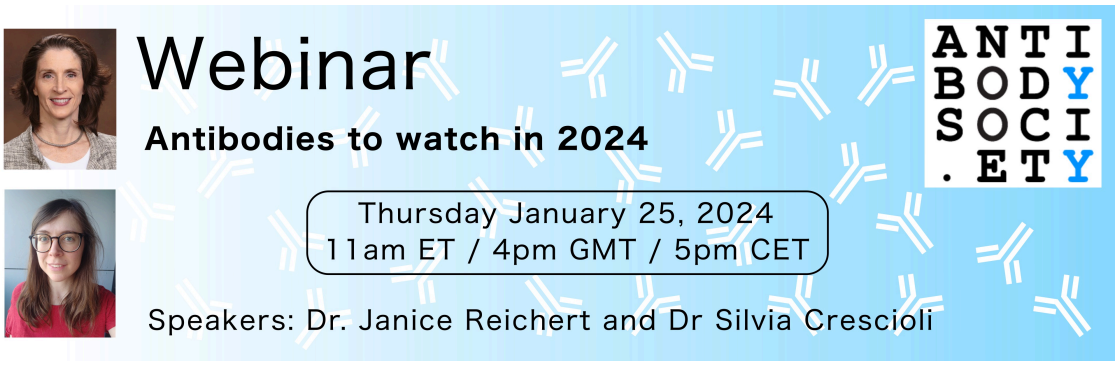
Antibody News You Should Know



For complete details, download the full article **"Antibodies to Watch in 2024" published in *mAbs* on January 5, 2024**.

Antibody News January 1-15, 2024

Topics summarized below:

- **BLA for axatilimab submitted**
- **EUA requested for VYD222**
- **FDA issues complete response letter for zolbetuximab BLA**
- **RYSTIGGO® (rozanolixizumab) approved in the EU**

Business news

On January 2, 2024, **Apollo Therapeutics announced** that during December 2023 it completed a second close of its Series C financing, raising an additional $33.5 million and bringing the total raised in this round by the Company during 2023 to $260 million. The company is progressing a broad and diversified

pipeline of over 20 uncorrelated therapeutic programs, with multiple assets about to enter the clinic in early 2024.

On January 3, 2024, **Manhattan BioSolutions, Inc. (MABS) announced** it has entered into an evaluation and potential licensing agreement with Biocytogen Pharmaceuticals (Beijing) Co., Ltd. Manhattan Bio gains access to antibodies targeting a promising new tumor antigen that is aberrantly overexpressed across multiple solid tumor types. The agreement provides MABS access to a diverse panel of lead fully-human monoclonal antibody assets generated via Biocytogen's RenMabTM and RenLite® transgenic mouse platforms. Manhattan Bio will evaluate the antibodies in cellular and biochemical assay studies to assess binding affinity, internalization, species cross-reactivity, and other developability parameters to determine suitability for incorporation into antibody-based therapeutic modalities carrying MABS' proprietary RNA-targeting payloads.

On January 5, 2024, **SanReno Therapeutics,** a clinical-stage company specializing in the discovery, development, and commercialization of innovative therapies for kidney diseases, announced its acquisition by Novartis. Following the acquisition's closure, SanReno becomes an indirect, wholly-owned subsidiary of Novartis. Established in late 2021 as a joint venture between the investor consortium and Chinook Therapeutics (now part of Novartis), SanReno holds exclusive rights in Greater China and Singapore late-stage assets targeting Immunoglobulin A Nephropathy (IgAN), including zigakibart, which obtained approval from China CDE for entry into the Phase 3 study in October 2023.

- Zigakibart (BION-1301) is a subcutaneously administered monoclonal antibody targeting APRIL.

On January 8, 2024, **Calypso Biotech announced** that it has entered into an agreement to be acquired by Novartis AG. Calypso, a spin-out from Merck, focuses on the research and development of monoclonal antibodies for an array of autoimmune indications and has expertise in IL-15 biology. The acquisition gives Novartis full rights to CALY-002, which Novartis intends to further explore across a wide variety of autoimmune indications with high unmet medical need. CALY-002 is currently being evaluated in a Phase 1b trial in patients with celiac disease and eosinophilic esophagitis.

- CALY-002 is a potential best-in-class therapeutic antibody that binds to and neutralizes IL-15.

On January 8, 2024, **Merck and Harpoon Therapeutics, Inc. announced** that the companies have entered into a definitive agreement under which Merck, through a subsidiary, will acquire Harpoon for $23.00 per share in cash for an approximate total equity value of $680 million. Harpoon's lead candidate, HPN328, is currently being evaluated in a Phase 1/2 clinical trial (NCT04471727) evaluating the safety, tolerability, and pharmacokinetics of HPN328 monotherapy in patients with advanced cancers associated with expression of DLL3. Additional pipeline candidates include HPN217, currently in Phase 1 clinical development for the treatment of patients with relapsed/refractory multiple myeloma, and several preclinical stage candidates, including HPN601.

- HPN328 is a T-cell engager targeting delta-like ligand 3 (DLL3) and albumin.
- HPN217 is a T-cell engager targeting B-cell maturation antigen and albumin.
- HPN601 is a conditionally activated T-cell engager targeting epithelial cell adhesion molecule (EpCAM) and albumin.

On January 8, 2024, **Immunome, Inc. and Zentalis Pharmaceuticals announced** that they have entered into an exclusive, worldwide license agreement under which Immunome has licensed from Zentalis' antibody-drug conjugate (ADC) ZPC-21, which is on track for IND submission in 1Q 2025, and Zentalis' proprietary ADC platform technology. Under the terms of the deal, Zentalis will receive an up-front payment of $35 million in cash and Immunome common stock. Zentalis will be eligible to receive up to $275 million in milestone payments for ZPC-21 and the platform technology in addition to mid-to-high single-digit royalties.

- ZPC-21 is an ADC targeting ROR1.

On January 9, 2024, **GSK plc and Aiolos Bio, Inc. announced** that they have entered into an agreement under which GSK will acquire Aiolos, a clinical-stage biopharmaceutical company focused on addressing the unmet treatment needs of patients with certain respiratory and inflammatory conditions, for a $1 billion upfront payment and up to $400 million in certain success-based regulatory milestone payments. The acquisition provides GSK with access to Aiolos' AIO-001, which is ready to enter Phase 2 clinical development for the treatment of adult patients with asthma, with potential for additional indications including chronic rhinosinusitis with nasal polyps. AIO-001 was exclusively licensed to Aiolos outside of Greater China by Jiangsu Hengrui Pharmaceuticals Co., Ltd.

