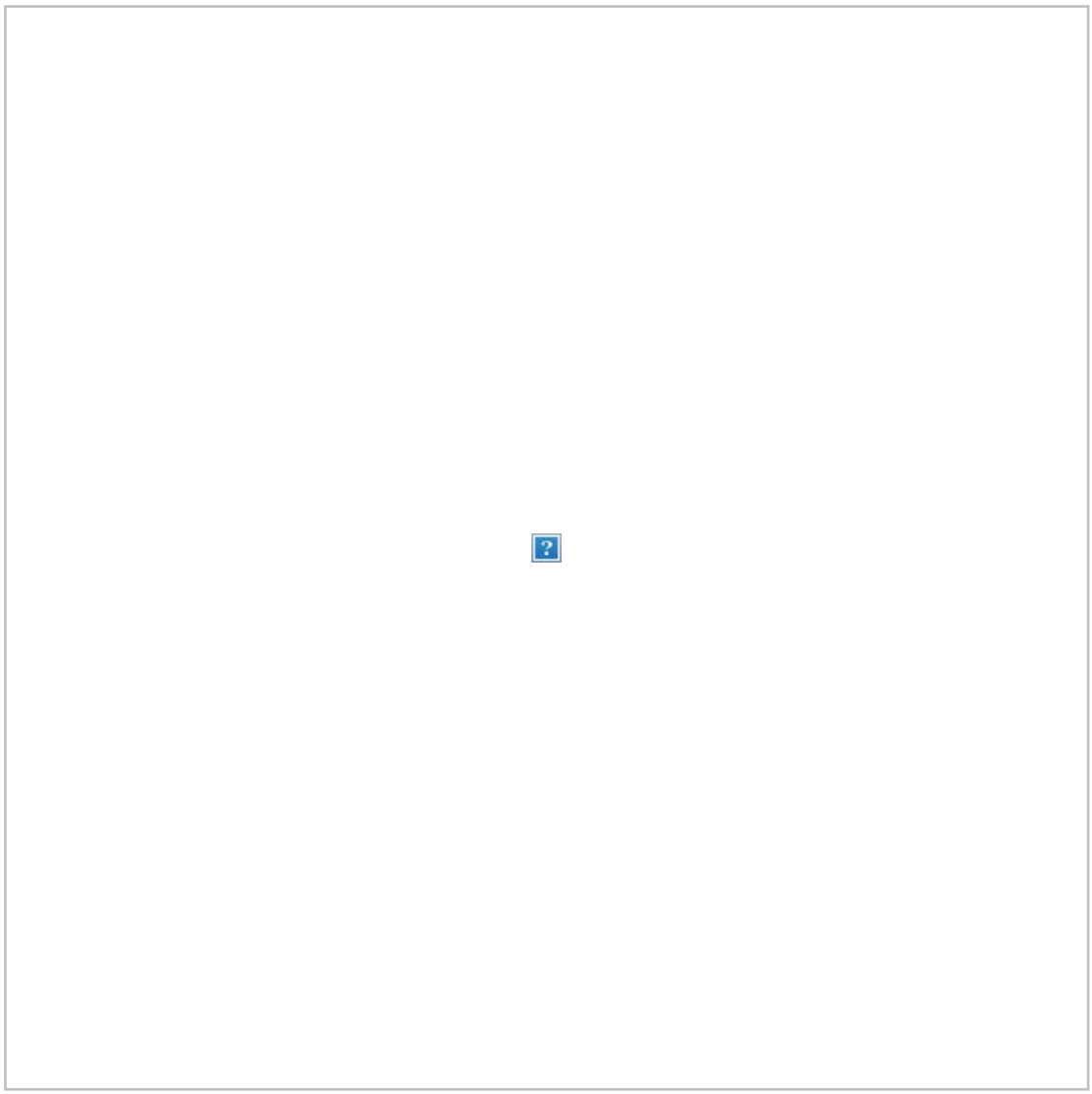
Antibody News You Should Know

July 1 - 15, 2022

Did you miss some Antibody News? Back issues can be found here.
Want your news faster? Follow us on LinkedIn!



An acquisition, agreement, and a new location are announced

On July 5, 2022, **AstraZeneca announced** an agreement to acquire TeneoTwo, Inc., including its Phase I clinical-stage CD19/CD3 T-cell engager, TNB-486, currently under evaluation in relapsed and refractory B-cell non-Hodgkin lymphoma. AstraZeneca will acquire all outstanding equity of TeneoTwo in exchange for an upfront payment of $100m on deal closing. Under the terms of the agreement,

AstraZeneca will make additional contingent R&D-related milestone payments of up to $805m and additional contingent commercial-related milestone payments of up to $360m to TeneoTwo's equity holders.

On July 6, 2022, **Twist Bioscience announced** the opening of its new Twist Boston location in Quincy, Massachusetts. Twist Boston, formerly known as Abveris, was acquired by Twist Bioscience in November 2021 to add in vivo antibody discovery expertise to Twist Biopharma's antibody discovery and optimization capabilities using robust, precisely written synthetic libraries. Twist Boston empowers the development of the next generation of biologics, cell therapies, vaccines, and diagnostics by using its DiversimAb™ family of hyperimmune mouse models to complete discovery and characterization services for global biopharma leaders. Antibodies discovered using the DiversimAb platform can be humanized using the Twist antibody optimization platform to develop superior biologics for rapid clinical advancement.

On July 12, 2022, **LegoChem Biosciences Inc. and Glycotope GmbH announced** that they have signed a Research Collaboration and License Agreement to develop an antibody-drug conjugate (ADC) by combining LegoChem Biosciences' proprietary ADC technology with one of Glycotope's investigational tumor targeting antibodies. Under the terms of the agreement LCB has the right to exercise its option for worldwide exclusive rights to develop and commercialize the selected antibody as ADC, upon successful completion of a feasibility study. If LegoChem Biosciences exercises these rights, Glycotope will receive an upfront payment, as well as development and sales milestone payments plus royalties.

First-in-human studies queued or started

On July 1, 2022, details were posted on clinicaltrials.gov for a Phase 1 dose escalation and expansion study (**NCT05441501**) of JNJ-80038114 for advanced stage prostate cancer. Sponsored by the Janssen Pharmaceutical Companies of Johnson & Johnson, the study will enroll an estimated 110 participants and has an estimated start date in Oct 2022.

- JNJ-80038114 is a T cell-redirecting agent targeting prostate specific membrane antigen.

On July 8, 2022, limited details were posted on clinicaltrials.gov for a first-in-human Phase 1/2 dose escalation and expansion study (**NCT05450562**) of SAR444200 administered as an intravenous injection in patients with glypican-3-positive solid tumors. Sponsored by Sanofi, the study will enroll an estimated 106 participants and has an estimated start date in July 2022.

- SAR444200 appears to be a protein-based molecule that targets glypican-3, based on the limited information available at this time.

On July 13, 2022, **Light Chain Bioscience - Novimmune SA announced** that the first patient was dosed in a first-in-human trial of NI-1801 in patients with advanced, metastatic, or recurrent solid malignancies expressing mesothelin (MSLN). The Phase 1 multi-center, open-label, dose escalation and expansion trial is expected to enroll approximately 40 patients with MSLN-expressing triple-negative breast, non-squamous non-small cell lung or ovarian cancer.

- NI-1801 is a human IgG1 bispecific antibody that targets MSLN and CD47.

Vilobelimab granted FDA Fast Track designation

On July 6, 2022, **InflaRx N.V. announced** that the US Food and Drug Administration (FDA) granted a Fast Track designation to the development of its first-in-class monoclonal antibody vilobelimab for the treatment of ulcerative pyoderma gangrenosum (PG). The company recently reported positive Phase 2a results in PG and encouraging Phase 3 results in mechanically ventilated COVID-19 patients. Vilobelimab is also in Phase 2 development for patients suffering from cutaneous squamous cell carcinoma.

- Vilobelimab is a chimeric IgG4 antibody that targets C5a.

