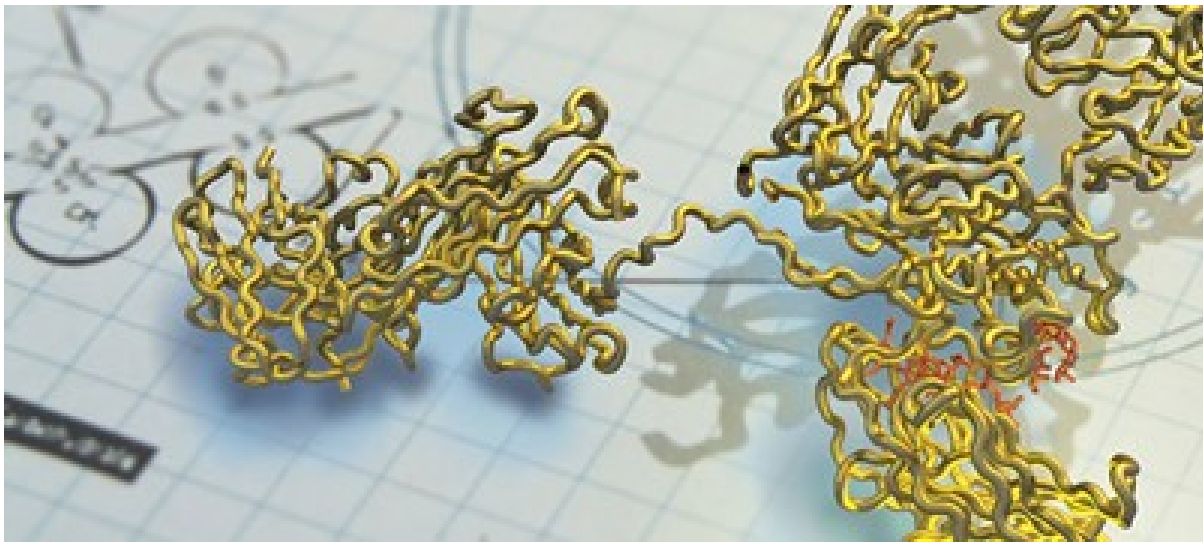
- Aducanumab is a human IgG1 antibody targeting amyloid beta.



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Completion of financing rounds announced

On May 3, 2022, [Dianthus Therapeutics, Inc. announced](#) the completion of its \$100 million Series A financing, which will be used to expand leadership and scientific teams, advance the company's lead program, DNTH103, to the clinic this year, and to accelerate additional discovery pipeline programs for people living with severe and rare autoimmune diseases.

- DNTH103 is a potent, next-generation monoclonal antibody that selectively targets the active form of complement C1s, potentially enabling a lower dosing volume and a less frequent subcutaneous administration that is further enhanced with half-life extension technology.

On May 3, 2022, [Tubulis GmbH announced](#) the successful completion of a €60 million (USD \$63 million) Series B financing, which will be used to advance Tubulis' proprietary pipeline of uniquely assembled antibody drug conjugates (ADCs), towards clinical evaluation as well as introduce programs addressing a range of solid tumor indications.

On May 9, 2022, [Engimmune Therapeutics AG, a Swiss biotech company developing novel T-cell receptor-based therapeutics, announced](#) the completion of a CHF 15.5 million (EUR 15.2 m / USD 16.7 m) seed financing round, co-led by

Pureos Bioventures and Novo Holdings. Engimmune is a spinout from the lab of Prof Sai Reddy at ETH Zurich and Dr Rodrigo Vazquez-Lombardi. Proceeds from the financing will be used to further build Engimmune's pipeline, expand the research team in Switzerland and build a foothold in Denmark, with a focus on GMP-certified manufacturing, clinical development, and regulatory affairs.

On May 10, 2022, to [Invetx, a pioneer in protein-based therapeutics for animal health, announced](#) that it has raised \$60.5 million in an oversubscribed Series B financing. The proceeds allow the company to advance its monoclonal antibody pipeline and pursue market approvals for therapeutics targeting chronic and serious diseases in dogs and cats.

Research collaboration news

On May 1, 2022, [Dragonfly Therapeutics, Inc. and Gilead Sciences announced](#) a collaboration designed to advance a number of Dragonfly's novel natural killer (NK) cell engager-based immunotherapies for oncology and inflammation indications. Under the agreement, Gilead will receive an exclusive, worldwide license from Dragonfly for DF7001. The agreement also grants Gilead options, after the completion of certain preclinical activities, to license exclusive, worldwide rights to develop and commercialize additional NK cell engager programs using the Dragonfly Tri-specific NK Engager (TriNKET™) platform.

- DF7001 is a TriNKET™ designed to activate and direct NK and cytotoxic T cell killing against cancer cells. The target of DF7001 is 5T4, a protein expressed on cancer cells and stromal cells that support tumor growth.

On May 10, 2022, [Twist Bioscience Corporation and Astellas Pharma Inc. announced](#) their research collaboration and exclusive option license agreement. Under the terms of the agreement, the companies will jointly conduct research activities to identify and optimize proprietary Twist antagonist antibodies, targeting an undisclosed checkpoint inhibitor pathway in the tumor microenvironment, as potential therapeutic development candidates.