- AIO-001 is a long-acting anti-thymic stromal lymphopoietin monoclonal antibody.

IND filed for CX-2052

On January 4, 2024, **CytomX Therapeutics announced** that an investigation new drug application has been filed for their ADC CX-2051. CX-2051 has demonstrated a wide predicted therapeutic index and strong preclinical activity and tolerability in multiple preclinical models, including colorectal cancer. Clinical initiation in EpCAM-expressing solid tumors is expected in the first half of 2024.

- CX-2051 is a conditionally activated, anti-EpCAM ADC with a topoisomerase-1 inhibitor (camptothecin) payload.

Phase 3 study of ADC DS-7300a to start

On January 12, 2024, details were posted on clinical trials.gov for a Phase 3 study (**NCT06203210**) evaluating the ADC DS-7300a (ifinatamab deruxtecan) vs. treatment of physician's choice in small cell lung cancer patients. Sponsored by Daiichi Sankyo, Inc., the study will enroll an estimated 468 patients and has an estimated start date is in March 2024.

- DS-7300a is a B7-H3-targeting ADC composed of a humanized anti-B7-H3 monoclonal antibody (MABX-9001a), an enzymatically cleavable peptide-based linker, and a novel exatecan derivative (DXd) that is a potent DNA topoisomerase I inhibitor.

Regulatory agency news & actions

BLA for axatilimab submitted

On January 2, 2024, **Syndax Pharmaceuticals announced** that a biologics license application (BLA) for axatilimab in adult and pediatric patients six years or older with chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy was submitted to the U.S. Food and Drug Administration (FDA) on December 28, 2023. The company also announced that it has exercised its option under the Company's 2021 collaboration agreement with Incyte to co-commercialize axatilimab in the U.S.

- Axatilimab is an anti-CSF-1R antibody.

EUA requested for VYD222

On January 3, 2024, **Invivyd, Inc. announced** that it has requested Emergency Use Authorization (EUA) from the FDA for VYD222 for the pre-exposure prevention of COVID-19 in immunocompromised adults and adolescents. The EUA submission was based on positive initial results from the CANOPY Phase 3 pivotal clinical trial of VYD222, as well as ongoing in vitro neutralization activity against relevant variants such as JN.1.

- VYD222 is a broadly neutralizing, half-life extended, anti-SARS-CoV-2 monoclonal antibody.

FDA issues complete response letter for zolbetuximab BLA

On January 8, 2024, **Astellas Pharma Inc. announced** the FDA issued a complete response letter on January 4, 2024, regarding the BLA for zolbetuximab for the treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive. The FDA stated that the agency cannot approve the BLA by their action date of January 12, 2024 due to unresolved deficiencies following its pre-license inspection of a third-party manufacturing facility for zolbetuximab. The FDA has not raised any concerns related to the clinical data, including efficacy or safety, of zolbetuximab, and is not requesting additional clinical studies. Astellas is working closely with the FDA and the third-party manufacturer to establish a timeline to quickly resolve the agency's feedback.

- Zolbetuximab is a chimeric anti- CLDN18.2 IgG1 monoclonal antibody.

RYSTIGGO® (rozanolixizumab) approved in the EU

On January 8, 2024, **UCB announced** that the European Commission granted a marketing authorization for RYSTIGGO® (rozanolixizumab) on January 5, 2024 as an add-on to standard therapy for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. FDA approved RYSTIGGO® for this indication in June 2023.

- Rozanolixizumab is a humanized IgG4 monoclonal antibody that binds to the neonatal Fc receptor, resulting in the reduction of circulating IgG.

Antibody News You Should Know

The **2024 AE&T Europe agenda is here** - London is calling, and so is the future of antibody advancements!

And, as a member of The Antibody Society you qualify for an additional 15% off the current price with VIP Code Simply **enter this code at checkout**. Hurry, **pass prices increase at midnight this Friday** February 2nd!

Register now to save up to £500 on your pass! Don't miss out on this unparalleled opportunity to be at the forefront of antibody innovation.

Antibody News January 15 - February 1, 2024

Topics summarized below:

Business news

On January 15, 2024, confectionery firm **Orion Group announced** that the company will acquire a 25.7 percent stake in LegoChem Biosciences for 550 billion won ($418 million). LegoChem Biosciences is known in the antibody therapeutics development area for their oncology and antibody-drug conjugate platform technology. The transaction, led by Orion's Hong Kong-based

subsidiary, Pan Orion Corp., involves a combination of a rights offering and share purchases. Orion will be LegoChem Biosciences' largest shareholder.

On January 22, 2024, **AC Immune announced** that the company will regain all global rights to the anti-amyloid beta antibody crenezumab and the anti-Tau antibody semorinemab following termination of the collaboration agreements with Genentech, a member of the Roche Group, and Roche. Both antibodies have been evaluated in clinical studies for Alzheimer's disease.

- Crenezumab is a humanized monoclonal antibody, an investigational treatment designed to slow AD progression by neutralizing neurotoxic beta-amyloid oligomers.
- Semorinemab is an investigational monoclonal anti-Tau antibody.

On January 25, 2024, **LAVA Therapeutics N.V. announced** that it has entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc., Rahway, NJ, USA to evaluate its anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in combination with LAVA-1207, a Gammabody® designed to target the prostate-specific membrane antigen (PSMA) to trigger the potent and preferential killing of PSMA-positive tumor cells, in patients with therapy refractory metastatic castration-resistant prostate cancer.

- LAVA- 1207 is a bispecific antibody of 78 kDa, comprising two heavy chains, each consisting of a humanized VHH domain antibody and a human IgG1 modified hinge region, CH2 and CH3 domain.

Phase 1 studies planned or started

On January 23, 2024, **CDR-Life Inc. announced** the clearance of an investigational new drug (IND application with the U.S. Food and Drug Administration (FDA) for CDR404, its lead program in development as a precision immunotherapy for solid tumors. CDR404 is based on the company's unique M-gager® technology for targeting intracellular tumor antigens through the major histocompatibility complex.

- CDR404 is an antibody-based, bivalent and bispecific MAGE-A4 T-cell engager.

