Antibody News You Should Know | April 1 - 15, 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 April 2, 2024, Ipsen and Sutro Biopharma announced an exclusive **global licensing agreement for STRO-003**. STRO-003, an antibody-drug conjugate (ADC) in the final stages of pre-clinical development, targets the ROR1 tumor antigen which is known to be overexpressed in many different cancer types including solid tumors and hematological malignancies. The agreement gives Ipsen exclusive worldwide rights to develop and commercialize STRO-003 and will be the first ADC candidate joining Ipsen's expanding portfolio.

On April 3, 2024, Genmab A/S and ProfoundBio, Inc. announced that the companies have entered into a definitive agreement for **Genmab to acquire ProfoundBio** in an all-cash transaction. ProfoundBio is a privately-owned clinical-stage biotechnology company developing next-generation ADCs and ADC technologies for the treatment of certain cancers, including ovarian cancer and other FRα-expressing solid tumors. Genmab will acquire ProfoundBio for USD 1.8 billion in cash, payable at closing, subject to adjustment for ProfoundBio's closing net debt and transaction expenses.

On April 3, 2024, **Diagonal Therapeutics**, a biotechnology company pioneering a new approach to discovering and developing agonist antibodies, launched with $128 million in financing. The Series A was co-led by BVF Partners and Atlas Venture, with participation from Lightspeed Venture Partners, RA Capital Management, Frazier Life Sciences, Viking Global Investors, Velosity Capital, and Checkpoint Capital. Diagonal was co-founded by Chief Executive Officer, Alex Lugovskoy, Ph.D., and Atlas and previously seeded by Atlas, Lightspeed Venture Partners, and Velosity Capital. The financing will support further advancement of the company's proprietary DIAGONAL platform and pipeline of novel therapeutics to value-creating milestones, including its lead program for the treatment of hereditary hemorrhagic telangiectasia (HHT), a severely debilitating bleeding disorder with limited therapeutic options, through clinical proof-of-concept. Diagonal's agonist antibody activates a receptor complex in the TGF-β superfamily genetically impaired in HHT

patients. In preclinical models of HHT, Diagonal's agonist antibodies prevent and reverse the formation of pathological vascular malformations.

On April 4, 2024, Aethon Therapeutics, Inc., a biotechnology company discovering and developing novel antibody therapeutics designed to attack cancer cells in tandem with targeted covalent inhibitor cancer therapies, announced that it has entered into a **collaboration agreement** with Revolution Medicines, a clinical-stage oncology company developing targeted therapies for patients with RAS-addicted cancers. Under the terms of the agreement, Aethon will use its HapImmune™ platform to discover novel bispecific antibodies to mount an immune attack directed towards cancer cells hit by Revolution Medicines' RAS(ON) inhibitors, with the goal of fueling tumor clearance and helping to establish immune memory.

On April 4, 2024, Caris Discovery™, the therapeutic research arm of Caris Life Sciences Life Sciences®, the leading next-generation AI TechBio company and precision medicine pioneer, announced a **multi-year strategic partnership** with Merck KGaA, which operates its healthcare business as EMD Serono in the U.S. and Canada, to accelerate the discovery and development of first-in-class ADCs for cancer patients. Under the terms of the agreement, Merck KGaA, will provide Caris with an upfront payment as well as research funding. In addition, Caris will be eligible for discovery, development, regulatory and sales-based milestone payments that may total up to $1.4 billion along with tiered royalties. Merck KGaA will receive an exclusive global license to develop, manufacture and commercialize ADC therapeutics for selected targets.

On April 5, 2024, University at Buffalo announced Abceutics Inc., Inc., a startup preclinical-stage biopharmaceutical company that was spun out of the laboratory of University at Buffalo researcher Joseph Balthasar PhD, was **acquired by the global biopharmaceutical company Merck**, known as MSD outside the U.S. and Canada. Merck acquired Abceutics for a potential consideration of up to $208 million, including

contingent milestone payments based upon the progress of candidates under the agreement. The work of Abceutics is synergistic with ADCs. The Abceutics team engineered “payload-binding selectivity enhancers” to bind and neutralize stray payload molecules, reducing the impact of these agents on otherwise healthy cells.