Phase 3 study for talquetamab to start soon

On July 13, 2022, details were posted on clinicaltrials.gov for a Phase 3 study (**NCT05455320**) of talquetamab (JNJ-64407564) in combination with daratumumab or in combination with daratumumab and pomalidomide versus daratumumab in combination with pomalidomide and dexamethasone in participants with relapsed or refractory multiple myeloma. Sponsored by The Janssen Pharmaceutical Companies of Johnson & Johnson, the study will enroll an estimated 810 participants and has an estimated start date in October 2022.

- Talquetamab is a humanized bispecific antibody that targets G protein-coupled receptor 5D (GPRC5D) and CD3. It was derived from Genmab's DuoBody® platform.

Positive Phase 3 results reported for concizumab

On July 10, 2022, **Novo Nordisk A/S reported** that Phase 3 data for concizumab show a 86% reduction in treated bleeds in hemophilia A or B with inhibitors. The company expects to submit concizumab for regulatory approval for the prophylactic treatment of hemophilia A or B with inhibitors in the second half of 2022 in the US and Japan, and in 2023 in the EU and the UK.

Concizumab is an anti-tissue factor pathway inhibitor monoclonal antibody. By blocking TFPI, concizumab encourages the production of thrombin, which helps to clot the blood and prevent bleeding.

Antibody therapeutics in regulatory review

On July 5, 2022, **Eisai Pharmaceuticals India Co., Ltd. and Biogen Inc. announced** that the FDA accepted the Biologics License Application (BLA) under the accelerated approval pathway for lecanemab for the treatment of mild cognitive impairment due to Alzheimer's disease (AD) and mild AD with confirmed presence of amyloid pathology in the brain. Eisai's application was granted Priority Review, with a Prescription Drug User Fee Act action date of January 6, 2023.

- Lecanemab is an anti-amyloid beta (Aβ) protofibril antibody.

On July 5, 2022, **Genentech announced** that the FDA has accepted the company's BLA and granted Priority Review for mosunetuzumab for the treatment of adults with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies. FDA's target date for a first action on the application is December 29, 2022. The BLA is based on positive results from the pivotal Phase 1/2 GO29781 study of mosunetuzumab, which showed high complete response rates, with the majority of responders (57% [95% CI: 49-70]) maintaining responses for at least 18 months, and manageable tolerability in people with heavily pretreated follicular lymphoma.

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

On July 6, 2022, **Coherus BioSciences and Shanghai Junshi Biosciences Co Ltd. announced** that the FDA has accepted for review the BLA resubmission for toripalimab in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma and for toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. The FDA has set a Prescription Drug User Fee Act action date for December 23, 2022.

- Toripalimab is a humanized IgG4 monoclonal antibody that targets PD-1.

On July 12, 2022, **Byondis announced** that the FDA accepted the company's submission of a BLA for their ADC [vic-]trastuzumab duocarmazine (SYD985) in patients with HER2-positive unresectable locally advanced or metastatic breast cancer. The company has been given a Prescription Drug User Fee Act action date of May 12, 2023. The BLA is supported by data from the pivotal Phase 3 TULIP® multi-center, open-label, randomized clinical trial comparing SYD985 to physician's

choice treatment in patients with pre-treated HER2-positive unresectable locally advanced or metastatic breast cancer.

- SYD985 is an anti-HER2 ADC that incorporates Byondis' proprietary duocarmazine linker-drug technology ByonZine®.

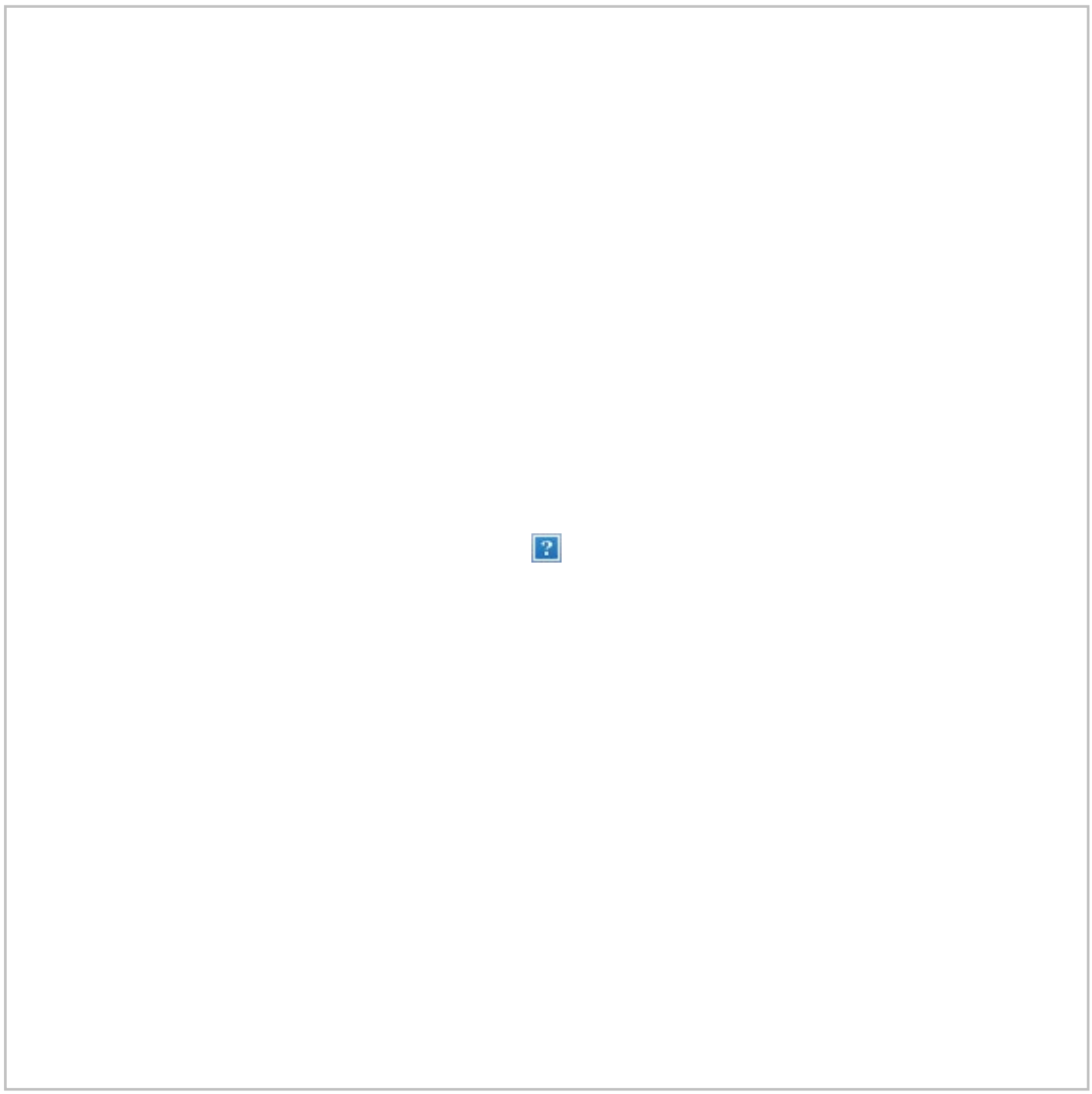
On July 14, 2022, **BeiGene announced** that FDA has deferred action on the BLA for tislelizumab as a second-line treatment for patients with unresectable or metastatic esophageal squamous cell carcinoma. The FDA has been unable to conduct required inspections in China due to COVID-19 related travel restrictions. As a result, the FDA is deferring action on the application until the inspections are complete. In the letter, the FDA cited only travel restrictions and the inability to complete inspections as the reason for the deferral. The application remains under review, and the FDA did not provide a new anticipated action date as they continue to monitor the public health situation and travel restrictions.

- Tislelizumab is an anti-PD-1 monoclonal antibody.