On January 24, 2024, **HARBOUR BIOMED announced** that the Company has been granted the clearance of an IND application from the FDA to initiate the first-in-human clinical trial in the U.S. for bispecific antibody HBM9027. The antibody was generated from Harbour BioMed's proprietary fully human HBICE® platform. The Phase I study will evaluate the safety, tolerability,

pharmacokinetics, and anti-tumor activity of HBM9027 in subjects with advanced solid tumors.

- HBM9027 is a crosslinking-dependent PD-L1xCD40 bispecific antibody.

On January 31, 2024, **23andMe Holding Co. announced** the FDA has cleared the IND application for 23ME-01473, a natural killer cell activator intended to treat cancer. 23andMe plans to evaluate '1473 in participants with advanced solid tumors in a Phase 1 clinical study beginning in the first half of 2024. The target for '1473 was discovered through 23andMe's proprietary research platform, the world's largest recontactable database of de-identified human genetic and phenotypic information.

- 23ME-01473 targets ULBP6 to restore anti-tumor immunity through NK and T cells.

On January 19, 2024, Visterra Inc. posted details for their ongoing first-in-human study (**NCT06212804**) of VIS954. Initiated in November 2023, this placebo-controlled, double-blind, single ascending dose study will assess the safety and tolerability of VIS954 in an estimated 54 healthy adult male and female participants.

- VIS954 is a C5a anaphylatoxin chemotactic receptor antagonist.

On January 23, 2024, **PharmAbcine Inc. announced** the initiation of patient dosing in the Phase 1a/b clinical trial of PMC-309 in patients with advanced or metastatic solid tumors. PMC-309 binds to VISTA in immunosuppressive cells, exhibiting excellent binding affinity at various pH conditions within the tumor microenvironment. By inhibiting VISTA, PMC-309 presents a differentiated mechanism of action contributing to anti-cancer effects through activation of T cells, activation of monocytes, and proliferation of M1 macrophages.

- PMC-309 is an anti-VISTA IgG1 monoclonal antibody.

Phase 3 studies planned or started

On January 29, 2024, **Alligator Bioscience AB announced** positive top-line results from the OPTIMIZE-1 Phase 2 study of the company's lead asset mitazalimab in 1st line metastatic pancreatic cancer. The open-label, multi-center study assessed the safety and efficacy of mitazalimab in combination with standard of care chemotherapy mFOLFIRINOX, in previously untreated, chemotherapy naive patients. Based on the emerging data from the OPTIMIZE-

1 study, the FDA has provided additional guidance and has endorsed OPTIMIZE-1 as a Phase 3 enabling study. Consequently, mitazalimab can proceed directly to a global Phase 3 registration study, which Alligator is preparing to initiate in early 2025.

- Mitazalimab is a human IgG1 agonistic antibody targeting CD40.

On January 22, 2024, **BioNTech SE and Duality Biologics announced** that the first patient with metastatic breast cancer has been treated in a pivotal Phase 3 trial evaluating the efficacy and safety of BNT323/DB-1303, which was built from DualityBio's proprietary Duality Immune Toxin Antibody Conjugates platform. The global, multi-center, open-label, randomized Phase 3 trial (NCT06018337) will assess the efficacy and safety of BNT323/DB-1303 compared to standard-of-care single-agent chemotherapy in chemotherapy-naïve patients with HR+ and HER2-low metastatic breast cancer that have progressed on hormone therapy.

- BNT323/DB-1303 is a third-generation topoisomerase-1 inhibitor-based antibody-drug conjugate targeting HER2.

Supplemental BLA for ENHERTU receives priority review

On January 29, 2024, **AstraZeneca and Daiichi Sankyo, Inc. announced** that a supplemental Biologics License Application for ENHERTU® (fam-trastuzumab deruxtecan-nxki) has been accepted and granted Priority Review in the US for the treatment of adult patients with unresectable or metastatic HER2-positive solid tumors who have received prior treatment or who have no satisfactory alternative treatment options. Notably, If approved, ENHERTU could become the first HER2-directed therapy and antibody-drug conjugate with a tumor-agnostic indication.

- ENHERTU is a HER2-directed antibody and topoisomerase inhibitor conjugate.

Antibody News You Should Know

Join us in Boston for the **Next-Generation Conjugates Summit**! Covering case-study led presentations on novel design concepts, key translational and clinical development challenges, and addressing challenging CMC roadblocks, the Next-Generation Conjugates Summit features talks by developers of a wide array of novel formats and payloads, with conjugate modality types including antibody-oligonucleotide conjugates, fragment-drug conjugates, Targeted Radiopharmaceutical Conjugates, small molecule-drug conjugates, bispecific-drug conjugates and more.
View the full agenda here.

Antibody News February 1 - 15, 2024

Topics summarized below:

Business news

On February 5, 2024, **Novartis announced** that it has entered into an agreement to make a voluntary public takeover offer to acquire MorphoSys AG, a Germany-based, global biopharmaceutical company developing innovative medicines in oncology. MorphoSys' pipeline includes a broad portfolio of partnered assets of which some are in partnership with Novartis, including the human anti-BAFFR antibody ianalumab (VAY736), which is studied across multiple immunological diseases and in hematology.

On February 7, 2024, **Evotec SE announced** that its Seattle-based subsidiary Just - Evotec Biologics expanded its relationship with Advanced BioScience Laboratories, Inc. The new agreement builds on previous collaborations between Just – Evotec Biologics and ABL to design highly efficient manufacturing processes for broadly neutralising antibodies (bNAbs) against HIV. Under the expanded relationship, Just – Evotec Biologics will develop a third bNAb and perform large-scale cGMP manufacturing campaigns for both this bNAb and a previously developed bNAb against HIV for a Phase I clinical study and provide release and stability testing services.

On February 7, 2024 **Scion Life Sciences, an affiliate of Petrichor, announced** the final close of its inaugural fund, which was oversubscribed with $310 million in capital commitments. The organization is a New York City-based life sciences venture capital firm dedicated to founding and building exceptional biotechnology companies that discover, develop, and seek to commercialize clinically transformational or curative new medicines. The firm leverages an asset selection strategy built on three investment pillars to mitigate risk and increase the probability of delivering transformational medicines for patients:

- Invest in therapeutic modalities and enabling technologies that are sufficiently mature to make clinically important medicines today or in the near term
- Invest in therapeutic areas, diseases, and drug targets where deep understanding of the underlying science makes powerful intervention possible
- Focus on clinical problems that can be addressed with the resources available to an independent biotechnology company

On February 12, 2024, **Alys Pharmaceuticals, an immuno-dermatology focused company, launched** with an R&D pipeline enabled by multiple platform technologies and a $100 million financing by Medicxi. Originating from the aggregation of six asset-centric Medicxi companies, Alys boasts a robust pipeline of innovative programs and platforms targeting multiple dermatological indications. Alys combines the assets and platforms of Aldena Therapeutics, Graegis Pharmaceuticals, Granular Therapeutics Ltd, Klirna Biotech, Nira Biosciences and Vimela Therapeutics.