Ichnos Sciences selects new clinical candidate

On May 9, 2022, [Ichnos Sciences announced](#) that they are advancing their preclinical pipeline, and have selected ISB 2001 as the next candidate to move into clinical development. The company has initiated IND-enabling studies for relapsed/refractory multiple myeloma and aims to advance ISB 2001 to a first-in-human study once clearance from the health authorities is received in 2023.

- ISB 2001 is a T-cell engaging trispecific antibody that targets BCMA, CD38, and CD3.

Rallybio Corporation in-licenses Sanofi's KY1066

On May 10, 2022, [Rallybio Corporation announced](#) that it has obtained worldwide exclusive rights to Sanofi's KY1066, which will be referred to as RLYB331 going forward, a preclinical potentially first-in-class antibody. RLYB331 has the potential to

address a significant unmet need for patients with severe anemia with ineffective erythropoiesis and iron overload, such as beta thalassemia (BT) and a subset of myelodysplastic syndromes (MDS), amongst others.

- RLYB331 is a monoclonal antibody that inhibits matriptase-2.

First-in-human clinical studies planned or started

On May 6, 2022, [Xencor announced](#) that Astellas has advanced ASP2138 into Phase 1 clinical development for the treatment of patients with gastric, gastroesophageal, or pancreatic cancers. To generate the molecule, Xencor applied XmAb bispecific Fc technology to an antigen pair provided by Astellas. The NCT05365581 study will enroll an estimated 240 participants and the estimated start date is May 31, 2022.

- ASP2138 is a T-cell engaging bispecific antibody that targets CLDN18.2 and CD3.

On May 6, 2022, [MacroGenics, Inc. posted details](#) on [clinicaltrials.gov](#) for a first-in-human clinical trial of MGD024. The NCT05362773 is a dose escalation and expansion study of MGD024 in patients with select relapsed or refractory hematologic malignancies. The study will enroll an estimated 90 participants and the estimated start date is in July 2022.

- MGD024 is a bispecific T-cell engaging DART® molecule targeting CD123 and CD3. The molecule is designed to target CD123-expressing leukemic cells for elimination by CD3-expressing T lymphocytes.

On May 9, 2022, [Sanofi posted details on clinicaltrials.gov](#) for a first-in-human study of SAR443765. The study will evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of SAR443765 in healthy adult participants and of a single dose of SAR443765 in participants with mild-to-moderate asthma. The study will enroll an estimated 72 participants and estimated start date is May 20, 2022.

- SAR443765 is an anti-IL-13/TSLP Nanobody® VHH.

On May 3, 2022, [Immatics and Bristol Myers Squibb posted details](#) on [clinicaltrials.gov](#) for a first-in-human clinical trial of IMA401. The NCT05359445 study will evaluate the safety, tolerability and initial anti-tumor activity of IMA401 in patients with recurrent and/or refractory solid tumors. The study, which is recruiting patients, will enroll an estimated 50 participants.

- IMA401, a half-life extended T Cell Engaging Receptor (TCER®) molecule, is composed of a TCR domain that targets an HLA-A*02-bound peptide derived both from melanoma-associated antigens MAGEA4 and MAGEA8 and a T cell recruiter domain.

Xencor terminates development of 2 bispecific antibodies

On May 6, 2022, [Xencor announced](#) that the company will stop internal development of 2 bispecific antibodies, tidutamab and XmAb841. Neither program demonstrated a competitive clinical profile in recent trials, and the company has decided to focus

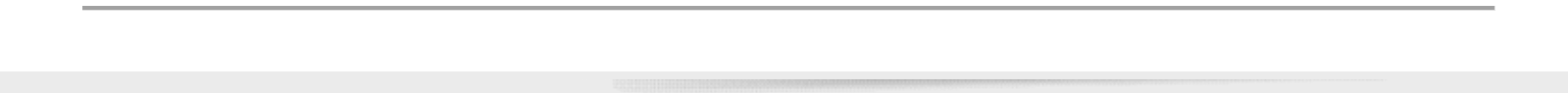
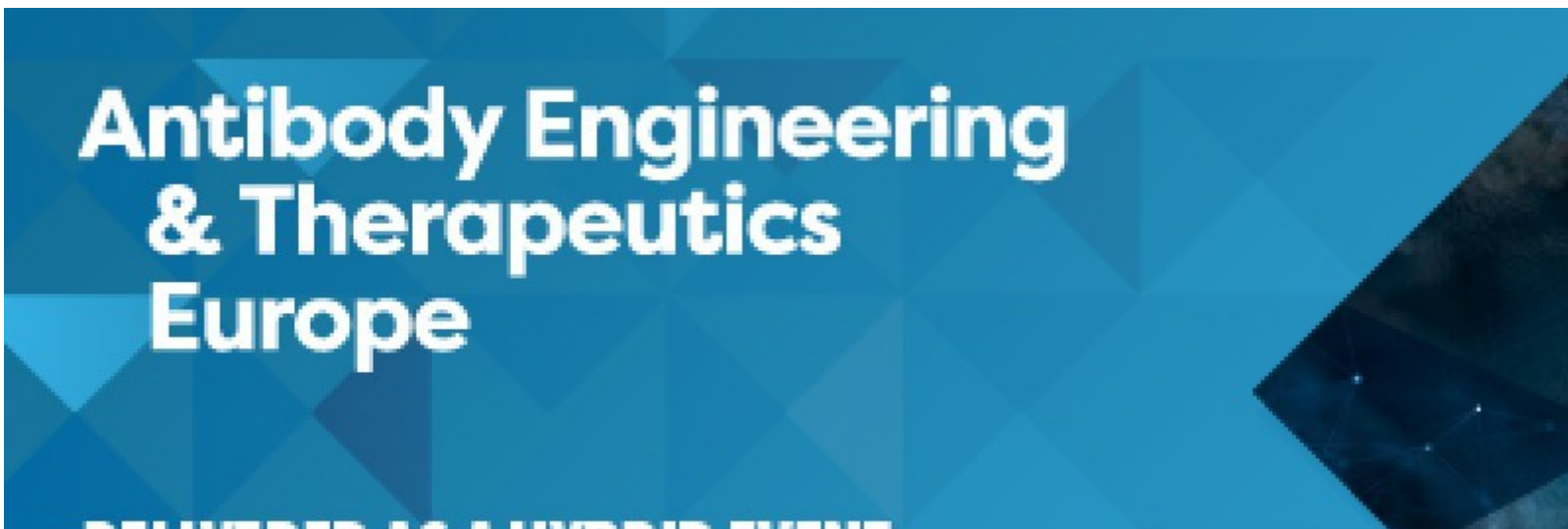
resources on new clinical programs. Tidutamab (XmAb18087) was being evaluated in a Phase 1/2 study ± pembrolizumab in subjects with advanced merkel cell carcinoma or extensive-stage small cell lung cancer. XmAb22841 was being evaluated in a Phase clinical study, both as a monotherapy and in combination with pembrolizumab, in patients with advanced solid tumors