Antibody News You Should Know

July 15 - August 1, 2022

Did you miss some Antibody News? Back issues can be found here.
Want your news faster? Follow us on LinkedIn!



Expansion, license agreement, and funding news

On July 19, 2022, **WuXi Biologics, a contract research, development and manufacturing organization (CRDMO), announced** it is establishing a cutting-edge, fully integrated CRDMO center in Singapore, including a research and development service center and large-scale drug substance and drug product manufacturing facilities for biologics. The company announced a 10-year USD$1.4

billion (S$2 billion) investment plan that will add 120,000L biomanufacturing capacity to WuXi Biologics' global network by 2026 and is anticipated to employ 1,500 research, development, and manufacturing staff when complete.

On July 20, 2022, **F-star Therapeutics announced** a license agreement with Takeda for a novel next-generation immuno-oncology bispecific antibody. Under the terms of the agreement, F-star will grant Takeda a worldwide, exclusive royalty-bearing license to research, develop, and commercialize a bispecific antibody against an immuno-oncology target using F-star's proprietary Fcab™ and mAb2™ platforms. Takeda will be responsible for all research, development, and commercialization activities under the agreement.

On July 20, 2022, **BigHat Biosciences** announced it has raised a $75 million Series B funding round, led by Section 32, with participation from new investors Amgen Ventures, Bristol Myers Squibb, Quadrille Capital, Gaingels, GRIDS Capital, among others. The investment brings BigHat's total funding to date to $100 million. The company aims to develop safer, more effective antibody therapies for patients using machine learning and synthetic biology.

On July 28, 2022, **Elevation Oncology, Inc.** announced that it entered into an exclusive license agreement with CSPC Megalith Biopharmaceutical Co., Ltd, a subsidiary of CSPC Pharmaceutical Group Limited, to develop and commercialize EO-3021 (SYSA1801), a differentiated, clinical stage (Phase 1) antibody-drug conjugate (ADC) targeting Claudin18.2, in all global territories outside Greater China (mainland China, Hong Kong, Macau and Taiwan). Under the terms of the agreement, Elevation Oncology will develop and commercialize EO-3021 in all global territories outside of Greater China. In exchange, CSPC will receive a one-time, upfront payment of $27 million. CSPC will also be eligible to receive up to $148 million in potential development and regulatory milestone payments and up to $1.0 billion in potential commercial milestone payments plus royalties on net sales.

On August 1, 2022, **Avalo Therapeutics, Inc. and Apollo Therapeutics Group Limited announced** that they entered into a worldwide, exclusive license agreement granting rights to Apollo to research, develop, manufacture and commercialize AVTX-007 (camoteskimab). Under the terms of the agreement, Apollo will assume responsibility for the future development of AVTX-007, including the ongoing clinical trial. Apollo will lead future clinical development in its selected therapeutic indications. The AVTX-007 program was originally licensed to Avalo by MedImmune Limited, a subsidiary of AstraZeneca plc, and such license was transferred to Apollo as part of the transaction.

- Camoteskimab is a human IgG1 monoclonal antibody targeting IL-18.

IPH6401 selected for IND-enabling studies

On July 21, 2022, **Innate Pharma SA announced** that Sanofi has made the decision to progress IPH6401/SAR'514 into investigational new drug (IND)-enabling studies, triggering a €3 million milestone payment. IPH6401/SAR'514 is derived from Sanofi's proprietary CROSSODILE® multi-functional platform, which comprises the Cross-Over-Dual-Variable-Domain (CODV) format. It induces a dual targeting of the natural killer (NK) activating receptors, NKp46 and CD16, for an optimized NK cell activation, based on Innate's ANKETTM (Antibody-based NK cell Engager Therapeutics) proprietary platform.

- IPH6401/SAR'514 is a BCMA-targeting NK cell engager.

FDA clears IND for STAR-0215

On July 28, 2022, **Astria Therapeutics, Inc. announced** the U.S. Food and Drug Administration (FDA) clearance of its IND application for STAR-0215, which the company is developing for the treatment of hereditary angioedema (HAE). STAR-0215 is designed to provide long-acting, effective attack prevention for HAE with dosing once every 3 months or longer. A Phase 1a trial (NCT05477160) of STAR-0215 in healthy volunteers is expected to initiate in the coming weeks, with preliminary results anticipated by year-end.

- STAR-0215 is an investigational monoclonal antibody inhibitor of plasma kallikrein.

First-in human studies started

On July 19, 2022, details were posted on clinicaltrials.gov for a Phase 1, multicenter, open-label first-in-human study (**NCT05464030**) of the ADC M9140 in participants with advanced solid tumors. Sponsored by EMD Serono Research & Development Institute, Inc., the study is currently recruiting an estimated 30 participants.

- M9140 is a next-generation, anti-CEACAM5 ADC based on an internally developed linker-payload technology.

On July 26, 2022, **Sutro Biopharma, Inc. announced** that the first patient has been dosed in a Phase 1 study of an investigational candidate resulting from the collaboration between Sutro and Merck for the development of a novel cytokine derivative therapeutic for the treatment of cancer. As a result of this milestone, Sutro will receive a $10 million payment from Merck. Sutro Biopharma is a clinical-stage oncology company pioneering site-specific and novel-format ADCs.

On July 28, 2022, **Tallac Therapeutics announced** that the first patient has been

dosed with TAC-001 in a Phase 1/2 clinical trial (NCT05399654) for patients with advanced or metastatic solid tumors. TAC-001 is the company's lead clinical candidate from its novel Toll-like Receptor Agonist Antibody Conjugate platform and the first to enter the clinic.

- TAC-001 is composed of a potent toll-like receptor 9 agonist (T-CpG) conjugated to an antibody against CD22, a receptor restricted to B cells, including tumor-infiltrating B cells.

News of marketing applications planned or in progress

On July 18, 2022, **Genmab announced** that AbbVie will submit a conditional marketing authorization application (MAA) with the European Medicines Agency (EMA) for subcutaneous epcoritamab, an investigational bispecific antibody, for the treatment of patients with relapsed/refractory diffuse large B-cell lymphoma. Genmab had previously announced that the company will submit a biologics license application (BLA) for epcoritamab with the FDA for the treatment of patients with relapsed/refractory large B-cell lymphoma, also in the second half of 2022.

- Epcoritamab, a T cell-engaging bispecific antibody targeting CD20 and CD3, was derived from Genmab's DuoBody® platform.

On July 18, 2022, **Byondis B.V. announced** that the EMA has validated the MAA for the company's investigational next-generation ADC trastuzumab duocarmazine (SYD985) in patients with HER2-positive unresectable locally advanced or metastatic breast cancer. The company had previously announced that the BLA for trastuzumab duocarmazine was accepted by FDA. The MAA is supported by data from Byondis' pivotal Phase III TULIP® multi-center, open-label, randomized clinical trial comparing SYD985 to physician's choice (PC) treatment in patients with pre-treated HER2-positive unresectable locally advanced or metastatic breast cancer (SYD985.002/NCT03262935). The study met its primary endpoint of progression-free survival, demonstrating a statistically significant improvement of 2.1 months over PC.

- Trastuzumab duocarmazine is composed of an anti-HER2 antibody conjugated to a duocarmycin cytotoxic payload via a cleavable linker.

On July 28, 2022, **ImmunityBio, Inc. announced** that FDA accepted for review a BLA for N-803 as a treatment for patients with BCG-unresponsive non-muscle-invasive bladder cancer carcinoma in situ with or without Ta or T1 disease. ImmunityBio filed the BLA based on positive results from a series of studies of the investigational treatment, including the ongoing QUILT 3.032 trial. The Prescription Drug User Fee Act target action date is May 23, 2023.

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

EMA recommends authorization of teclistamab, tezepelumab, and faricimab

On July 22, 2022, **EMA announced** that its human medicines committee recommended several antibody-based medicines for approval at its July 2022 meeting, including Tecvayli* (teclistamab), Tezspire (tezepelumab), and Vabysmo (faricimab).