On April 10, 2024, TORL BioTherapeutics, LLC announced its closing of an **oversubscribed $158 million Series B-2 financing.** The financing led by Deep Track Capital, with new participation from leading global biotechnology investors including RA Capital Management, Perceptive Advisors, and Avidity Partners as well as all existing biotechnology investors. Proceeds from this Series B-2 financing will be used to continue the clinical development of TORL-1-23, the Company's first-in-class ADC to treat CLDN 6+ tumors, through Phase 1 and a pivotal Phase 2 trial that will start in the second half of 2024. This Phase 2 trial is designed to facilitate regulatory review and potential approvals for TORL-1-23 as a new therapy for patients with CLDN 6+, platinum-resistant ovarian cancer. Proceeds will also be used to fund the on-going Phase 1 studies for the TORL-2-307 program, both a monoclonal antibody (mAb) and an ADC, for the treatment of CLDN 18.2+ solid tumors, TORL-3-600, an ADC for the treatment of CDH17+ colorectal cancer, and TORL-4-500, an ADC for the treatment of Delta like non-canonical Notch Ligand 1 (DLK1) positive solid tumors.

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 April 8, 2024, Zymeworks Inc. has provided details for preclinical programs, including **ZW191, which may enter clinical studies soon**. The preclinical activity profile supports ZW191 development across multiple tumor types, including FRα-high/mid/low ovarian cancers and other FRα-expressing indications, including non-small cell lung cancer, endometrial cancer, and triple-negative breast cancer. An investigational new drug submission or foreign equivalent is planned for 2024.

- ZW191 is a FRα-targeting ADC differentiated by its novel antibody and novel topoisomerase I inhibitor payload.

On April 11, 2024, details were posted for a first-in-human study (**NCT06359002**) that will evaluate safety, PK, immunogenicity, and anti-leukemia activity of BYON4413 in patients with acute myeloid leukemia and myelodysplastic neoplasms. Sponsored by Byondis and due to start in May 2024, the study will enroll an estimated 100 participants.

- BYON4413 comprises an anti-CD123 humanized IgG1 antibody that is site-specifically conjugated to Byondis' proprietary duocarmazine linker-drug.

On April 12, 2024, details were posted for a Phase 1 study (**NCT06363383**) of MB-001, an antibody therapeutic that will be orally administered to healthy volunteers. The mAb is formulated in hard shell capsules for oral use as a single administration or multiple daily administrations over five consecutive days. Sponsored by Mage Biologics, the study will enroll an estimated 48 participants and is due to start in May 2024. Mage was launched in mid-2023 to develop a monoclonal antibody targeting ulcerative colitis that was specifically designed for oral administration utilizing Tillotts Pharma AG's sustained release approach to ensure optimal and local treatment.

On April 8, 2024, CytomX Therapeutics announced the **first patient has been dosed in a Phase 1** dose escalation study (NCT06265688) of CX-2051 in patients with advanced solid tumors. The CX-2051 Phase 1 dose escalation is designed to efficiently test the safety and preliminary anti-tumor activity of CX-2051, to provide initial clinical proof of concept to inform a potential decision to move into dose expansions in 2025.

- CX-2051 is an anti-EPCAM masked PROBODY® ADC. The cytotoxic payload utilized in CX-2051 is a derivative of camptothecin, a topoisomerase-1 inhibitor.

Phase 3 Study Started

On April 4, 2024, details were posted on clinicaltrials.gov for a Phase 3 study (**NCT06346392**) to assess the efficacy and safety of AZD0901 compared to Investigator's choice of therapy as the 2L+ treatment for participants with advanced or metastatic gastric or GEJ adenocarcinoma expressing CLDN18.2. Sponsored by AstraZeneca, the study started in March and will enroll an estimated 589 participants. AstraZeneca licensed the ADC from KYM Biosciences, a joint venture established by affiliates of Keymed Biosciences and Lepu Biopharma.

- AZD0901 (CMG901) is an ADC comprising of a Claudin 18.2-specific antibody, a cleavable linker and a toxic payload, monomethyl auristatin E.

https://clinicaltrials.gov/study/NCT06346392?intr=AZD0901%20&rank=1

Regulatory Agency News

On April 2, 2024, AstraZeneca and Daiichi Sankyo announced the **Biologics License Application (BLA) for datopotamab deruxtecan** (Dato-DXd) has been accepted in the US for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior systemic therapy for unresectable or metastatic disease. The Prescription Drug User Fee Act date, the US Food and Drug Administration action date for its regulatory decision, is during the first quarter of 2025. The companies previously submitted a BLA for datopotamab deruxtecan based on results from the pivotal TROPION-Lung01 Phase III trial, which is under review in the US for the treatment of adult patients with locally advanced or metastatic nonsquamous non-small cell lung cancer who have received prior systemic therapy. Additional regulatory submissions for datopotamab deruxtecan in lung and breast cancer are underway globally.