- Tidutamab is a humanized, affinity-optimized anti-SSTR2 Fab x anti-CD3 scFv bispecific antibody with full Fc domain.
- XmAb22841 (bavunalimab) is an immunoglobulin half-IgG1-kappa/scFv-h-CH2-CH3 targeting LAG3 and CTLA-4.

FDA issues a complete response letter for bimekizumab's BLA

On May 13, 2022, **UCB announced** that the U.S. Food and Drug Administration has issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis. The CRL states that certain pre-approval inspection observations must be resolved before approval of the application. In August 2021, bimekizumab received marketing authorization in countries of the European Union (EU)/European Economic Area (EEA) and Great Britain, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. In January 2022, bimekizumab received marketing authorization in Japan for the treatment of plaque psoriasis, generalized pustular psoriasis and psoriatic erythroderma in patients who are not sufficiently responding to existing treatments. In February and March 2022, bimekizumab received marketing authorization in Canada and Australia, respectively, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

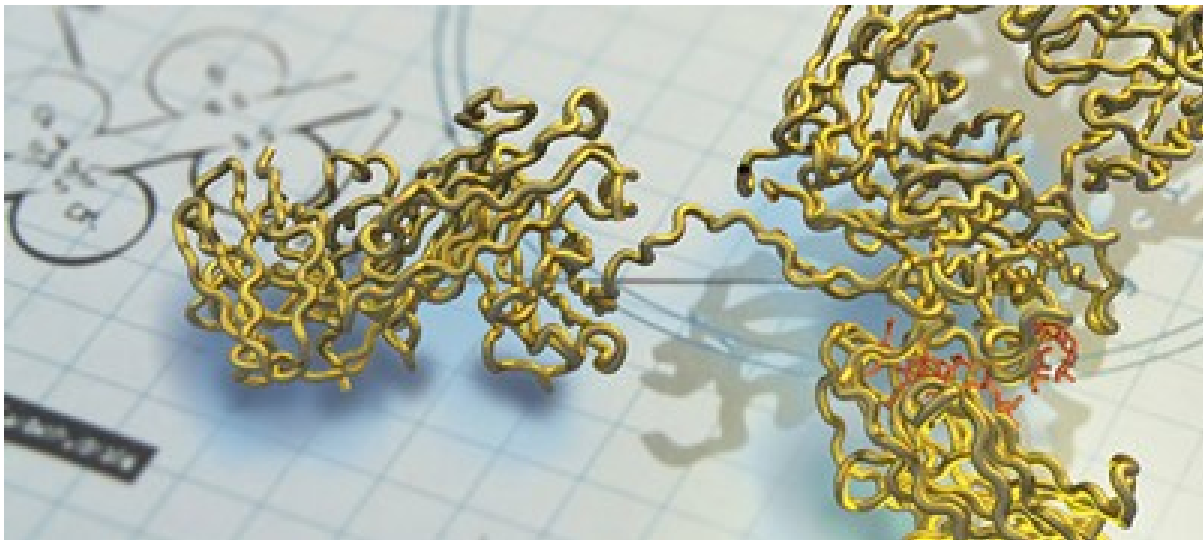
- Bimekizumab is a humanized IgG1 antibody that neutralizes the biologic function of both IL-17A and IL-17F.



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Top 200 pharmaceuticals by retail sales in 2021

[This very useful list](#) was compiled and produced by M. Haziq Qureshi from the Njarðarson Group (The University of Arizona). The work shows that more than half of the top 20 drugs by sales in 2021 are antibody-based (8 are mAbs and 3 more are Fc fusion proteins).