The committee recommended granting a conditional marketing authorisation for Tecvayli* (teclistamab) for the treatment of adults with relapsed and refractory multiple myeloma, who have received at least three prior therapies; a BLA for teclistamab is undergoing review by FDA.

The CHMP also gave a positive opinion for Tezspire (tezepelumab), intended as an add-on treatment in adult and adolescent patients with severe asthma, and for Vabysmo (faricimab), intended for the treatment of adults with neovascular age-related macular degeneration and visual impairment due to diabetic macular oedema. Both tezepelumab and faricimab are already FDA-approved products.

- Teclistamab is a T cell-engaging bispecific antibody that targets BCMA and CD3.
- Tezepelumab is a human IgG2 antibody targeting thymic stromal lymphopoietin.
- Faricimab is a bispecific 1+1 CrossMab that targets VEGF-A and Ang-2.

Anti-PD-1 pucotenlimab approved in China

On July 22, 2022, **LEPU BIOPHARMA announced** that its first innovative biological drug, Puyouheng (pucotenlimab), has been conditionally approved for marketing in China by the National Medical Products Administration. The drug is applicable for patients with unresectable or metastatic microsatellite instability-high or mismatch repair deficient advanced solid tumors, which are as follows:

● Patients with advanced colorectal cancers have progressed following previous treatment with a fluoropyrimidine, oxaliplatin and irinotecan;

● Patients with other advanced solid tumors that have progressed following at least previous first-line therapy with no satisfactory alternative treatment options.

The approval is based on a multi-center, open-label, Phase 2 clinical study with a primary study endpoint of the objective response rate (ORR) assessed by the Independent Review Committee (IRC) according to the RECIST1.1.

- Pucotenlimab is an anti-PD-1 monoclonal antibody.

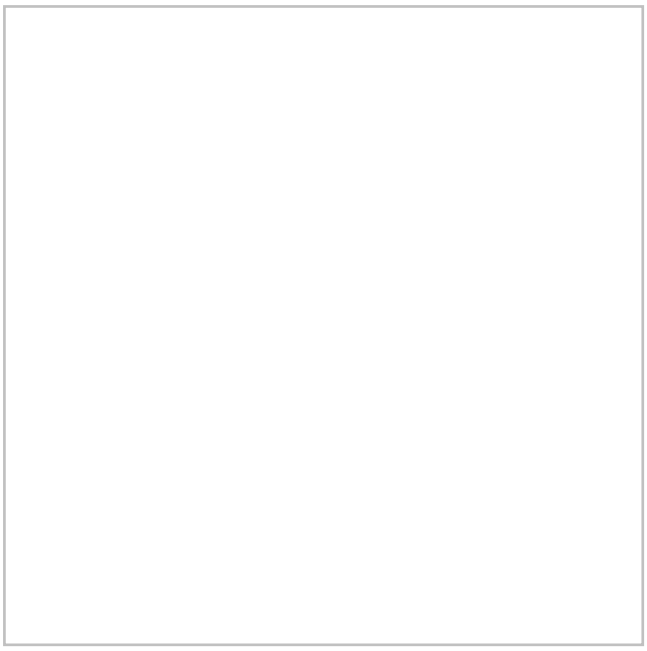
From: The Antibody Society
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Aug 1 - 15, 2022
Date: Tuesday, August 16, 2022 3:01:00 AM

View this email in your browser

Antibody News You Should Know

August 1 - 15, 2022

Did you miss some Antibody News? Back issues can be found here.
Want your news faster? Follow us on LinkedIn!



Acquisitions in the news

On August 4, 2022, **Gilead Sciences, Inc. and MiroBio Ltd**, a privately-held U.K.-based biotechnology company focused on restoring immune balance with agonists targeting immune inhibitory receptors, announced that the companies have entered into a definitive agreement pursuant to which Gilead will acquire MiroBio for approximately $405 million in cash, subject to customary adjustments. MiroBio's lead investigational antibody, MB272, entered Phase 1 clinical trials, with the first patient dosed earlier this week.

- MB272 is a selective agonist of immune inhibitory receptor B- and T-Lymphocyte Attenuator (BTLA).

On August 8, 2022, **Pfizer Inc. and Global Blood Therapeutics, Inc. (GBT) announced** the companies have entered into a definitive agreement under which Pfizer will acquire GBT. Amongst their assets, GBT is developing inclacumab to treat vaso-occlusive crises in patients with sickle cell disease. GBT acquired rights to inclacumab from Roche Holding in 2018. Inclacumab, which has received Orphan Drug and Rare Pediatric Disease designations from the U.S. Food and Drug Administration (FDA), is being evaluated in two Phase 3 clinical trials as a potential quarterly treatment to reduce the frequency of vaso-occlusive crisis (VOCs) and to reduce hospital readmission rates due to VOCs.

- Inclacumab is a human IgG4 monoclonal antibody that targets P-selectin.

Collaborations in the news

On August 5, 2022, **Genmab and BioNTech SE announced** an expansion of their global strategic collaboration to develop and commercialize novel immunotherapies for the treatment of cancer patients. Under the expansion, Genmab and BioNTech will jointly work to research, develop, and commercialize novel monospecific antibody candidates for various cancer indications. The first monospecific antibody candidate, GEN1053/BNT313, is expected to enter clinical trials by the end of 2022. Under the terms of the agreement, the companies will equally share the development costs and potential future profit deriving from GEN1053/BNT313.

- GEN1053/BNT313 is a CD27 antibody based on the HexaBody® technology, specifically engineered to form an antibody hexamer (a formation of six antibodies) upon binding its target on the cell membrane of the T cells.

On August 5, 2022, **Innovent Biologics Inc announced** that Sanofi SA would invest HK$2.42 billion ($307.88 million) in the biopharmaceutical group to jointly develop 2 cancer drugs in China. The 2 drugs are the antibody-drug conjugate (ADC) SAR408701 which is under evaluation as a treatment for lung, gastric and other cancers, as well as SAR444245, a recombinant human IL-2 molecule irreversibly bound to a PEG chain to block alpha-binding while retaining near-native affinity for beta/gamma IL-2 receptor subunits.

- SAR408701 (tusamitamab ravtansine) is composed of a humanized IgG1 anti-CEACAM5 antibody conjugated to the microtubule-disrupting drug DM4 via a linker that is stable in plasma but cleavable inside cells.

On August 8, 2022, **Mersana Therapeutics, Inc. announced** a global collaboration that provides GSK plc an exclusive option to co-develop and commercialize anti-HER2 XMT-2056. XMT-2056 is designed to activate the innate immune system through STING signaling in both tumor-resident immune cells and in tumor cells. Mersana expects to initiate a Phase 1 clinical trial of XMT-2056 to investigate its potential in a range of HER2-expressing tumors such as breast, gastric and non-small-cell lung cancers. The FDA has granted an orphan drug designation to XMT-2056 for the treatment of gastric cancer.

- XMT-2056 is an Immunosynthen ADC that targets a novel epitope of HER2.

Evorpacept granted US Fast Track designation

On August 1, 2022, **ALX Oncology announced** that the FDA granted Fast Track designation to evorpacept (ALX148), a next generation CD47 blocker, in combination with KEYTRUDA® (anti-PD-1 pembrolizumab) for the first-line treatment of adult patients with PD-L1 positive advanced head and neck squamous cell carcinoma (HNSCC). Evorpacept is being evaluated in the Phase 2 ASPEN-03 study, which is investigating the anti-tumor efficacy of evorpacept plus pembrolizumab in patients with first-line metastatic or unresectable, recurrent PD-L1 positive HNSCC, and a Phase 2 investigator-sponsored study (NCT05167409) in combination with ERBITUX® (cetuximab) and KEYTRUDA® in patients with refractory microsatellite stable metastatic colorectal cancer who have progressed on at least two lines of systemic therapy.

- ALX148 is a fusion protein composed of an engineered high affinity CD47 binding domain of SIRPα linked to an inactive Fc region of human immunoglobulin.