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

On April 6, 2024, AstraZeneca and Daiichi Sankyo announced that ADC **ENHERTU® (trastuzumab deruxtecan) has been approved** in the U.S. as the first tumor agnostic, HER2 directed therapy for previously treated patients with metastatic HER2+ solid

tumors. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. ENHERTU, a specifically engineered HER2 directed ADC discovered by Daiichi Sankyo, is being jointly developed and commercialized by Daiichi Sankyo and AstraZeneca.

- *Enhertu* consists of a HER2 monoclonal antibody attached to a number of topoisomerase I inhibitor payloads, (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

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.

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

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development. This issue features new company launches and collaborations, advances in the antibody clinical pipeline, and regulatory updates.

Business News

On April 16, 2024, Cullinan Therapeutics **announced a corporate name change** from Cullinan Oncology to Cullinan Therapeutics, reflecting their strategic expansion into autoimmune diseases. They also announced that clinical development of CLN-978 will focus exclusively on autoimmune diseases, pursuing systemic lupus erythematosus as a first indication. CLN-978 is a half-life extended CD19xCD3 bispecific T cell engager construct.

On April 22, 2024, Salubris Biotherapeutics, Inc. **announced a new capital infusion** of $35 million to fund continued research and development of clinical and pre-clinical programs. SalubrisBio also provided progress updates for JK07, the first investigational antibody fusion protein for heart failure, JK08, the first investigational IL15-CTLA4 antibody fusion for solid tumors and JK06, a first-in-class biparatopic antibody-drug conjugate (ADC) targeting a known tumor antigen.

On April 23, 2024, **Xaira emerged from stealth** with $1 billion in committed capital led by ARCH Venture Partners and Foresite Capital, with additional investment from F-Prime Capital, New Enterprise Associates (NEA), Sequoia Capital, LUX Speed Capital, Lightspeed, Menlo Ventures, Two Sigma Ventures, SV Angel and others. Xaira is led by renowned scientist Dr. Marc Tessier-Lavigne, former Chief Scientific Officer of Genentech and former President of Rockefeller and Stanford Universities. Its executives include co-founder Hetu K, formerly of Meta and the Institute for Protein Design; Arvind Rajpal, formerly of Genentech; and Don Kirkpatrick, formerly of Interline and Genentech. Xaira was co-founded by Dr. David Baker, Professor of Biochemistry and Director of Institute for Protein Design, University of Washington.

On April 24, 2024, Biolojic Design, Ltd. announced that Nektar **exercised its license option** to develop a program resulting from the companies' research collaboration initiated in 2021. The antibody program selected for development (now known as NKTR-0165) is designed to modulate the tumor necrosis factor receptor type II pathway in order to agonize T regulatory cells and other anti-inflammatory cell populations, making this a promising approach to stimulating the immune system in ulcerative colitis, multiple sclerosis,

vitiligo, and other autoimmune disease states.

On April 25, 2024, RevOpsis Therapeutics announced it has successfully **closed its first seed funding round**, raising $16.5 million to propel its mission to develop and commercialize treatments for chronic multifactorial diseases through the company's fully human multispecific proprietary Rev-Mod Platform. RO-104, RevOpsis' current lead candidate, is a first-in-class human modular tri-specific biologic designed to address all three clinically validated dominant angiogenic pathways (VEGF-A, VEGF-C, Ang-2) implicated in retinal vascular disease progression, including neovascular age-related macular degeneration.

On April 26, 2024, Alligator Bioscience AB announced that Orion Corporation, a global pharmaceutical company based in Finland, has **selected the lead bispecific antibodies** from the companies' second development program, and is exercising its option to develop these molecules under the existing 2021 research collaboration and license agreement. The exercise of this development option triggers an undisclosed milestone payment to Alligator. Under the initial agreement signed in August 2021, Alligator employed its proprietary phage display libraries and RUBY® bispecific antibody format to develop immuno-oncology product candidates based on design

criteria identified by Orion. In January 2023, the agreement was expanded to include the development of a second bispecific antibody. Alligator is eligible for development, approval and sales milestone payments in addition to royalties if Orion continues developing and commercializing the resulting product candidates.

On April 26, 2024, Evotec Biologics, the biologics segment of Evotec SE **announced the launch** of its proprietary J.CHO™ High Expression System ("J.CHO") for antibody expression. As part of Just – Evotec Biologics' highly-intensified continuous bioprocessing platform, J.CHO™ optimizes clinical and commercial biotherapeutic production processes by providing higher productivity and high quality of complex antibody formats, including candidate antibodies, Fc-fusions, and bispecific antibodies.