New company Tentarix Biotherapeutics forms SAB

On May 20, 2022, [Tentarix Biotherapeutics LP](#), a biotechnology company developing first-in-class targeted, conditional antibody-based multifunctional biotherapies, announced the formation of a Scientific Advisory Board (SAB) and appointments to its Board of Directors and leadership team. Founding members of the SAB include Drs. Tom Bumol, Brian Kuhlman, and John Teijaro. Tentarix is developing multifunctional biologics, called Tentacles™, that are targeted, synergistic and conditional, i.e., they activate a target cell population only when all desired receptors are present.

Preclinical antibody-drug conjugate granted Orphan Drug designation by FDA

On May 19, 2022, [Mersana Therapeutics, Inc. announced](#) that the US Food and Drug Administration (FDA) has granted

orphan drug designation to XMT-2056, the company's lead Immunosynthen STING-agonist antibody-drug conjugate (ADC), for the treatment of gastric cancer. Mersana plans to initiate a Phase 1 trial of XMT-2056 in a range of HER2-expressing tumors, such as breast, gastric and non-small-cell lung cancers, in mid-2022.

- XMT-2056 is an ADC that targets a novel epitope of HER2 with differentiated binding from trastuzumab and pertuzumab, potentially allowing for broad combinability with approved and investigational HER2 therapies.

Novel antibodies poised to enter clinical studies

On May 18, 2022, details were posted on clinical trials.gov for a Phase 1, first-in-human study ([NCT05378425](#)) of the immune checkpoint modulatory molecule NTX-1088 as monotherapy and combined with pembrolizumab in patients with advanced solid malignancies. Sponsored by Nectin Therapeutics, the study has an estimated enrollment of 90 participants and an estimated start date in June 2022.

- NTX1088 is an IgG4 mAb targeting the poliovirus receptor (PVR, CD155) with high affinity, blocking its interactions with TIGIT and CD96, preventing their immune inhibitory signaling.

On May 19, 2022, [Tallac Therapeutics announced](#) that the FDA has cleared their Investigational New Drug Application for TAC-001 for patients with advanced solid tumors. Tallac plans to initiate a Phase 1/2 clinical study of systemically administered TAC-001 for patients with advanced solid tumors in the second half of 2022

- TAC-001 is a toll-like receptor agonist antibody conjugate (TRAAC) composed of a potent toll-like receptor 9 agonist (T-CpG) conjugated to an anti-CD22 antibody.

On May 23, 2022, [Salubris Biotherapeutics announced](#) the submission of the first clinical trial application (CTA) in Europe for its lead oncology program, JK08. The CTA seeks approval to initiate a Phase 1/2 study evaluating JK08 monotherapy for the treatment of advanced solid tumors. Upon obtaining regulatory approvals, the company plans to initiate recruitment during the third quarter of 2022.

- JK08 is a CTLA-4-specific antibody conjugated with an IL-15/sushi domain fusion peptide.

First clinical studies of new antibodies are initiated

On May 18, 2022, [Surrozen, Inc. announced](#) the start of the first clinical study of their bispecific antibody SZN-1326, which is a potential treatment of moderate to severe ulcerative colitis. The three-part Phase 1/1b, randomized, placebo-controlled, single- and multiple-ascending-dose study (ACTRN12622000344796) will evaluate the safety, pharmacokinetics (PK), and activity of SZN-1326 in healthy volunteers initially, then participants with moderate to severe ulcerative colitis will be enrolled.

- SZN-1326, a Fzd5-targeted Wnt-mimetic (SWAP) bi-specific antibody, was designed using Surrozen's SWAP™ technology.

On May 24, 2022, details were posted on clinical trials.gov for a Phase 1/1b, open-label, dose-finding, first-in-human study ([NCT05387265](#)) to evaluate the safety and antitumor activity of CX-904 in advanced solid tumors. Sponsored by CytomX Therapeutics, the study started in February 2022 and will recruit an estimated 100 participants.

- CX-904 is a conditionally activated T-cell bispecific antibody designed to bind to both epidermal growth factor receptor on cancer cells and to the CD3 receptor on T cells selectively in the tumor microenvironment.

On May 26, 2022, [Q32 Bio Inc. announced](#) the start of a first-in-human study of ADX-097, which is a tissue-targeted inhibitor of complement activation that minimizes systemic complement blockade. The Phase 1, first-in-human, clinical study is designed to assess the safety, PK and pharmacodynamics of ADX-097 in two parts. The study consists of a randomized, placebo-controlled, double-blind SAD/MAD component in healthy volunteers and an open-label, SAD/MAD component in patients with complement-related skin diseases.

- ADX-097 is a humanized anti-C3d monoclonal antibody linked to five N-terminal consensus repeats of the complement inhibitor factor H (fH1-5).

Marketing applications submitted or accepted

On May 23, 2022, [ImmunityBio, Inc. announced](#) that the company submitted a Biologics License Application (BLA) to the FDA for N-803 (Inbakcept) plus Bacillus Calmette-Guérin (BCG) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer carcinoma in situ with or without Ta or T1 disease. The FDA previously granted N-803 Breakthrough Therapy and Fast Track designations for this indication. The BLA submission for BCG-unresponsive NMIBC is based on data from 171 subjects from Phase I and 2 trials in bladder cancer and on 84 subjects treated in ImmunityBio's Pivotal Phase 2/3 QUILT 3032 study of the combination of N-803 and BCG.