First-in-human studies queued or started

On August 10, 2022, details were posted on clinicaltrials.gov for a first-in-human Phase 1 study (**NCT05494918**) that will assess the safety, tolerability and pharmacokinetics of JSKN003 in patients with advanced or metastatic solid malignant tumors. Sponsored by Alphamab Oncology, the study will enroll an estimated 45 patients and has an estimated start date of August 12, 2022.

- JSKN003 is a bispecific ADC that targets domain II and IV of HER2.

On August 11, 2022, details were posted on clinicaltrials.gov for a Phase 1 study (**NCT05496595**) that will evaluate DCBY02 (Part A) or DCSZ11 (Part B) as a monotherapy in patients with advanced or metastatic solid tumors. Sponsored by DynamiCure Biotechnology, the study will enroll an estimated 96 patients and has an estimated start date in September 2022.

- DCBY02 and DCSZ11 are monoclonal antibodies that target CD93.

On August 10, 2022, **Arbele Pty Ltd announced** the successful dosing of the first patient in Australia in a first-in-human Phase 1 study (NCT05411133) of ARB202 for the treatment of advanced gastrointestinal cancers patients who failed standard treatment. The study will enroll an estimated 68 patients. Given tolerability, potential expansion cohorts will further evaluate the safety and efficacy of ARB202 in specific indication(s) and in combination with other therapy.

- ARB202 is a bispecific T-cell engaging antibody targeting CDH17 and CD3.

First Phase 2 study of ponsegromab to start

On August 8, 2022, details were posted on clinicaltrials.gov for a placebo-controlled, 4-arm Phase 2 study (**NCT05492500**) to investigate symptoms, function, health-related quality of life and safety with repeated subcutaneous administration of ponsegromab (PF-06946860) versus placebo in adult participants with heart failure. Sponsored by Pfizer, the study will enroll an estimated 416 patients and has an estimated start date in September 2022.

- Ponsegromab is an IgG1 monoclonal antibody that targets growth differentiation factor 15.

Crovalimab enters regulatory review in China

On August 10, 2022, **Chugai announced** that the National Medical Products Administration of People's Republic of China accepted the world's first filing of a regulatory application for crovalimab and granted priority review for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). The application is submitted by Roche China based on a Chinese Phase 3 clinical trial (COMMODORE 3 study) for PNH. Crovalimab was designated in China as a Breakthrough Therapy for the disease in July 2021.

- Crovalimab is an anti-C5 recycling antibody. Recycling antibodies are designed to achieve pH-dependent antigen binding so that a single antibody molecule can bind with the antigen multiple times, enabling a longer efficacy compared with a conventional antibody.

Approvals in the US and EU

On August 5, 2022, the **FDA approved Enhertu (fam-trastuzumab-deruxtecan-nxki)**, an anti-HER2 ADC for the treatment of patients with unresectable or metastatic HER2-low breast cancer. This is the first approved therapy targeted to patients with the HER2-low breast cancer subtype, which is a newly defined subset of HER2-negative breast cancer. Enhertu received priority review and breakthrough therapy designations for this indication. Enhertu was first approved in the US in 2019.

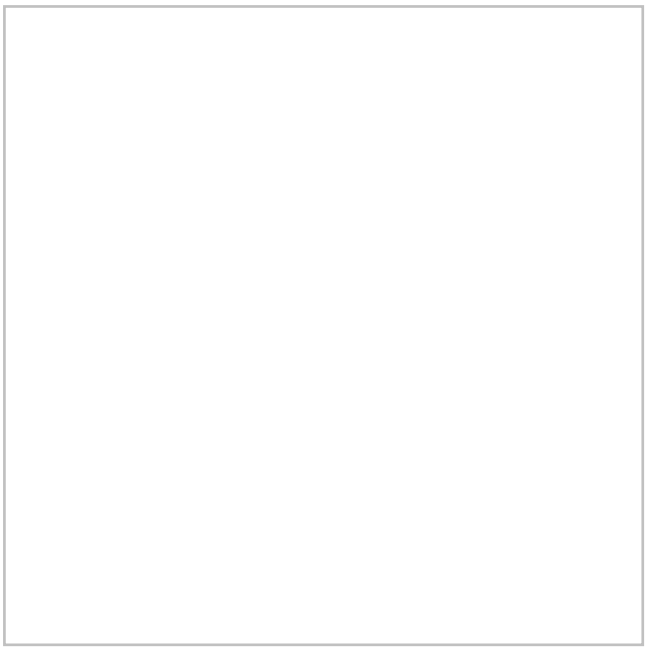
On August 11, 2022, the **European Commission granted marketing authorization for VYVGART™ (efgartigimod alfa-fcab)** as an add-on to standard therapy for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating immunoglobulin G (IgG) autoantibodies. It is the first and only approved FcRn blocker.

From: The Antibody Society
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Aug 15 - Sep 1, 2022
Date: Friday, September 2, 2022 9:01:52 AM

Antibody News You Should Know

August 15 - September 1, 2022

Did you miss some Antibody News? Back issues can be found here.
Want your news faster? Follow us on LinkedIn!



INBRX-109 granted Orphan Drug designation in the EU

On August 15, 2022, **Inhibrx, Inc. announced** that the European Commission, based on a positive opinion issued by the European Medicines Agency, has granted orphan medicinal product designation to INBRX-109 for the treatment of chondrosarcoma. The US Food and Drug Administration (FDA) previously granted Fast Track designation to INBRX-109 for the treatment of patients with unresectable or metastatic conventional chondrosarcoma and orphan-drug designation to INBRX-109 for chondrosarcoma. INBRX-109 is being evaluated in a randomized, blinded, placebo-controlled, potential registration-enabling Phase 2 trial of conventional chondrosarcoma, which is currently ongoing.

- INBRX-109 is a tetravalent death receptor 5 (DR5) agonist antibody designed to exploit the tumor-biased cell death induced by DR5 activation.

First-in-human studies queued or started

On August 15, 2022, details were posted on clincaltrials.gov for a Phase 1 first-in-human, multicenter, open-label, dose escalation followed by an expansion phase clinical study (**NCT05501821**) of KBA1412 given as monotherapy or in combination with pembrolizumab in adults with advanced solid malignant tumors. Sponsored by Kling Biotherapeutics, the study has an estimated enrollment of 106 participants and is currently recruiting patients.

- KBA1412, a patient-derived, human monoclonal antibody targeting CD9.

On August 22, 2022, **DynamiCure Biotechnology announced** that the FDA cleared its investigational new drug application to advance, DCBY02, the first monoclonal antibody candidate from the company's DC-6001 anti-CD93 development program, into a Phase 1 study (NCT05496595). DynamiCure plans to submit the IND for the second monoclonal antibody from the DC-6001 program, DCSZ11, in the fourth quarter of 2022.

- DCBY02 and DCSZ11 are anti-CD93 monoclonal antibodies, each of which has demonstrated distinct in vitro and in vivo properties and the ability to block different epitopes of CD93 in pre-clinical development.

On August 22, 2022, details were posted on clinicaltrials.gov for a Phase 1 dose escalation study (**NCT05509985**) to evaluate the safety, tolerability and pharmacokinetics of ASKG315 as a single agent and in combination with pembrolizumab in patients with advanced solid tumors. Sponsored by AskGene Pharma, Inc., the study has an estimated enrollment of 100 participants and an estimated start date of September 9, 2022.

- ASKG315 is an IL-15 antibody-cytokine fusion molecule derived from the SmartKine® platform, which can effectively match cytokine activity with that of the targeting antibody.

On August 23, 2022, details were posted on clinicaltrials.gov for a Phase 1 multicenter, open-label, first-in-human study (**NCT05511844**) of ORM-5029 in subjects with HER2-expressing advanced solid tumors. Sponsored by Orum Therapeutics, the study has an estimated enrollment of 87 participants and an estimated start date in October 2022.

- ORM-5029 is composed of SMol006, a highly-potent GSPT1 degrader conjugated to pertuzumab via a clinically-validated Val-Cit PABc linker.