Phase 1 Studies Planned or Started

On April 18, 2024, D2M Biotherapeutics announced that the **first patient had been dosed** in a Phase 1, open-label, dose escalation and expansion study of DM919. This Phase 1, first-in-human, multicenter, dose-escalation and expansion trial (NCT06328673) will evaluate the safety, tolerability, pharmacokinetics,

pharmacodynamics, and clinical activity of DM919 alone and in combination with anti-PD1 therapy in patients with advanced or metastatic solid tumors.

- DM919 is a novel monoclonal antibody targeting MICA/B to restore and promote anti-tumor response by T and natural killer cells.

On April 29, 2024, Light Chain Bioscience announced that the **first patient was treated** in a Phase 1 study of NILK-2301, a κλ body-based T cell engager for the immunotherapy of CEACAM5-expressing cancers. Light Chain Bioscience | Novimmune SA, in partnership with LamKap Bio Group, is leading the clinical development of this innovative therapy in collaboration with two clinical hospitals highly experienced in early clinical development and immunotherapy of cancer, Val d'Hebron Institute of Oncology (VHIO) and START Madrid – FJD, led by Prof Josep Tabernero and Victor Moreno, respectively.

- NILK-2301 is an anti-CEACAM5xCD3 bispecific antibody.

On April 17, 2024, details were posted on clinicaltrials.gov for a Phase 1b study (**NCT06371417**) of the effects of RAY121, an inhibitor of classical complement pathway, after multiple dose administration in patients with immunological diseases. Sponsored by Chugai

Pharmaceutical, the study has an estimated enrollment of 144 participants and an estimated start date in May 2024.

- RAY121 is a therapeutic antibody that applies the recycling antibody® technology created by Chugai.

Pipeline Updates

On April 15, 2024, **Longbio Pharma (Suzhou) Co., Ltd. announced** the release of preclinical data for LP-005 at the 2024 World Congress of Nephrology. LP-005 is a novel bifunctional complement antibody fusion protein targeting both C3 and C5. The company's leading pipeline is a next-generation anti-IgE antibody (LP-003), which is about to start Phase 3 study in 2024Q2; BLA preparation is planned for 2025H1. The second leading pipeline is a bi-functional complement antibody fusion-protein (LP-005), which is in Phase 1, with a Phase 2/3 planned to start in 2024Q2.

On April 15, 2024, Walden Biosciences, a private, venture-backed company focused on disease-modifying therapies for the treatment of kidney diseases, **announced results** from the Company’s Phase 1+ clinical study of WAL0921 in healthy subjects. WAL0921 is a

humanized monoclonal antibody that binds circulating free soluble urokinase plasminogen activator receptor (suPAR) and its membrane bound form, uPAR, and inhibits their pathological activity, which causes kidney diseases. The company plans to initiate Phase 2 basket study in glomerular kidney diseases in 2Q24.

Regulatory Agency News

On April 30, 2024, **Genmab A/S and Pfizer Inc. announced** that U.S. Food and Drug Administration has approved the supplemental Biologics License Application for TIVDAK® (tisotumab vedotin-tftv) for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. This FDA action converts the September 2021 accelerated approval of TIVDAK to a full approval. TIVDAK is the first ADC with demonstrated overall survival data to be granted full FDA approval in this patient population.

- TIVDAK® (tisotumab vedotin-tftv) is composed of Genmab's human monoclonal antibody directed to tissue factor and Pfizer's ADC technology that utilizes a protease-cleavable linker

that covalently attaches the microtubule-disrupting agent monomethyl auristatin E to the antibody.

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Business News

On May 6, 2024, **Biocytogen announced** a TCR-mimic antibody evaluation and potential licensing agreement with BioCopy AG, a research-based biotechnology company headquartered in Basel, Switzerland. The agreement grants BioCopy access to fully human TCR-mimic antibodies targeting an intracellular antigen generated by Biocytogen's proprietary RenTCR-mimicTM mice. BioCopy will conduct an evaluation and retain the option to license these antibodies for the development of novel cancer therapies.

On May 7, 2024, **Zenas BioPharma announced** the closing of an upsized $200 million Series C preferred stock financing. The financing round was led by SR One along with NEA, Norwest Venture Partners, and Delos Capital with significant participation from Enavate Sciences and Longitude Capital. Proceeds will support ongoing mid- to late-stage clinical development programs for the Company's lead product candidate, obexelimab.

- Obexelimab is a bifunctional monoclonal antibody designed to bind both CD19 and FcγRIIb to inhibit the activity of B cells, plasmablasts, and CD19-expressing plasma cells.