- N-803 is a fusion protein consisting of a mutated superagonist IL-15 (N72D) bound to IL-15R α sushi domain linked to an IgG1 Fc domain.

On May 23, 2022, [ImmunoGen, Inc. announced](#) that the FDA accepted and filed the BLA 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 application has been granted Priority Review designation and FDA has set a Prescription Drug User Fee Act (PDUFA) action date of November 28, 2022.

- Mirvetuximab soravtansine is an ADC comprising a humanized IgG1 antibody targeting FR α conjugated to the cytotoxic drug DM4 via a cleavable linker.

On May 26, 2022, **Genentech announced** that new pivotal data on its investigational bispecific antibody, glofitamab, which will be presented for the first time at the 2022 American Society of Clinical Oncology Annual Meeting from June 3-7. Data from the pivotal Phase 2 NP30179 study have been submitted for approval to the European Medicines Agency, and submissions to additional health authorities worldwide are planned this year. Data from the study demonstrated that, after a median follow-up of more than 12 months, fixed-duration glofitamab induces durable complete responses in patients with relapsed or refractory diffuse large B-cell lymphoma who had received a median of three prior therapies.

- Glofitamab is a T cell-engaging bispecific antibody that targets CD20 and CD3.

On May 31, 2022, **Y-mAbs Therapeutics, Inc. announced** that the BLA for OMBLASTYS® (omburtamab) for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma has been accepted for priority review by the FDA. The FDA set an action date of November 30, 2022, and indicated in the BLA filing communication letter that it is planning to hold an advisory committee meeting in October 2022 to discuss the application.

- Omburtamab is a radiolabeled (I-131) murine antibody targeting B7-H3 (CD276).

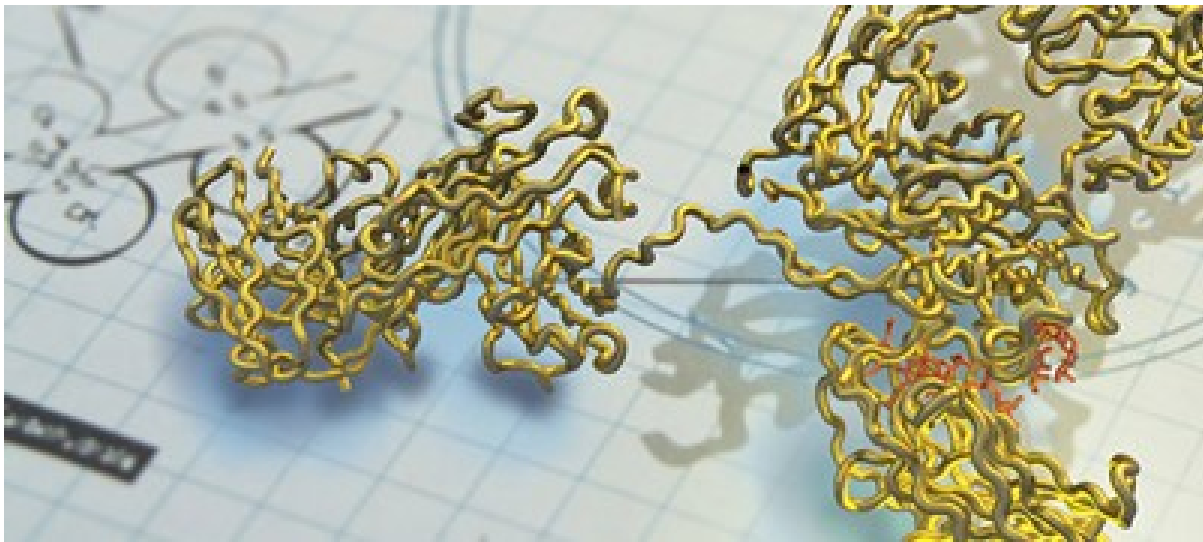
A blue banner with white text that reads "Antibody Engineering & Therapeutics Europe". The background features a pattern of overlapping triangles and a dark, starry space-like image on the right side.

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Financing news

On June 7, 2022, [PineTree Therapeutics Inc. announced](#) that the company raised \$23.5 million for Series A1 funding. The investments will be used to advance their Oncology and Viral Diseases platforms, including TAER-TAB™ (Tumor Associated Essential Receptor Targeting AntiBody) This antibody-based receptor degradation platform targets and potentially degrades drug-resistant or difficult-to-treat receptors present on many types of tumors and on different types of immune and disease cells.

On June 14, 2022, [Dren Bio announced](#) the completion of their \$65 million Series B financing, increasing their total capital received to date to over \$156 million. Their Targeted Myeloid Engager and Phagocytosis Platform is designed for discovery of bispecific antibodies for the co-engagement of a conserved, microbial phagocytic

receptor highly expressed on myeloid cells, along with a specific target antigen expressed on a pathologic cell or other disease-causing agent of interest. Dren Bio's first development candidate using the platform, DR-0201, co-engages a validated target expressed on the surface of B cells.