On August 23, 2022, details were posted on clinicaltrials.gov for a Phase 1 open-label, multicenter study (**NCT05519449**) of JANX007 in subjects with metastatic castration-resistant prostate cancer. Sponsored by Janux Therapeutics, the study has an estimated enrollment of 90 participants and an estimated start date in August 2022.

- JANX007 is a tumor-activated T-cell engager with PSMA- and CD3-binding domains, a peptide mask that inhibits CD3 engagement on T cells, an albumin-binding domain appended to the mask to extend circulating half-life, and a tumor protease cleavable linker.

On August 22, 2022, **Cue Biopharma announced** the initiation of their Phase 1 study of CUE-102. The trial (NCT05360680) is a multi-center, open-label, Phase 1 dose escalation and expansion study evaluating the safety, tolerability, anti-tumor activity, and immunogenicity of CUE-102 in HLA-A*0201 positive patients with WT1-positive recurrent/ metastatic cancers who have failed conventional therapies. The study is designed to enroll approximately 50 patients.

- CUE-102 consists of two human leukocyte antigen (HLA) molecules presenting a WT1 peptide, four affinity-attenuated IL-2 molecules, and an

effector attenuated human immunoglobulin G (IgG1) Fc domain.

BLA for efanesoctocog alfa granted priority review by FDA

On August 30, 2022, **Sanofi announced** that the FDA has accepted for priority review the Biologics License Application for efanesoctocog alfa (BIVV001[rFVIIIFc-VWF-XTEN) for the treatment of hemophilia A, a rare and life-threatening bleeding disorder. The priority review is based on pivotal data from the XTEND-1 Phase 3 study (NCT04161495). The target action date for the FDA decision is February 28, 2023. Sanofi and Sobi® collaborate on the development and commercialization of efanesoctocog alfa.

- Efanesoctocog alfa is a novel recombinant factor VIII therapy that incorporates innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to potentially extend its time in circulation.

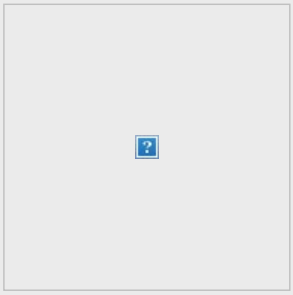
Teclistamab approved in the EU

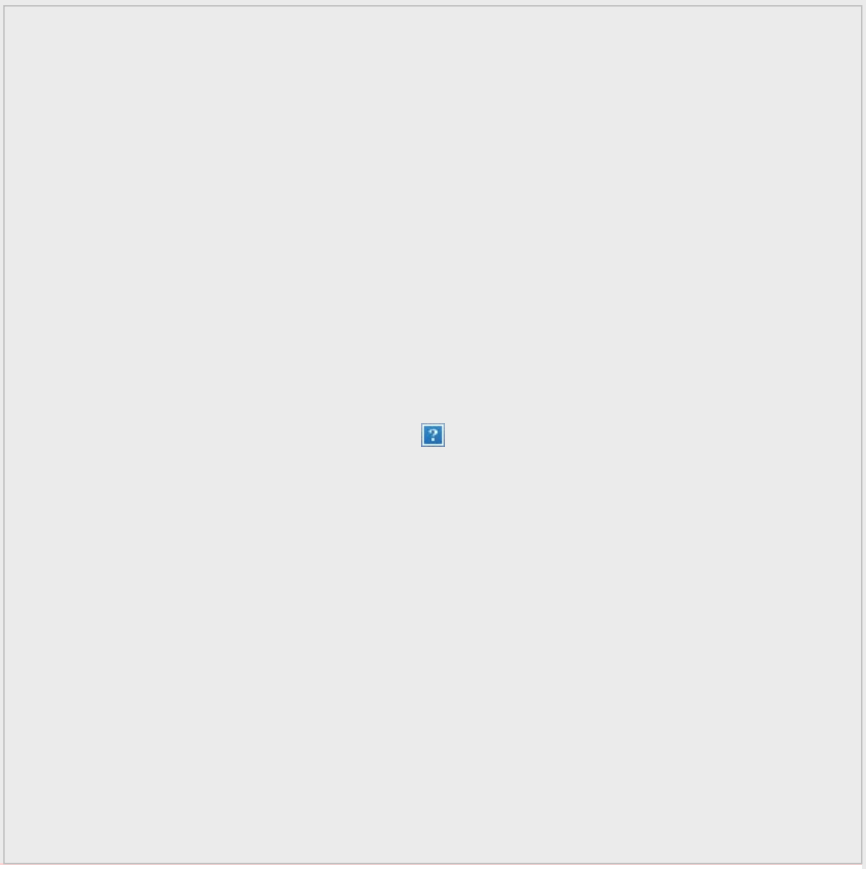
On August 24, 2022, **The Janssen Pharmaceutical Companies of Johnson & Johnson announced** the first approval worldwide for the bispecific antibody TECVAYLI® (teclistamab). The European Commission granted a conditional marketing authorisation of TECVAYLI® as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM). This authorization was supported by positive results from the multicohort, open-label Phase 1/2 MajesTEC-1 study (NCT03145181 and NCT04557098), evaluating the safety and efficacy of teclistamab in adults with RRMM.

- Teclistamab is a bispecific, T-cell engaging IgG4 DuoBody® that targets BCMA and CD3.

From: The Antibody Society
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Sep 1 - 15, 2022
Date: Friday, September 16, 2022 10:01:32 AM

View this email in your browser





Antibody News You Should Know

September 1 - 15, 2022

Registration is open!

Business news

On September 2, 2022, **Biointron Biological Inc. Biological Inc., a CRO company, focused on antibody discovery, announced** it had raised nearly 500 million RMB ($75M) for Series B funding. The funding will mainly be used for the expansion of CRO service capacity, the production of advanced R&D and manufacturing service lines, and the continued expansion of business development.

On September 7, 2022, **Good Therapeutics, Inc. announced** it has entered into a definitive merger agreement to be acquired by Roche. With this acquisition, Roche will gain rights to Good Therapeutics' innovative, conditionally active, PD-1-regulated IL-2 program and an exclusive right to the platform technology for the development of PD-1-regulated IL-2 receptor agonist therapeutics.
Following the close of the Roche acquisition, the Good Therapeutics team plans to apply the technology for the design of conditionally active therapeutics to other targets in immuno-oncology and beyond in a new company, Bonum Therapeutics.

On September 12, 2022, **Adagio Therapeutics announced** it has changed its name to Invivyd. Along with the

new name, the company has adopted a new logo and refreshed its corporate website to reflect the company's strategy moving forward. The Invivyd corporate mission is to provide antibody solutions that provide superior protection against viral diseases.

New licensing agreements

On September 6, 2022, **Emergence Therapeutics AG and Synaffix announced** that the companies have entered into a licensing agreement of up to $360 million, providing Emergence access on a target-specific basis to Synaffix's proprietary antibody-drug conjugate (ADC) technologies comprising GlycoConnect™, HydraSpace™ and SYNtecan E™ linker-payload. Under the terms of the agreement, Emergence Therapeutics secures rights to develop multiple ADCs against undisclosed targets. Emergence will be responsible for the research, development, manufacturing, and commercialization of the ADCs. Synaffix will be responsible for the manufacturing of components that are specifically related to its proprietary technologies.

On September 9, 2022, **Heidelberg Pharma AG announced** that their subsidiary Heidelberg Pharma Research GmbH and Takeda signed a license agreement granting Takeda an exclusive license to commercially develop an Antibody Targeted Amanitin Conjugate directed to a previously selected target molecule. Heidelberg Pharma receives an undisclosed milestone payment and is eligible to receive potential future clinical development, regulatory and sales-related milestone payments.

INDs for new antibody therapeutics planned or filed

On September 12, 2022, **Centessa Pharmaceuticals plc announced** non-clinical pharmacokinetic and safety data in non-human primates for LB101, its first LockBody® candidate for solid tumors. Data support continued advancement of LB101 toward IND submission late this year.