On May 9, 2024, **Cell Surface Bio (CSB) emerged** from stealth mode and launched VeRSaMAb research antibodies with the vision of delivering "antibodies that always work," answering the call of the scientific community for reliable reagents with uncompromising quality. Providing monoclonal antibodies that are extensively validated, recombinantly cloned, and exquisitely specific, CSB is being built to transform the >$10 billion antibody reagent market where currently half of the antibodies sold do not work as designed. A spin-out of Philadelphia's Integral Molecular, CSB leverages the parent company's 20+ years of expertise developing and characterizing therapeutic antibodies that target complex and conserved proteins on the cell surface.

On May 9, 2024, **Bluejay Therapeutics announced** the successful closure of a $182

million Series C financing round. This capital infusion will accelerate the clinical development of BJT-778, as the treatment for chronic hepatitis D (HDV). The funds will also support the progression of additional promising candidates in Bluejay's robust pipeline for the treatment for chronic hepatitis B. As previously announced, BJT-778 has received PRIME designation from the European Medicines Agency based on early results from the Phase 1/2 study in HDV.

- BJT-778 is a potentially best-in-class fully human IgG1 monoclonal antibody against hepatitis B surface antigen (anti-HBsAg mAb), being developed for both chronic HBV and HDV.

On May 9, 2024, **The Jackson Laboratory (JAX), an independent, nonprofit biomedical research organization, and AbTherx, an innovator in biotechnology, announced** a strategic partnership to develop and commercialize cutting-edge tools to expedite antibody discovery and derisk the development of vital new therapies. This collaboration will include co-development activities and leverages JAX's extensive experience in model research and AbTherx's Atlas™ Mouse platform to address critical challenges facing drug developers of all sizes.

On May 9, 2024, **Commit Biologics exited from stealth** with €16m in seed funding from Bioqube Ventures and Novo Holdings. Commit plans to accelerate development of its Bispecific Complement Engaging (BiCE™) platform, which uses single domain antibodies that bind to the complement protein C1q to activate the complement system, a fast-acting and potent part of the innate immune system. BiCE™ is a modular system that can arm antibodies to direct the complement system in a highly targeted way, so that it selectively kills cancer cells or immune cells that drive autoimmune diseases. Commit is a spin-out from Aarhus University in Denmark, which has built a global reputation as a center of excellence in complement system biology over the last three decades. The Company was initially incubated and supported by the BioInnovation Institute in Denmark.

Event News You Should Know

Join us on June **6th** for our next webinar featuring Dr. **Jin Lu** - [registration is open!]

Reserve your spot now!

Register now

Phase 1 Studies Planned or Started

On May 6, 2024, details were posted on clinical trials.gov for a first-in-human study ([NCT06400472]) to assess the safety, tolerability, and preliminary efficacy of LY4170156 in participants with selected advanced solid tumors. Sponsored by Eli Lilly and Company, the study will enroll an estimated 220 participants and has an estimated start date in May 2024.

- LY4170156, an antibody-drug conjugate targeting folate receptor α

On May 10, 2024, details were posted on clinical trials.gov a Phase 1 study (NCT06406348) of ALIA-1758, which is intended as a treatment for Alzheimer's disease. Sponsored by Aliada Therapeutics, the study will evaluate ALIA-1758 in healthy volunteers and has an estimated start date in May 2024.

- ALIA-1758 is an anti-pyroglutamate amyloid beta (3pE-Aβ) antibody. An anti-TfR Delivery Module conjugated to the Fc transports 3pE-Aβ antibodies into the brain at a higher concentration than naked antibodies, leading to more efficient target clearance. An optimized Fc domain increases half-life, reduces effector function, and leads to clearance of bound antibodies through a mechanism that reduces pro-inflammatory cytokine release and immune exhaustion.

On May 10, 2024, details were posted on clinical trials.gov a first-in-human, Phase 1/2 study (NCT06413680) of REGN10597 in patients with advanced solid organ malignancies. Sponsored by Regeneron, the study will enroll an estimated 150 participants and has as estimated start date in September 2024.

- REGN10597 is a PD-1-targeted, receptor-masked IL-2 immunocytokine with attenuated systemic IL-2 activity but maintained capacity to engage endogenous IL-2Rα on PD-1+ T cells.

Regulatory Agency News

On May 7, 2024, Mabwell (Shanghai) Bioscience Co., Ltd. announced that 9MW2821 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of esophageal cancer. A Phase 3 clinical study of 9MW2821 monotherapy has officially been initiated in patients with locally advanced or metastatic urothelial carcinoma who have previously received platinum-based chemotherapy and PD-(L)1 inhibitor therapy.

- 9MW2821 is an Nectin-4-targeting antibody-drug conjugate.