On June 14, 2022, **Spirea Limited announced** that the company has secured funding of £2.4 million with investments from high-profile UK and US investors, including US-based R42 Group, ACF Investors, o2h Ventures, Syndicate Room and the Cambridge Angels. Spirea will use the funds to initiate its pipeline of superior and differentiated antibody-drug conjugates in the treatment of solid tumors where there is a high unmet need.

Collaboration news

On June 1, 2022, **Astellas Pharma Inc. and GO Therapeutics announced** that Xyphos Biosciences, Inc., (a wholly owned subsidiary of Astellas) and GO have entered into a strategic research collaboration and license agreement to develop novel Immuno-Oncology therapeutics. The two companies will collaborate exclusively to identify novel antibodies with high affinity to two different glycoprotein targets and apply these antibodies to a range of therapeutic modalities. Under the terms of the agreement, Xyphos will pay GO Therapeutics US\$20.5 million in upfront cash. Milestone and contingency payments could total up to another US\$763 million.

On June 2, 2022, **Specifica, Inc. announced** an agreement with the global healthcare company Sanofi under which Specifica's patented Generation 3 Antibody Discovery Platform will be transferred to Sanofi. The Gen 3 libraries combine clinically validated antibody frameworks with compatible binding loop sequences (CDRs) from natural human antibodies that have been purged of sequence-based developability liabilities. The comprehensive technology transfer package will enable the integration of Specifica's Gen 3 platform into Sanofi's antibody discovery programs.

On June 2, 2022, **Boehringer Ingelheim and the A*STAR - Agency for Science,**

Technology and Research (A*STAR) announced a global licensing agreement under which Boehringer Ingelheim will obtain exclusive worldwide rights to research, develop and commercialize products based on a panel of innovative, tumor-specific antibodies from A*STAR. Boehringer Ingelheim aims to use these antibodies to direct therapeutic effector mechanisms such as antibody-drug conjugates and T-cell engagers exclusively to tumor cells, and to that end develop a range of highly targeted cancer treatments. Under the terms of the agreement, Boehringer Ingelheim will be responsible for further research, preclinical and clinical development as well as commercialization of targeted cancer therapies using the antibodies from A*STAR. A*STAR may receive payments totalling >100 million EUR in upfront and success-based development and commercialization milestones.

First Phase 1 studies planned or initiated

On June 3, 2022, details were posted on clinicaltrials.gov for a first-in-human Phase 1, open-label, dose finding study ([NCT05403554](https://clinicaltrials.gov/ct2/show/study/NCT05403554)) of NI-1801 in patients with mesothelin-expressing solid cancers. Sponsored by Light Chain Bioscience - Novimmune SA, the study has an estimated enrollment of 40 participants. The study was initiated on April 29, 2022, and has an estimated primary completion date of June 30, 2025.

- NI-1801 is a bispecific antibody that targets mesothelin and CD47.

On June 14, 2022, **Alphamab Oncology announced** that the first patient was dosed in a Phase 1 clinical study (KN052-CHN-001; [NCT05309512](https://clinicaltrials.gov/ct2/show/study/NCT05309512)) of its proprietary bispecific antibody KN052 in patients with advanced solid tumors in China. The study has an estimated enrollment of 45 participants and an estimated primary completion date in February 2023.

- KN052 is a bispecific antibody targeting PD-L1 and OX40.

On June 14, 2022, details were posted on clinicaltrials.gov for a Phase 1/2, open-label, multicenter study ([NCT05417321](https://clinicaltrials.gov/ct2/show/study/NCT05417321)) to evaluate the safety, pharmacokinetics, pharmacodynamics, and efficacy of HB0036 in subjects with advanced solid tumors.

Sponsored by Shanghai Huaota Biopharmaceutical Co., Ltd. the study has an estimated enrollment of 80 participants and an estimated start date of June 10, 2022, although the study is listed as not yet recruiting.

- HB0036 is a bispecific antibody targeting PD-L1 and TIGIT.

Emactuzumab queued for first Phase 3 study

On June 14, 2022, details were posted on clinicaltrials.gov for a Phase 3, randomized, placebo-controlled, double-blind study ([NCT05417789](https://clinicaltrials.gov/ct2/show/study/NCT05417789)) of emactuzumab to assess efficacy and safety in subjects with tenosynovial giant cell tumor (TANGENT). Sponsored by SynOx Therapeutics Limited, the study has an estimated enrollment of 128 patients, and an estimated start date of June 30, 2022.

- Emactuzumab is a humanized IgG1 antibody that binds CD115 (aka colony stimulating factor-1 receptor) and blocks the dimerization interface of this receptor.