On February 13, 2024, **ProfoundBio announced** an oversubscribed $112 million Series B financing supported by a syndicate of top healthcare dedicated and mutual fund institutional investors. This financing is expected to accelerate the development of its comprehensive antibody-drug conjugate (ADC) portfolio, including the planned pivotal trial of rinatabart sesutecan (Rina-S) for the treatment of ovarian cancer. Key programs include:

- Rina-S, a folate receptor-alpha (FRα) targeted ADC, in Phase 2 trials for ovarian and endometrial cancers, with pivotal studies in ovarian cancer planned for later this year.
- PRO1160, a CD70 targeted ADC, in Phase 1 trials with initial results expected in 2024.
- PRO1107, a protein tyrosine kinase 7 (PTK7) targeted ADC, in Phase 1 trials with initial results anticipated in 2025.
- PRO1286, a bi-specific ADC, anticipated to enter the clinic in 2024.

On February 14, 2024, **NextPoint Therapeutics, Inc. announced** the closing of a $42.5M Extension to its Series B financing round resulting in a total of $122.5M raised in the Series B financing. The funds will be used to advance the company's two immuno-oncology clinical programs, NPX267 and NPX887, as well as propel the development of additional therapeutic modalities in the pipeline that target the novel HHLA2 tumor antigen.

Phase 1 studies planned or started

On February 2, 2024, details were posted on clinicaltrials.gov for a Phase 1/2 study (**NCT06239194**) of MDX2001, a tetraspecific antibody designed to optimize T cell function while preventing tumor antigen escape. Sponsored by ModeX Therapeutics Inc., the study will enroll an estimated 115 patients with solid tumors and has an estimated start date in May 2024.

- MDX2001 simultaneously engages two T cell receptors (CD28, CD3) and two tumor antigens.

On February 13, 2024, details were posted on clinicaltrials.gov for a Phase 1 study (**NCT06255665**) of JNJ-79032421. Sponsored by Johnson & Johnson, the study is currently recruiting patients with advanced stage solid tumors. The study aims to determine recommended Phase 2 dose(s) (RP2Ds) of JNJ-79032421 and to determine the safety and tolerability of JNJ-79032421 at the RP2D(s).

- JNJ-79032421 is a T-cell redirecting agent targeting mesothelin.

On February 14, 2024, details were posted on clinicaltrials.gov for a Phase 1 study (**NCT06258304**) of GIGA-564 in participants with locally advanced or metastatic solid tumor malignancies. Sponsored by GigaGen Inc, the study has an estimated start date in March 2024.

- GIGA-564 is an anti-CTLA-4 monoclonal antibody that binds to an epitope very close to that of ipilimumab but exhibits strongly reduced checkpoint inhibition, and it depletes intratumoral Tregs via enhanced Fc receptor activity.

Phase 2 study of AOC 1044 started

On February 6, 2024, details were posted on clinicaltrials.gov for a Phase 2 study (**NCT06244082**) of AOC 1044. Sponsored by Avidity Biosciences, Inc., the study, which is enrolling by invitation, is designed to evaluate the pharmacodynamic effect of AOC 1044 on dystrophin protein production in skeletal muscle, as well as the long-term safety, tolerability, pharmacokinetics, and exploratory efficacy of AOC 1044, in Duchenne muscular dystrophy participants with mutations amenable to exon44 skipping.

- AOC 1044 consists of a proprietary monoclonal antibody that binds to the transferrin receptor 1 conjugated with phosphorodiamidate morpholino oligomers targeting exon 44.

Positive Phase 3 results for nipocalimab

On February 5, 2024, **Johnson & Johnson Innovative Medicine announced** that, in the Phase 3 VIVACITY study in generalized myasthenia gravis (gMG), nipocalimab met the primary endpoint, achieving statistically significant reduction in MG-ADLa score from baseline over weeks 22 to 24 compared with placebo. gMG is a chronic, life-long, rare, and highly debilitating autoantibody-driven neuromuscular disease characterized by fluctuating muscle weakness. Johnson & Johnson plans to present full results from the Phase 3

VIVACITY study at an upcoming scientific medical congress and engage with global regulatory authorities about bringing nipocalimab to patients living with gMG.

- Nipocalimab is a human, aglycosylated, effectorless, anti-FcRn monoclonal antibody.

Latozinemab granted Breakthrough Therapy Designation

On February 7, 2024, **Alector, Inc. and GSK plc announced** that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to latozinemab for the potential treatment of frontotemporal dementia with a progranulin gene mutation (FTD-GRN). Latozinemab, the most advanced progranulin-elevating candidate in clinical development for FTD-GRN, is currently being studied in the pivotal INFRONT-3 Phase 3 study, which achieved target enrollment in October 2023.

- Latozinemab is a monoclonal antibody that blocks sortilin.

Regulatory agency news

On February 2, 2024, **Regeneron announced** that the European Medicines Agency has accepted for review the Marketing Authorization Application for linvoseltamab to treat adult patients with relapsed/refractory multiple myeloma who have progressed after at least three prior therapies.

- Linvoseltamab is a bispecific antibody designed to bridge B-cell maturation antigen on multiple myeloma cells with CD3-expressing T cells to facilitate T-cell activation and cancer-cell killing.

On February 15, 2024, **Galderma announced** that the FDA has accepted its Biologics License Applications for nemolizumab for the treatment of prurigo nodularis and for adolescents and adults with moderate to severe atopic dermatitis. The European Medicines Agency has also accepted the Marketing Authorization Applications for nemolizumab in prurigo nodularis and atopic dermatitis.

- Nemolizumab is a monoclonal antibody specifically designed to inhibit IL-31.