On May 13, 2024, **Merus N.V. announced** that the FDA has granted Breakthrough Therapy Designation for petosemtamab for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) whose disease has progressed following treatment with platinum based chemotherapy and an anti-PD-1 or anti-PD-L1C antibody. This designation follows receipt of Fast Track Designation for petosemtamab for the treatment of patients with recurrent or metastatic HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an PD-1 antibody announced in August 2023.

- Petosemtamab (MCLA-158) is a Biclonics® low-fucose human full-length IgG1 antibody targeting the epidermal growth factor receptor and the leucine-rich repeat containing G-protein-coupled receptor 5.

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Business News

On May 16, 2024, PROTEOLOGIX Inc, Inc., a privately-held biotechnology company focused on bispecific antibodies for immune-mediated diseases, announced that it entered into a definitive agreement to be acquired by Johnson & Johnson for $850 million in cash, with potential for an additional milestone payment. Proteologix's portfolio includes:

- PX128, a bispecific antibody targeting IL-13 plus TSLP, which is ready to enter phase 1 development for moderate to severe atopic dermatitis (AD) and moderate to severe asthma, and
- PX130, a bispecific antibody targeting IL-13 plus IL-22, which is in preclinical development for moderate to severe AD.

Since AD and asthma are both heterogeneous diseases with different disease-driving pathways in distinct patient subpopulations, targeting multiple pathways offers the potential to deliver high-bar efficacy and remission.

On May 20, 2024, AstraZeneca announced plans for a $1.5 billion manufacturing facility for antibody-drug conjugates (ADCs) in Singapore. The planned greenfield facility, supported by the Singapore Economic Development Board, will be AstraZeneca's first end-to-end ADC production site, fully incorporating all steps of the manufacturing process at a commercial scale. AstraZeneca aims to begin design and construction of the manufacturing facility by the end of 2024, with targeted operational readiness from 2029.

On May 21, 2024, Pheon Therapeutics, which is developing next-generation ADCs for a wide range of hard-to-treat cancers, announced the completion of a $120m Series B financing to fund the development of its pipeline of differentiated ADCs. The financing was led by TCGX with participation from other new investors BVF Partners, Lightspeed and Perceptive Advisors, alongside existing investors Atlas Venture, Brandon Capital, Forbion, and Research Corporation Technologies. The new financing will be used to

further advance Pheon's differentiated ADC pipeline through clinical proof of concept. The first three assets are aimed at an undisclosed novel target which is highly overexpressed in a wide range of solid tumors. The first program has demonstrated an unprecedented preclinical therapeutic index while utilizing a DAR8 Topoisomerase-1 inhibitor linker-payload, whereas the next two ADCs utilize other linker-payload technologies to mine the broad potential of this target. The company expects to start its first Phase 1 clinical trial in 2024 and rapidly advance towards dose expansion cohorts.

On May 24, 2024, LabGenius, a drug discovery company pioneering the use of machine learning for the discovery of novel therapeutic antibodies, announced that it has closed a £35 million Series B financing round. The investment brings LabGenius' total funding to date to £58 million. LabGenius will use the capital raised to expand the scope of its ML-driven discovery platform and progress a wholly-owned pipeline of multispecific antibodies towards the clinic. Building on the success of a recent research collaboration with Sanofi, the extended platform capability will facilitate broader strategic partnerships across multiple therapeutic modalities.

On May 29, 2024, Nona Biosciences, a global biotechnology company providing a total solution from "Idea to IND", ranging from target validation and antibody discovery through preclinical research, announced that it has entered into a license agreement with AstraZeneca for preclinical monoclonal antibodies that will be used to create targeted therapies in oncology. Under the terms of the agreement, Nona Biosciences shall receive US$19 million upon completion of the transaction. Nona is eligible to receive an additional US$10 million in potential near-term milestone payments and up to US$575 million upon achieving specified development, regulatory, and commercial milestones, as well as tiered royalty payments on net sales. In addition, Nona is eligible to receive payments for the option programs should AstraZeneca exercise these options.

On May 28, 2024, Johnson & Johnson announced that it entered into an agreement with

Numab Therapeutics AG Therapeutics to acquire its wholly owned subsidiary for the global rights to NM26, a Phase 2-ready bispecific antibody that targets IL-4Rα (type I and type II receptors) and IL-31, in an all-cash transaction of approximately $1.25 billion. The targets of NM26 are involved in clinically proven pathways in atopic dermatitis.

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Phase 1 Studies Planned or Started

On May 16, 2024, details were posted on clinicaltrials.gov for a Phase 1 study (NCT06418061) of the bispecific ADC antibody IBI3005 in subjects with unresectable,

locally advanced or metastatic solid tumors. Sponsored by Innovent Biologics, the study will enroll an estimated 198 participants and has an estimated start date in June 2024.