Mosunetuzumab approved in the European Union

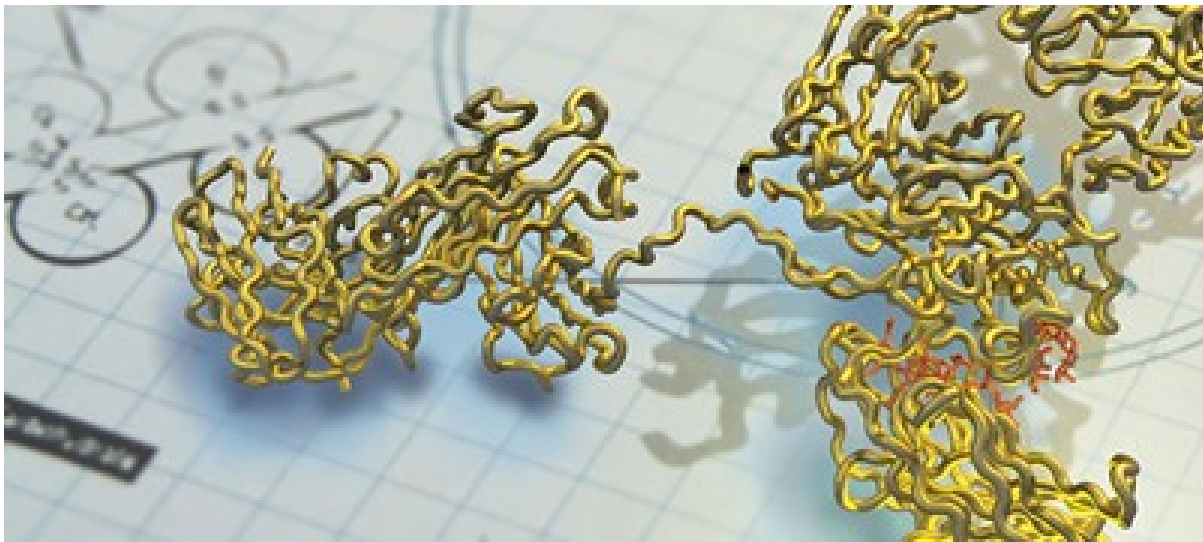
On June 8, 2022, [Roche announced](#) that the European Commission granted conditional marketing authorization for the bispecific antibody Lunsumio® (mosunetuzumab), for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies. The approval is based on the Phase 1/2 GO29781 study, in which Lunsumio induced high complete response rates, with the majority of complete responses lasting for at least 18 months in people with heavily pre-treated FL

- Mosunetuzumab is a bispecific T-cell engaging antibody targeting CD20 and CD3

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Financing news

On June 9, 2022, [CHARM Therapeutics](#), a 3D deep-learning research company discovering and developing transformational medicines founded by David Baker, Ph.D. and Laksh Aithani, announced a \$50M Series A financing co-led by F-Prime Capital and OrbiMed, with General Catalyst, Khosla Ventures, Braavos and Axial also participating. CHARM Therapeutics is pioneering end-to-end 3D deep-learning to discover and develop transformational medicines against previously hard-to-drug targets. The Company's proprietary platform, DragonFold, applies expertise in protein-ligand co-folding to deliver transformational medicines targeting challenging molecular targets in cancer and other disease areas.

On June 23, 2022, [DEM Biopharma, Inc.](#), a new immuno-oncology company developing therapies that target novel innate immune system checkpoints

announced its initial \$70 million financing led by founding investor Longwood Fund and Alta Partners. DEM Bio is pioneering novel immunotherapeutics designed to unleash macrophages and other myeloid effector cells to eliminate tumors by targeting novel 'don't eat me' (DEM) and 'eat me' (EM) signals on cancer cells and macrophages.

On June 29, 2022, [MiroBio Ltd](#) announced the completion of a US\$97million (£80 million) Series B financing led by Medicxi with participation from new investors, OrbiMed and Monograph Capital and existing Series A investors, Oxford Science Enterprises, Samsara BioCapital, SR One and Advent Life Sciences. Funds will primarily be used to advance MiroBio's two lead antibody candidates into clinical trials and obtain safety and efficacy data in patients with autoimmune diseases. MB272 and MB151 are differentiated, precision-engineered checkpoint receptor agonists for B- and T-Lymphocyte Attenuator and PD-1, respectively,

Collaboration and licensing news

On June 16, 2022, [Exelixis and BioInvent International AB announced](#) that they entered into an option and license agreement focused on the identification and development of novel antibodies for use in IO therapeutics. The collaboration is intended to expand Exelixis' portfolio of antibody-based therapies and will combine BioInvent's cancer immunology and antibody biology expertise with Exelixis' expertise and resources in antibody engineering and antibody-drug conjugate technologies, and proven history of developing and commercializing oncology therapeutics.

On June 23, 2022, [Scancell Ltd announced](#) plans to develop GlyMab® antibodies into T cell redirecting bispecific (TCB) antibodies and take them into the clinic. To create TCB antibodies, Scancell will combine its proprietary GlyMab® antibodies, which target sugar motifs rather than proteins and are designed to have superior affinity and selectivity profiles, with in-licensed Fc silencing technology from Oxford-based mAbsolve.

On June 28, 2022, **Astellas Pharma Inc. and Sutro Biopharma, Inc. announced** a worldwide, strategic collaboration and licensing agreement focused on the discovery and development of novel immunostimulatory antibody-drug conjugates (iADCs). The collaboration leverages the unique cancer-fighting potential of iADCs as a novel modality, enabled by Sutro's ability to engineer complex conjugated antibodies, and Astellas' global oncology R&D expertise.

Acquisition news

On June 23, 2022, **invoX Pharma**, a wholly owned subsidiary of Sino Biopharmaceutical Limited focused on research and development and business development activities outside of China, and F-star Therapeutics, Inc. announced that the companies have entered into a definitive agreement whereby invoX will acquire all of the issued and outstanding shares of F-star common stock for \$7.12 per share. The proposed acquisition values F-star at approximately \$161 million. The transaction has been unanimously approved by the invoX and F-star Boards of Directors and is expected to close in the second half of 2022.