On February 8, 2024, **Chugai Pharmaceutical Co., Ltd. announced t**hat crovalimab (Chinese product name: 派圣凯®), a monoclonal antibody discovered by Chugai, was approved by the National Medical Products

Administration of People's Republic of China for treatment of adults and adolescents with paroxysmal nocturnal hemoglobinuria not been previously treated with complement inhibitors. As F. Hoffmann-La Roche Ltd. is responsible for the development of crovalimab outside Japan and Taiwan, the regulatory application was filed by a China affiliate of Roche. China is the first country in the world to approve crovalimab.

- Crovalimab is a humanized anti-complement inhibitor C5 monoclonal antibody.

Antibody News You Should Know

Join us at the #1 European antibody engineering conference. Created in conjunction with The Antibody Society, this year's conference is coming to London – a true hub of the antibody community. Boasting 9 topic streams covering the need to know updates in industry, you will dive into:

- Fc Engineering
- Novel Approaches to Antibody Discovery
- Challenges in Discovery & Optimization of Multispecific Antibodies
- Agonist Antibodies
- Conditionally Active Biotherapeutics
- Emerging Modalities: ADCs, Degraders and Beyond
- Computational Approaches to Antibody Discovery and Optimization
- Co-Stimulatory Antibodies and Combination Approaches in Oncology
- Antibody Theranostics

View the full agenda here.

Antibody News February 15 - March 1, 2024

Topics summarized below:

Phase 2 studies started
Regulatory agency news

Business news

On February 15, 2024, **Firefly Bio emerged** from stealth mode with a $94 million Series A financing co-led by founding investor Versant Ventures and by MPM BioImpact alongside Decheng Capital and with participation from Eli Lilly & Company. Firefly has developed a novel platform to treat cancer using degrader antibody conjugates. Firefly's platform combines the respective strengths of antibody-drug conjugates (ADCs) and degraders while overcoming their deficiencies. The result is a new class of therapeutics able to precisely drug a range of intracellular biological targets that were previously hampered by therapeutic index issues when delivered systemically.

On February 20, 2024, **ENPICOM, an innovative bioinformatics software solutions provider, announced** a collaboration with Erasmus Medical Center, Rotterdam, a distinguished leader in cancer research. The aim of this partnership is to identify and develop nanobodies against cancer by utilizing ENPICOM's immune repertoire data analysis services and software solutions.

On February 20, 2024, **Isomab Ltd, a UK-based biotechnology company, announced** the closing of a £7.5 million (approximately US$9.4 million) Seed financing round. Founded in 2022, IsomAb is developing isoform-specific disease modifying antibody treatments for serious and life-threatening diseases with an initial focus on peripheral ischaemia. The Seed funding round enables the company to advance the pre-clinical development of its lead antibody, ISM-001.

On February 21, 2024, **Charles River Laboratories announced** a strategic agreement with Wheeler Bio, Inc., an antibody contract development and manufacturing organization focused on preclinical and early clinical supply of recombinant proteins, providing clients access to Wheeler's Portable CMC® (Chemistry, Manufacturing and Controls) platform. This new alliance provides early-stage biotechnology companies a unique solution to rapidly transition from pre-clinical activities to first-in-human clinical trials.

On February 21, 2024, **ONO Pharmaceutical Co., Ltd. announced** that it has entered into a drug discovery collaboration agreement with Epsilon Molecular Engineering Inc. to generate novel VHH antibodies, aiming at the creation of

innovative VHH antibody drugs. Under the terms of this agreement, EME will obtain novel humanized VHH antibodies against multiple targets selected by Ono, by leveraging EME's proprietary humanized VHH screening platform, "The Month". Ono will conduct various tests to evaluate the activities (in vitro and in vivo assay) of humanized VHH antibodies obtained by EME to discover and develop antibody drug candidates. Ono will hold option rights to exclusively develop and commercialize the antibody drug candidates generated through the collaboration worldwide. Ono will pay EME an upfront payment, and milestone payments based on the progress of research and clinical development.

On February 22, 2024, **AbbVie Inc. and Tentarix Biotherapeutics announced** a multi-year collaboration focused on the discovery and development of conditionally-active, multi-specific biologic candidates in oncology and immunology. The collaboration will integrate AbbVie's expertise in oncology and immunology with Tentarix's proprietary Tentacles™ platform. Tentacles™ are multi-functional, conditionally-active antibody-based biologics that are designed specifically to activate immune cells that can modulate disease pathways, while potentially mitigating safety concerns associated with non-specific targeting of other immune cells.

On February 26, 2024, **iBio, Inc., an AI-driven innovator of precision antibody immunotherapies, announced** that it has entered into an asset purchase agreement with Otsuka Pharmaceutical Co., Ltd., pursuant to which Otsuka acquired iBio's assets related to its preclinical PD-1 agonist antibody program. Under the terms of the Agreement, iBio will receive an upfront payment of $1.0 million in cash at closing. iBio will also be eligible to receive additional contingent cash payments totaling up to $52.5 million upon the achievement of certain pre-specified clinical development and commercial milestones.

On February 28, 2024, **AbbVie Inc. and OSE Immunotherapeutics announced** a strategic partnership to develop OSE-230, a monoclonal antibody designed to resolve chronic and severe inflammation, currently in the pre-clinical development stage. OSE-230 is a first-in-class monoclonal antibody designed to activate ChemR23, a G-Protein Coupled Receptor (GPCR) target. Activation of ChemR23 may offer a novel mechanism for the resolution of chronic inflammation, modulating functions of both macrophages and neutrophils.

Advances in antibody discovery programs

On February 15, 2024, **Lantern Pharma Inc., in collaboration with academic research partners, announced** advances in the development, synthesis, and preclinical proof-of-concept of a novel, highly potent, cryptophycin-based ADC. The company leveraged RADR®, a proprietary AI platform for oncology drug development, for target selection and molecular payload characterization in ADCs, and a unique, controlled conjugation approach for maximizing drug-to-antibody ratios while controlling for non-specific conjugation. Lantern expects to move towards Investigational New Drug (IND) application development of the ADC program during 2024 with a focus on select solid tumors that are unresponsive or refractory to current therapies.

On February 21, 2024, **Absci Corporation announced** the initiation of IND-enabling studies for ABS-101, an antibody designed using Absci's de novo generative AI foundation model. Given a target structure, Absci uses this model to designate a specific epitope of interest, allowing for the engineering of epitope-specific antibodies to access novel biology. Absci then uses its AI lead optimization models to further engineer candidates to have an optimal clinical development profile. Absci expects to submit an IND for ABS-101 in the first quarter of 2025, and, subject to clearance of the IND, initiate Phase 1 studies for this program shortly thereafter.