- IBI3005 is a bispecific monoclonal antibody-camptothecin derivative conjugate

On May 17, 2024, details were posted on clinicaltrials.gov for a Phase 1 study (NCT06419634) of Orum Therapeutics' ORM-6151 (BMS-986497) for the treatment of patients with acute myeloid leukemia or high-risk myelodysplastic syndromes. Sponsored by Bristol Myers Squibb, the study will enroll an estimated 35 patients and is due to start in late May 2024.
Orum Therapeutics has developed a new class of ADC payloads, called neoDegraders, to specifically degrade intracellular target proteins within cancer cells via the E3 ubiquitin ligase pathway. Conjugated to antibodies, neoDegraders are designed to be delivered specifically to cancer cells and degrade the intracellular target protein and cause tumor cell death.

- ORM-6151 (BMS-986497) is a first-in-class, anti-CD33 antibody-enabled GSPT1 degrader.

On May 23, 2024, Abdera Therapeutics announced that the U.S. Food and Drug Administration (FDA) cleared the company's Investigational New Drug application for ABD-147 for the treatment of small cell lung cancer and large cell neuroendocrine carcinoma. Abdera plans to initiate a Phase 1 clinical trial in the second half of 2024.

- ABD-147 is a next-generation precision radiopharmaceutical antibody-based therapy designed to deliver Actinium-225, a highly potent alpha-emitting radioisotope, to solid tumors expressing DLL3.

On May 20, 2024, GigaGen Inc, a subsidiary of Grifols, announced that the first patient has been dosed in a Phase 1 clinical trial (NCT06258304) evaluating the safety and tolerability of GIGA-564 for the treatment of metastatic or locally advanced solid tumors.

The trial is being conducted by researchers at the National Cancer Institute, part of the National Institutes of Health, in close partnership with GigaGen.

- GIGA-564 is an anti-CTLA-4 monoclonal antibody.

Phase 3 Study News

On May 16, 2024, MoonLake Immunotherapeutics announced that the first patients have been screened at a U.S. trial site in its global Phase 3 clinical program, VELA, evaluating sonelokimab, an investigational Nanobody® designed to treat inflammatory disease, in patients with moderate-to-severe hidradenitis suppurativa. Two Phase 3 studies (NCT06411379, NCT06411899) are recruiting 400 patients each.

- Sonelokimab (M1095) is a ~40 kDa humanized Nanobody® consisting of three VHH domains covalently linked by flexible glycine-serine spacers. With two domains, sonelokimab selectively binds with high affinity to IL-17A and IL-17F, thereby inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers. A third central domain binds to human albumin, facilitating further enrichment of sonelokimab at sites of inflammatory edema.

On May 21, 2024, GSK announced positive results from Phase 3 severe asthma trials of depemokimab (GSK3511294). The Phase 3 SWIFT-1 and SWIFT-2 studies assessed the efficacy and safety of depemokimab versus placebo in adults and adolescents with severe asthma with type 2 inflammation characterised by blood eosinophil count. Both SWIFT-1 and SWIFT-2 met their primary endpoints of a reduction in the annualised rate of clinically significant exacerbations (asthma attacks) over 52 weeks. The full results of SWIFT-1 and SWIFT-2 will be presented at an upcoming scientific congress and will be used to support regulatory submissions to health authorities worldwide.

- Depemokimab (GSK3511294) is a long-acting anti-IL-5 monoclonal antibody.

Regulatory Agency News

On May 24, 2024, Akeso, Inc. announced that ivonescimab combined with chemotherapy for the treatment of epidermal growth factor receptor (EGFR) mutated locally advanced or metastatic non-squamous non-small cell lung cancer patients who have progressed after

EGFR tyrosine kinase inhibitors treatment, has been granted marketing approval by the National Medical Products Administration of the People's Republic of China. The approval of by the NMPA is based on AK112-301/HARMONi-A (CTR20213079), a randomized, double-blinded, multi-center Phase III clinical trial with primary endpoint of progression-free survival and secondary endpoint of overall survival (OS) in China.

- Ivonescimab is an anti-PD-1/VEGF bispecific antibody independently developed by Akeso.

On May 29, 2024, Jazz Pharmaceuticals announced that the FDA has accepted and granted Priority Review of the Biologics License Application (BLA) for zanidatamab, for the treatment of previously treated, unresectable, locally advanced, or metastatic human epidermal growth factor receptor 2 (HER2)-positive biliary tract cancer. Under the Prescription Drug User Fee Act (PDUFA), FDA has set a target action date of November 29, 2024.