FDA designations granted

On June 21, 2022, **Phanes Therapeutics, Inc. announced** that the US Food and Drug Administration (FDA) granted their bispecific antibody PT217 an orphan drug designation for the treatment of small cell lung cancer (SCLC). PT217 is being developed for patients with SCLC and other neuroendocrine cancers. The company expects to file an investigational new drug (IND) application for PT217 by the third quarter of 2022.

- PT217 targets Delta-like ligand 3 and cluster of differentiation 47 (CD47).

On June 29, 2022, **The Janssen Pharmaceutical Companies of Johnson & Johnson announced** that FDA has granted Breakthrough Therapy Designation for talquetamab (JNJ-64407564) for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-

CD38 antibody. Derived from Genmab's DuoBody® technology, JNJ-64407564 is currently being evaluated in a Phase 1/2 clinical study for the treatment of relapsed or refractory multiple myeloma (NCT03399799) and is also being explored in combination studies (NCT04586426).

- JNJ-64407564 is a bispecific antibody that targets G protein-coupled receptor 5D, which is overexpressed on multiple myeloma cells, and CD3 on T cells.

First Phase 1 studies planned or initiated

On June 15, 2022, [Phanes Therapeutics, Inc. announced](#) that it received clearance from the US FDA to commence Phase 1 studies with PT886, which is being developed for patients with gastric, gastroesophageal junction and pancreatic cancers. PT886 was derived from Phanes' proprietary PACbody™ and SPECpair™ platforms, which are designed to build native IgG-like bispecific antibodies that enhance drug-like properties.

- PT886 is a native IgG-like bispecific antibody that targets Claudin18.2 and CD47.

On June 21, 2022, details were posted on [clinicaltrials.gov](#) for a Phase 1 study ([NCT05424822](#)) of JNJ-80948543 in participants with non-Hodgkin lymphoma and chronic lymphocytic leukemia. Sponsored by Janssen Research & Development, LLC, the study's estimated enrollment is 180 and the estimated start date is September 2, 2022.

- JNJ-80948543 is a trispecific, T-cell redirecting antibody that targets CD3 on T lymphocytes and surface antigens on mature healthy and malignant B-lymphocytes.

On June 22, 2022, details were posted on [clinicaltrials.gov](#) for a first-in-human Phase 1/2 multicenter, open-label, dose escalation and dose expansion study ([NCT05427812](#)) that will evaluate single-agent ISB 1442 in participants with relapsed/refractory multiple myeloma. Sponsored by Ichnos Sciences, the study's estimated enrollment is 121 and the estimated start date is July 15, 2022.

- ISB 1442 combines two proprietary anti-CD38 binding arms, each targeting different regions on CD38, with an antagonistic anti-CD47 arm, making it equivalent to a trispecific antibody.

On June 27, 2022, details were posted on clinicaltrials.gov for a Phase 1 multiple dose study ([NCT05433142](https://clinicaltrials.gov/ct2/show/study/NCT05433142)) to evaluate the safety and tolerability of bispecific antibody XmAb819 in subjects with relapsed or refractory clear cell renal cell carcinoma. Sponsored by Xencor, the study's estimated enrollment is 95 and is currently recruiting patients.

- XmAb819, which targets ENPP3 and CD3, is engineered with the multi-valent XmAb 2+1 bispecific antibody format.

Zilovertamab queued for first Phase 3 study

On June 24, 2022, details were posted on clinicaltrials.gov for a randomized, double-blind, placebo-controlled, multicenter Phase 3 study ([NCT05431179](https://clinicaltrials.gov/ct2/show/study/NCT05431179)) evaluating zilovertamab plus ibrutinib versus ibrutinib plus placebo in patients with relapsed/refractory mantle cell lymphoma. Sponsored by Oncternal Therapeutics, the study's estimated enrollment is 365 and the estimated start date is in September 2022.

- Zilovertamab is a humanized IgG1 monoclonal antibody that binds with high affinity to a biologically important epitope on the extracellular domain of Receptor-tyrosine kinase-like Orphan Receptor 1 (ROR1).

Genmab plans BLA for epcoritamab

On June 30, 2022, [Genmab announced](#) its intent to submit a biologics license application (BLA) to the FDA for subcutaneous epcoritamab, an investigational bispecific antibody derived from their DuoBody® platform, for the treatment of patients with relapsed/refractory large B-cell lymphoma (LBCL) in the second half of 2022. Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration. An ongoing Phase 3, open-label, randomized

trial is evaluating epcoritamab as a monotherapy in patients with relapsed/refractory DLBCL (NCT04628494)

- Epcoritamab is a T-cell engaging bispecific antibody that targets CD20 and CD3.

Cadonilimab approved in China

On June 29, 2022, **Akeso Biomedical, Inc. announced** that their bispecific antibody cadonilimab (开坦尼®) received marketing approval from China's National Medical Products Administration for the treatment of relapsed or metastatic cervical cancer patients who progressed on or after platinum-based chemotherapy. It is China's first immunotherapy bispecific antibody approved for marketing.

- Cadonilimab is an anti-PD1 antibody with 2 additional scFv-derived binding sites for CTLA-4 attached to termini of the Fc.



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