- ABS-101 is a potential best-in-class anti-TNF-like ligand 1A antibody.

Phase 1 studies planned or started

On February 20, 2024, details were posted on clinicaltrials.gov for a first-in-human study (**NCT06265688**) to characterize the safety, tolerability, and antitumor activity of CX-2051 in adult subjects with advanced solid tumors. Sponsored by CytomX Therapeutics, the study will enroll an estimated 124 participants and has an estimated start date of March 31, 2024.

- CX-2051 is a conditionally activated ADC composed of an anti-EpCAM antibody conjugated to a derivative of camptothecin, a topoisomerase-1 inhibitor.

On February 23, 2024, details were posted on clinicaltrials.gov for a Phase 1 study (**NCT06274437**) designed to evaluate safety, tolerability and preliminary anti-tumor activity of BND-35 administered alone and in combination with nivolumab or with cetuximab. Sponsored by Biond Biologics Ltd, the study will enroll an estimated 280 patients and has an estimated start date in April 2024.

- BND-35 is an innovative antibody targeting the Ig-like transcript 3 (ILT3) receptor, in development for the treatment of solid tumors known to have a suppressive tumor microenvironment.

On February 26, 2024, details were posted on clinicaltrials.gov for a first-in-human Phase 1 dose escalation and expansion study (**NCT06276491**) of XmAb®541. Sponsored by Xencor, the study will enroll an estimated 212 patients with solid tumors and has an estimated start date in May 2024.

- XmAb®541 is a 2+1 bispecific antibody targeting Claudin-6 and CD3.

Phase 2 studies started

On February 20, 2024, details were posted on clinicaltrials.gov for a Phase 2 study (**NCT06268886**) to assess the effectiveness, safety, and tolerability of BMS-986446 in participants with early Alzheimer's disease. Sponsored by Bristol Myers Squibb, the study, due to start in March 2024, will enroll an estimated 475 participants. BMS licensed the molecule from Prothena Corporation plc.

- BMS-986446 is an anti-tau antibody that specifically binds with high affinity the R1, R2, and R3 repeats within the MTBR of tau and targets both 3R and 4R tau isoforms.

On February 26, 2024, **Dianthus Therapeutics, Inc. announced** the initiation of the Phase 2 MaGic trial of DNTH103 in patients with generalized myasthenia gravis. The initiation follows U.S. Food and Drug Administration (FDA) clearance of the Phase 2 IND application for DNTH103. Top-line results from this trial are anticipated in the second half of 2025.

- DNTH103 is a monoclonal antibody that acts as a selective inhibitor of the active C1s protein in the complement system’s classical pathway.

Regulatory agency news

On February 19, 2024, **AstraZeneca and Daiichi Sankyo**’s biologics license application (BLA) for datopotamab deruxtecan has been accepted by FDA for the treatment of adult patients with locally advanced or metastatic nonsquamous non-small cell lung cancer who have received prior systemic therapy. The Prescription Drug User Fee Act (PDUFA) date, the target action

date for FDA's regulatory decision, is during the fourth quarter of 2024. The antibody was developed in collaboration with Sapporo Medical University.

- Datopotamab deruxtecan is composed of a humanized anti-TROP2 IgG1 monoclonal antibody attached to topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

On February 21, 2024, **Regeneron announced** that FDA has accepted for Priority Review the BLA for linvoseltamab to treat adult patients with relapsed/refractory multiple myeloma that has progressed after at least three prior therapies. The target action date for the FDA decision is August 22, 2024. The company had previously submitted a marketing application for linvoseltamab for relapsed/refractory multiple myeloma to the European Medicines Agency.

- Linvoseltamab is an investigational bispecific antibody designed to bridge B-cell maturation antigen on multiple myeloma cells with CD3-expressing T cells to facilitate T-cell activation and cancer-cell killing.

On February 27, 2024, **Incyte announced** that FDA has accepted for Priority Review the BLA for axatilimab for the treatment of chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy. The PDUFA date for FDA's decision is August 28, 2024.

- Axatilimab is a humanized IgG4 antibody that targets colony stimulating factor-1 receptor.

On February 20, 2024, **argenx SE, a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, announced** that FDA has accepted for priority review a supplemental Biologics License Application for VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of chronic inflammatory demyelinating polyneuropathy. The application has been granted a PDUFA target action date of June 21, 2024.

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

Antibody News You Should Know

Antibody News March 1 - 15, 2024

Topics summarized below:

Business news

On March 1, 2024, **Absci Corporation, a data-first generative AI drug creation company, announced** the closing of its underwritten public offering of 19,205,000 shares of its common stock at a public offering price of $4.50 per share, before deducting underwriting discounts and commissions. Absci intends to use the net proceeds from the offering to fund activities such as the development of its internal asset programs and continued investment in its Integrated Drug Creation™ platform, including related AI and wet-lab technologies. The platform enables Absci to go from AI-designed antibodies to wet lab-validated candidates in as little as six weeks.

On March 6, 2024, **Gilead Sciences, Inc. and Merus N.V. announced** a research collaboration, option and license agreement to discover novel dual tumor-associated antigens targeting trispecific antibodies. Gilead and Merus agreed to collaborate on the use of Merus' proprietary Triclonics® platform along with Gilead's oncology expertise to research and develop multiple, separate preclinical research programs.

On March 11, 2024, **AbCellera and Biogen Inc. announced** they have entered into a strategic collaboration to discover antibodies for a novel target that enables the delivery of biotherapeutics to the brain for indications in neuroscience. Under the terms of the agreement, AbCellera will receive an upfront payment and is eligible to receive additional milestone payments should the research programs achieve certain research, developmental and regulatory milestones. AbCellera is also eligible to receive potential royalties on future net sales of products that result from the collaboration.

Phase 1 studies planned or started

On March 4, 2024, details were posted on clinicaltrials.gov for a first-in-human Phase 1/2 study (**NCT06290388**) of 23ME-01473, which targets stress-induced ligands found on the surface of cancer cells that bind to their receptor, NKG2D, on natural killer and T cells. Sponsored by 23andMe the study will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary clinical activity of 23ME-01473 given by intravenous infusion in participants with advanced solid cancers who have progressed or are intolerant of available standard therapies. The study will enroll an estimated 82 patients and has an estimated start date in March 2024.