- LB101 is a tetravalent, bispecific antibody targeting PD-L1 and CD4 via constitutive Fabs (anti-PD-L1) that drive tumor enrichment and contingent Fabs (anti-CD47) that are unlocked in the tumor microenvironment by natural processes.

On September 13, 2022, **Akeso, Inc. released** encouraging preclinical results in a poster featuring AK130 at the 2022 European Society for Medical Oncology Congress. The Fc-silenced, IgG4 antibody is designed to inhibit TIGIT-mediated immunosuppression while decreasing the TGF-ß levels in the tumor microenvironment. The company also announced that the IND for AK130 was accepted by China's National Medical Products Administration.

- AK130 is composed of an anti-TIGIT monoclonal antibody fused to the extracellular domain of human transforming growth factor-ß receptor II.

First-in-human studies started

On September 7, 2022, **CASI Pharmaceuticals, Inc. and partner BioInvent International AB announced** that they advanced BI-1206, in combination with rituximab, into a Phase 1 dose-escalation and expansion study of patients with relapsed/refractory non-Hodgkin's lymphoma. The Phase 1 study in China will assess the safety, tolerability, pharmacology, and clinical activity of BI-1206.

- BI-1206 is a first-in-class human monoclonal antibody targeting FcγRIIB.

On September 12, 2022, **Alector, Inc. announced** the initiation of a first-in-human Phase 1 trial of AL044. The study is investigating the safety profile, PK/PD, and target engagement of AL044 in healthy adults. AL044 was designed to mimic and exceed the beneficial activities of the protective MS4A4A gene variant in Alzheimer's disease, as determined by AL044's ability to partially phenocopy the gene expression signature of the protective MS4A4A gene variant and to increase sTREM2 levels in the CSF of non-human primates in a dose-dependent manner.

- AL044 as a humanized, MS4A4A function-modulating monoclonal antibody that is intended to be delivered by intravenous, peripheral infusion into the bloodstream.

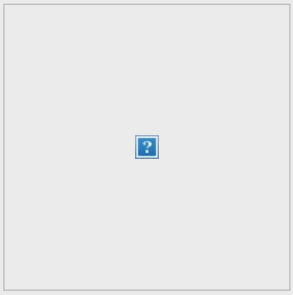
Antibody therapeutic approvals in the US

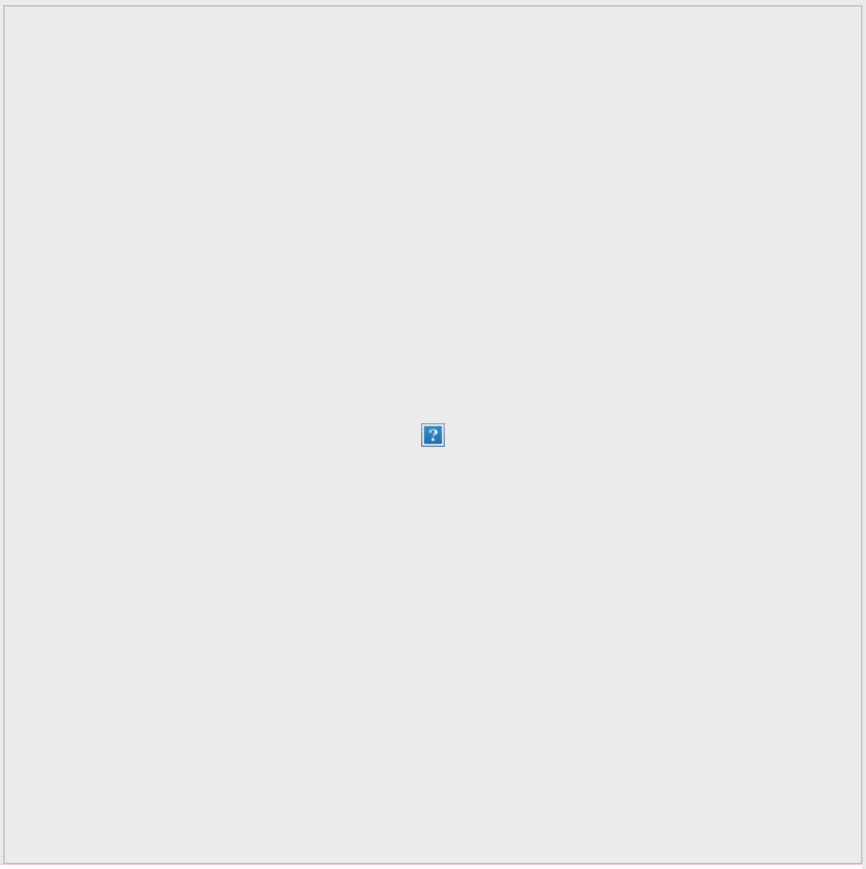
On September 1, 2022, the **U.S. Food and Drug Administration (FDA) approved SPEVIGO** (spesolimab-sbzo) for generalized pustular psoriasis (GPP) flares in adults. Developed by Boehringer Ingelheim, SPEVIGO is a novel, selective antibody that blocks the activation of the interleukin-36 receptor, a key part of a signaling pathway within the immune system shown to be involved in the cause of GPP. The product is the first approved treatment option adults with GPP flares.

On September 2, 2022, the **FDA approved Imfinz**i (anti-PD-L1 durvalumab) for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC) in combination with chemotherapy (gemcitabine plus cisplatin). BTC is a group of rare and aggressive gastrointestinal cancers that form in the cells of the bile ducts (cholangiocarcinoma), gallbladder or ampulla of Vater. Durvalumab was previously approved by FDA for the treatment of adult patients with unresectable, Stage III non-small cell lung cancer whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; and, in combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer.

From: The Antibody Society
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Sep 15 - Oct 1, 2022
Date: Sunday, October 2, 2022 1:00:44 PM

View this email in your browser





Antibody News You Should Know

September 15 - October 1, 2022

Registration is open!

Business news

On September 26, 2022, **Seagen Inc. and LAVA Therapeutics N.V. announced** an exclusive license agreement in which Seagen will work to develop, manufacture and commercialize LAVA-1223. LAVA-1223 is an advanced preclinical asset that utilizes LAVA's proprietary Gammabody™ technology to target epidermal growth factor receptor-expressing solid tumors. LAVA will receive an upfront payment of $50 million, with potential for milestones of up to approximately $650 million and royalties. Seagen also has an option to nominate up to two additional tumor targets for bispecifics using LAVA's proprietary Gammabody™ platform.

XMT-1660 granted Fast Track designation

On September 12, 2022, **Mersana Therapeutics announced** that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to their clinical stage antibody-drug conjugate XMT-1660 for the treatment of adult patients with advanced or metastatic triple-negative breast cancer. The company recently initiated a Phase 1 trial investigating the safety, tolerability and anti-tumor activity of XMT-1660 in patients with solid tumors, including in breast, endometrial and ovarian cancers.

- XMT-1660 is a B7-H4-directed Dolasynthen antibody-drug conjugate with a precise, target-optimized drug-to-antibody ratio (DAR 6) and Mersana's clinically validated DolaLock microtubule inhibitor payload with controlled bystander effect.

Phase 1 studies planned or started

On September 19, 2022, A**lligator Bioscience AB and Aptevo Therapeutics Inc announced** that the Investigational New Drug (IND) application for ALG.APV-527 has been cleared by FDA, allowing the companies to initiate clinical trials evaluating the molecule for the treatment of 5T4-expressing tumor antigens in multiple solid tumor types. ALG.APV-527 has dual functions: tumor-binding and 4-1BB immunomodulatory agonist effects.

- ALG.APV-527 is a bispecific antibody targeting 4-1BB and 5T4.