- 23ME-01473 is an anti-ULBP6/2/5 monoclonal antibody.

On March 12, 2024, details were posted on clinicaltrials.gov for a first-in-human study (**NCT06303505**) of the antibody-drug conjugate (ADC). Sponsored by Tubulis GmbH and due to start in May 2024, the Phase 1 study aims are to evaluate the safety/tolerability, pharmacokinetics and preliminary efficacy of TUB-040 and to find the best dose of TUB-040 in patients with ovarian cancer and non-small cell lung cancer.

- TUB-040 is composed of an IgG1 antibody targeting Napi2b connected to its payload, the Topoisomerase I inhibitor Exatecan, through a cleavable linker system.

On March 6, 2024, **Innate Pharma SA announced** the first patient was dosed in its Phase 1/2 multicenter trial (NCT06088654) investigating the safety and tolerability of IPH6501, an antibody-based NK cell engager therapeutic (ANKET), in patients with relapsed and/or refractory CD20-expressing B-cell non-Hodgkin's lymphoma. The study has an estimated enrollment of 184 participants.

- IPH6501 is a tetraspecific molecule engaging two NK cell activating receptors NKp46 and CD16a (FcγRIIIa), the β chain (CD122) of the interleukin-2 receptor (IL-2R), and the CD20 antigen expressed on malignant B cells.

On March 7, 2024, details were posted on clinical trials.gov for a first-in-human study of NM32-2668 (**NCT06299163**) that is currently recruiting patients. Sponsored by Numab Therapeutics AG, the study aims to evaluate NM32-2668 for safety and immunogenicity, determine the maximal tolerated dose and recommended Phase 2 dose, define the pharmacokinetics, and explore the pharmacodynamics, and obtain preliminary evidence of the clinical activity in an estimated 180 patients with advanced solid tumors.

- **NM32-2668** is an anti-ROR1/CD3/anti-HSA T-cell engaging, tri-specific antibody with half-life extension.

Phase 3 studies planned

On March 6, 2024, details were posted on clinicaltrials.gov for a Phase 2/3 study (**NCT06295731**) that will evaluate the efficacy and safety of INBRX-106 combined with the anti-PD-1 antibody pembrolizumab versus pembrolizumab (+ placebo in Phase 3) as first-line treatment for patients with locally advanced recurrent or metastatic head and neck squamous cell carcinoma incurable by local therapies, expressing PD-L1 with a combined proportion score (CPS) ≥20. Sponsored by Inhibrx, Inc., the study will enroll an estimated 420 participants and has an estimated start date in May 2024.

- INBRX-106 is a hexavalent OX40 agonist antibody.

On March 12, 2024, details were posted for two Phase 3 studies (**NCT06290128**, **NCT06290141**) of Sanofi's antibody therapeutic riliprubart in participants with refractory chronic inflammatory demyelinating polyneuropathy. The studies will enroll an estimated 140-160 people and both studies are due to start in March 2024.

- Riliprubart (SAR445088, BIVV020) is an anti-Complement C1s antibody.

On March 13, 2024, **Takeda announced** positive topline results from a Phase 2, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability and efficacy of mezagitamab in patients with persistent or chronic primary immune thrombocytopenia. Takeda intends to initiate a global Phase 3 trial of mezagitamab in patients with primary immune thrombocytopenia in Fiscal Year 2024.

- Mezagitamab is a fully human immunoglobulin IgG1 with high affinity for CD38 expressing cells (including plasmablasts, plasma cells, natural killer cells) resulting in their depletion.

Regulatory agency news

On March 4, 2024, **Daiichi Sankyo announced** the European Medicines Agency has validated two marketing authorization applications (MAA) for Daiichi Sankyo and AstraZeneca's ADC datopotamab deruxtecan in two types of cancer. One MAA is for the treatment of adult patients with locally advanced or metastatic nonsquamous non-small cell lung cancer who require systemic therapy following prior treatment. The other MAA is for the treatment of adult patients with unresectable or metastatic hormone receptor positive, HER2 negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have progressed on and are not suitable for endocrine therapy and received at least one additional systemic therapy.

- Datopotamab deruxtecan is a specifically engineered TROP2-directed DXd ADC discovered by Daiichi Sankyo and being jointly developed by Daiichi Sankyo and AstraZeneca.

On March 14, 2024, **BeiGene, Ltd. announced** that the FDA has approved TEVIMBRA® (tislelizumab-jsgr) as monotherapy for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. TEVIMBRA will be available in the U.S. in the second half of 2024. FDA's approval follows other marketing approvals for tislelizumab previously granted in China, the European Union and the UK.

- Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages.

Antibody News You Should Know | March 15 - April 1, 2024

Topics

Dear Valued Member,

Welcome to the latest edition of Antibody News, your go-to source for updates on topics relating to global antibody therapeutics development. This issue features new company launches and collaborations, advances in the antibody clinical pipeline, and regulatory updates.

Business News

On March 18, 2024, Samsung Life Science Fund, created jointly between Samsung Biologics, Samsung Bioepis, and Samsung C&T, and managed by Samsung Ventures, and BrickBio, Inc. **announced Samsung's investment in BrickBio**, a preclinical-stage biopharmaceutical company focused on developing precision biologics using an expanded genetic code. Samsung affiliates will work with BrickBio to evaluate, manufacture, and develop advanced molecules and therapies using BrickBio's proprietary protein engineering technology for antibody-drug conjugates (ADCs), AAV gene therapy, and other modalities.

On March 19, 2024, Fusion Pharmaceuticals Inc., a clinical-stage oncology company focused on developing next-generation radioconjugates (RC) as precision medicines, **announced the company has entered into a definitive agreement to be acquired** by AstraZeneca. The acquisition marks a major step forward in AstraZeneca delivering on its ambition to transform cancer treatment and outcomes for patients by replacing traditional regimens like chemotherapy and radiotherapy with more targeted treatments. Fusion Pharmaceuticals' pipeline includes FPI-2265, an actinium-225-based PSMA targeting RC currently in a Phase 2 trial, and FPI-2068, an EGFR-cMET targeted RC in Phase 1 clinical trials.

On March 20, 2024, Clasp Therapeutics, a biotechnology company bringing unparalleled precision to immuno-oncology using next-generation T cell engagers (TCEs), **launched today with $150 million in financing**. The round was led by Catalio Capital Management, Third Rock Ventures and Novo Holdings. Clasp is developing modular TCEs tailored to

each patient's immune system that are directed to common oncogenic driver mutations, resulting in off-the-shelf, antibody-like medicines that can specifically target a wide variety of hard-to-treat tumor types.