On September 21, 2022, **Immunitas Therapeutics announced** that the FDA has cleared the IND application for IMT-009. The Phase 1 study is designed to evaluate the safety, tolerability, pharmacodynamic biomarkers, and preliminary efficacy of IMT-009, as well as identify the Recommended Phase 2 Dose. The antibody binds with high affinity and selectivity to CD161, a receptor that is broadly expressed on NK and a subset of memory T cells, blocking interactions between the receptor and its cognate ligand, CLEC2D, which is expressed on the surface of both cancer cells and immune cells.

- IMT-009 is an Fc-attenuated human monoclonal antibody against CD161, a novel immuno-oncology target.

On September 16, 2022, details were posted on clinicaltrials.gov for a **Phase 1b/2 study (NCT05543629) of BMS-986442** in combination with nivolumab or nivolumab and chemotherapies in participants with advanced solid tumors and non-small cell lung cancer. Sponsored by Bristol Myers Squibb (BMS), the study will enroll an estimated 225 participants and has an estimated start date of September 28, 2022. BMS licensed the antibody from Agenus.

- BMS-986442 / AGEN1777 is an Fc-enhanced anti-TIGIT bispecific that targets a second major inhibitory receptor expressed on T and natural killer cells.

On September 21, 2022, details were posted on clinicaltrials.gov for a **first-in-human study (NCT05547321) of OMTX705** as single agent and in combination with pembrolizumab in patients with advanced solid tumors. Sponsored by Oncomatryx Biopharma, the study will enroll an estimated 120 participants and has an estimated start date in October 2022.

- OMTX705 is composed of a humanized anti-fibroblast activation protein antibody conjugated to cytolysin, α-pore-forming toxin.

On September 21, 2022, **Lassen Therapeutics announced** the initiation of dosing in a Phase 1 study of LASN01. The Phase 1 single and multiple ascending dose study will evaluate the safety, tolerability, immunogenicity, and pharmacokinetics of LASN01 in healthy volunteers.

- LASN01, a novel interleukin-11 receptor-blocking antibody, represents a promising approach for multiple diseases characterized by unchecked fibrosis.

Phase 2 study of sonelokimab planned

On September 26, 2022, **MoonLake Immunotherapeutics AG announced** that the company is advancing the tri-specific nanobody sonelokimab into a Phase 2 study in patients with active psoriatic arthritis. This is a global clinical study that includes sites in several European countries. MoonLake Immunotherapeutics in-licensed sonelokimab (M1095/ALX-0761) from Merck KGaA, Darmstadt, Germany. The antibody originated at Ablynx, which was acquired by Sanofi.

- Sonelokimab targets IL-17A, IL17F, and human serum albumin.

Phase 3 studies planned or started

On September 27, 2022, details were posted on clincaltrials.gov for a Phase 3 placebo-controlled study

(**NCT05556096**) to evaluate the safety and efficacy of ALXN1720 in adults with generalized myasthenia gravis. Sponsored by Alexion Pharmaceuticals, Inc., the study will enroll an estimated 200 participants and has an estimated start date of October 14, 2022.

- ALXN1720 is a novel anti-C5 albumin-binding bispecific mini-body optimized for subcutaneous delivery that binds and prevents activation of human C5.

On September 27, 2022, **Oncternal Therapeutics announced** the initiation of its Phase 3 global registrational study of zilovertamab, ZILO-301 (NCT05431179), for the treatment of patients with relapsed/refractory mantle cell lymphoma. An interim analysis, designed to support submission of a biologics license application (BLA) seeking accelerated FDA approval, will be conducted based on an endpoint of Objective Response Rate plus Duration of Response. The estimated primary completion date of this study is in November 2026.

- Zilovertamab is a humanized IgG1 monoclonal antibody designed and developed to bind with high affinity to a biologically important epitope on the extracellular domain of receptor-tyrosine kinase-like orphan receptor 1.

Nirsevimab recommended for approval in the EU

On September 16, 2022, **AstraZeneca and Sanofi announced** that Beyfortus (nirsevimab) has been recommended for marketing authorization in the European Union (EU) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants during their first RSV season. The recommendation by the European Medicines Agency was based on results from the Beyfortus clinical development program, including the MELODY Phase 3 and MEDLEY Phase 2/3 trials.

- Nirsevimab is an anti-RSV human IgG1 antibody engineered with YTE mutations in the Fc region to extended the half-life of the molecule.

Faricimab approved in the EU

On September 15, 2022, the **European Commission approved Vabysmo® (faricimab)** for the treatment of neovascular or age-related macular degeneration (nAMD) and visual impairment due to diabetic macular edema (DME). The approval was based on Phase 3 data that showed people with nAMD and DME treated with Vabysmo up to every four months achieved similar outcomes compared to receiving treatment every two months with aflibercept.

- Vabysmo® is a bispecific CrossMab developed by Roche that blocks the activities of angiopoietin-2 and vascular endothelial growth factor-A.

BLA submitted for supplemental approval of efgartigimod

On September 21, 2022, **argenx SE announced** that the company has submitted a biologics license application to the FDA for subcutaneous (SC) efgartigimod (1000 mg efgartigimod-PH20) for the treatment of generalized myasthenia gravis in adult patients. SC efgartigimod is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. An approval would expand the route of administration and dosing schedules available for generalized myasthenia gravis patients. Intravenously administered efgartigimod (VYVGART) was approved by FDA in 2021 for this indication.

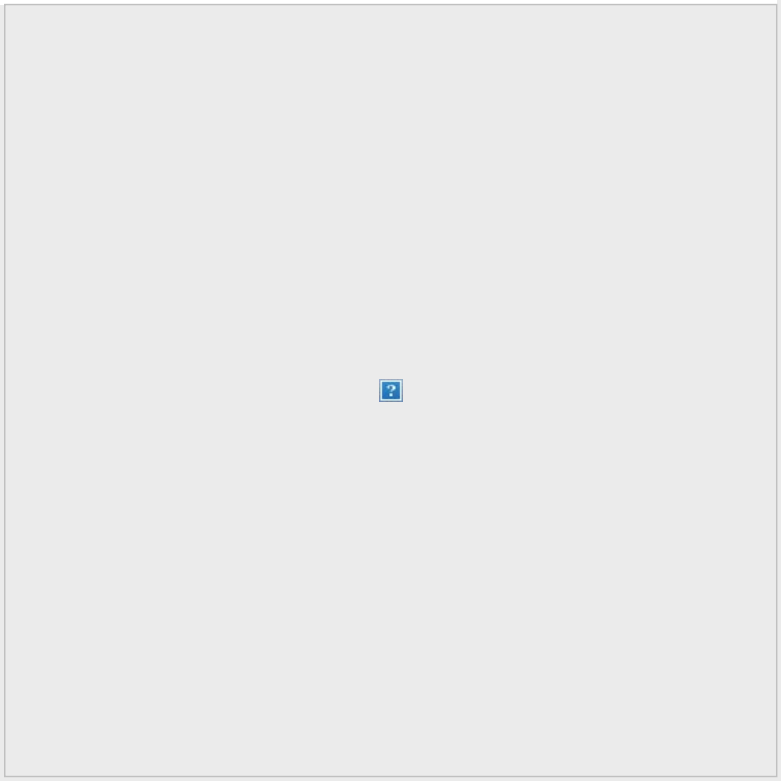
- Efgartigimod is an IgG1 Fc fragment designed for increased affinity for FcRn. It competes with IgG to occupy FcRn and reduce overall IgG recycling.

Dupixent approved for prurigo nodularis

On September 28, 2022, the **FDA granted a supplemental approval for Dupixent (dupilumab)** for the treatment of adult patients with prurigo nodularis, a chronic, debilitating skin disease. With this approval, Dupixent becomes the first and only medicine specifically indicated to treat prurigo nodularis in the U.S. Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement. The approval represents the second dermatology indication for Dupixent and fifth disease indication overall in the U.S.

- Dupixent is a human monoclonal antibody that inhibits the signaling of the interleukin-4 and interleukin-13

pathways.



Our mailing address is:
The Antibody Society
247 Prospect St
Framingham, MA 01701-4828