Event News You Should Know

Join us on **April 25th** for our next webinar featuring Dr. **Ross Chambers** - **registration is open!** Reserve your spot now!

Register now

Phase 1 Studies Planned or Started

On March 20, 2024, LAVA Therapeutics N.V. **announced recent corporate highlights and financial results** for the fourth quarter and year ended December 31, 2023. In this press release, the company noted that an IND submission for LAVA-1266 is expected in Q2 2024. This antibody TCE will be evaluated as a treatment of hematological malignancies, including acute myeloid leukemia and myelodysplastic syndromes.

- LAVA-1266 is designed to target Vγ9Vδ2 (Vgamma9 Vdelta2) T cells and CD123.

On March 29, 2024, details were posted on clinicaltrials.gov for a Phase 1 study (**NCT06336707**) that will evaluate the safety, tolerability, pharmacokinetics, and efficacy of HS-20089 in combination with other antitumor agents (adebrelimab with or without platinum; bevacizumab with or without platinum) in subjects with advanced solid tumors. Sponsored by Hansoh BioMedical R&D Company, the study will enroll an estimated 1048 patients and is due to start in April 2024.

- HS-20089 is an ADC composed of a humanized IgG1 anti-B7-H4 monoclonal antibody conjugated to the topoisomerase I inhibitor payload via a protease-cleavable linker, with an average drug-to-antibody ratio (DAR) of about 6.

On March 15, 2024, details were posted on clinicaltrials.gov for a Phase 1 study (**NCT06238479**) of LY4101174 (ETx-22) that is recruiting participants with recurrent, advanced or metastatic solid tumors. Sponsored by Eli Lilly and Company, the study has an estimated enrollment of 280 participants. The LY4101174 ADC was developed by Emergence Therapeutics AG, a subsidiary of Lilly.

- **LY4101174 (ETx-22)** is an Fc-silent ADC composed of a humanized antibody targeting Nectin-4 conjugated to topoisomerase I inhibitor payload exatecan (DAR8) using the hydrophilic monodisperse polysarcosine (PSAR) drug-linker.

On March 25, 2024, Apogee Therapeutics, Inc. **announced that it has initiated dosing** of healthy volunteers in its first clinical trial for APG808, a novel subcutaneous monoclonal

antibody, which is being developed as a treatment for people living with moderate-to-severe COPD, asthma and other inflammatory and immunology diseases. The APG808 Phase 1 trial is designed as a double-blind, placebo-controlled, first-in-human, single-ascending dose trial in healthy volunteers.

- APG808 is an extended half-life monoclonal antibody targeting IL-4Rα.

Phase 3 Study Planned

On March 18, 2024, Alpine Immune Sciences, Inc. reports that they **intend to initiate RAINIER, a pivotal phase 3 study of the Fc fusion protein povetacicept** in IgA nephropathy and DENALI, a phase 2 study of povetacicept in systemic lupus erythematosus in the second half of 2024, pending regulatory agreement. Povetacicept (ALPN-303) is a dual antagonist of the BAFF (B cell activating factor) and APRIL (a proliferation inducing ligand) cytokines, which play key roles in pathogenesis of multiple autoimmune diseases via their roles in the activation, differentiation and/or survival of B cells, particularly antibody-secreting cells, as well as T cells and innate immune cells.

- Povetacicept is an Fc fusion protein based upon an engineered TACI (transmembrane activator and CAML interactor) domain.

Regulatory Agency News

On March 22, 2024, Invivyd, Inc. announced that **PEMGARDA™ (pemivibart), formerly VYD222 has received emergency use authorization** from the U.S. Food and Drug Administration (FDA) for the pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination.

- Pemivibart is a half-life extended anti-SARS-CoV-2 monoclonal antibody.

On March 25, 2024, Regeneron Pharmaceuticals, Inc. has announced that the **FDA issued Complete Response Letters (CRLs) for the Biologics License Application** for bispecific antibody odronextamab in relapsed/refractory (R/R) follicular lymphoma (FL) and in R/R diffuse large B-cell lymphoma (DLBCL), each after two or more lines of systemic therapy. The only approvability issue is related to the enrollment status of the confirmatory trials. The CRLs – one for R/R FL and one for R/R DLBCL – did not identify any approvability issues with the odronextamab clinical efficacy or safety, trial design, labeling or manufacturing. Regulatory review of odronextamab remains ongoing by the European Medicines Agency for the treatment of R/R DLBCL and R/R FL.

- Odronextamab (REGN1979), which targets CD20 and CD3, is a hinge-stabilized human bispecific antibody based on an IgG4 isotype modified to reduce Fc binding.

On March 26, 2024, Astellas Pharma announced that **Japan's Ministry of Health, Labour and Welfare (MHLW) had that day approved VYLOY™ (zolbetuximab)** for patients with CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer. VYLOY is the first and only CLDN18.2-targeted therapy approved by any regulatory agency in the world. The approval is based on results from the Phase 3 SPOTLIGHT and GLOW clinical trials for first-line treatment in patients with locally advanced unresectable or metastatic HER2-

negative gastric or gastroesophageal junction adenocarcinoma whose tumors were CLDN18.2 positive.

- VYLOY™ is an anti-Claudin 18.2 monoclonal antibody.

On March 26, 2024, argenx SE announced that **Japan's MHLW approved VYVGART (efgartigimod alfa)** for intravenous (IV) use in adults with primary immune thrombocytopenia (ITP). The approval of VYVGART is based on results from the global Phase 3 ADVANCE-IV trial, which were published in the September 2023 issue of The Lancet. ADVANCE successfully met its primary endpoint, demonstrating that a higher proportion of chronic ITP patients receiving VYVGART achieved a sustained platelet count response compared to placebo. VYVGART is the first approved FcRn blocker in the United States, EU and China for the treatment of adults with generalized myasthenia gravis (gMG) who are anti- acetylcholine receptor antibody positive and in Japan for the treatment of adults with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies.

- VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor, resulting in the reduction of circulating IgG autoantibodies.

Thank you for your interest in antibody research and development and your ongoing support of The Antibody Society! More information about the **late-stage clinical pipeline of antibody therapeutics** and those that are **approved or in regulatory review in any country** can be found in our searchable online tables.