- Zanidatamab is a HER2-targeted biparatopic bispecific antibody,

On May 30, 2024, Astellas Pharma Inc. announced that the FDA has acknowledged the company’s resubmission of the BLA for zolbetuximab for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are CLDN18.2 positive. If approved, zolbetuximab would be the first CLDN18.2-targeted therapy approved for this patient population in the U.S. Under PDUFA, the FDA has set a new target action date of November 9, 2024.

- Zolbetuximab, a first-in-class investigational claudin-18.2-targeted monoclonal antibody.

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.

Antibody News You Should Know | June 1 - 15, 2024

Topics

Dear Valued Member,

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Business News

On June 3, 2024, Biolojic Design, Ltd. which uses computational biology and artificial intelligence to transform antibodies into programmable, intelligent medicines, announced that it has entered into a multi-target drug discovery collaboration with Merck KGaA, Darmstadt, Germany. The partnership will leverage Biolojic Design's AI-driven discovery platform to design therapeutic antibodies for the treatment of cancer and immunological disorders. Under the terms of the agreement, Biolojic Design will receive a low double-digit million euro upfront payment and research funding from Merck KGaA, Darmstadt, Germany, and be eligible for drug discovery, development, regulatory and commercial milestone payments that may total up to €346 million. Biolojic Design will also be eligible to receive tiered royalties on net product sales.

On June 5, 2024, Telix Pharmaceuticals Limited announced the launch of its initial public offering in the United States of 17,000,000 American Depositary Shares, each representing one ordinary share in Telix. The target size of the Offering is US$200 million in gross proceeds. Telix is a commercial-stage biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic ('theranostic') radiopharmaceuticals, including antibody-based molecules.

On June 11, 2024, Bright Peak Therapeutics announced that it raised $90 million in a Series C financing. The round was led by Johnson & Johnson Innovation – JJDC, with participation from additional new investors Venrock, KB Investment, and Northleaf Capital Partners. Existing investors participating in the round include founding investor Versant Ventures along with Fidelity Management & Research Company, RA Capital Management, Qatar Investment Authority, Invus, Alexandria Venture Investments, and an undisclosed leading healthcare investment fund. Proceeds from the Series C financing will be used to advance BPT567 into a Phase 1/2a clinical trial and accelerate a pipeline of next-generation immunotherapies.

- BPT567 is a first-in-class PD1-IL18 immunoconjugate designed to provide simultaneous blockade of the PD(L)-1 checkpoint pathway and targeted delivery of IL-18 signaling.

On June 13, 2024, AbbVie and FutureGen Biopharmaceutical (Beijing) Co., Ltd. announced a license agreement to develop FG-M701, an antibody for the treatment of inflammatory bowel disease (IBD) currently in preclinical development. FG-M701 is uniquely engineered with potential best-in-class functional characteristics with the goal to drive greater efficacy and less frequent dosing as a therapy for IBD.

- FG-M701 is a human monoclonal antibody targeting TL1A, a clinically validated target in IBD.

Event News You Should Know

Join us on July **25th** for our next webinar featuring Dr. Shun Zhou - **registration is open!** Reserve your spot now!

Register now

Phase 1 Studies Planned or Started

On June 5, 2024, Pierre Fabre Group announced the filing of an investigational new drug application (IND) to the U.S. Food and Drug Administration (FDA) to initiate a first-in-human (FIH) Phase 1/2 clinical trial with PFL-002/VERT-002 for solid tumors including non-small cell lung cancer. The antibody was optimized preclinically by Vertical Bio, which was acquired by Pierre Fabre Laboratories in 2023. Pierre Fabre Laboratories is progressing PFL-002/VERT-002 into clinical development and hopes to enroll the first patient in the FIH trial by the end 2024.

- PFL-002/VERT-002 is a monoclonal antibody acting as a degrader of c-MET.

On June 3, 2024, FibroGen, Inc. announced that the FDA has cleared the company's IND of FG-3165 for treatment of solid tumors characterized by high Gal9 levels of expression. The FDA's IND clearance enables FibroGen to initiate a Phase 1 clinical trial evaluating the

safety and efficacy of FG-3165 in patients with select solid tumors. The trial is anticipated to begin enrollment in the second half of 2024.

- FG-3165 is a galectin-9 (Gal9) targeted monoclonal antibody.

On June 7, 2024, Pfizer posted details for a first-in-human study (NCT06448364) of PF-07329640 in patients with solid tumors. The study, which will evaluate the effects of the PF-07329640 alone or in combination with bevacizumab or sasanlimab, will recruit an estimated 220 patients.

- PF-07329640 is a tetravalent antibody designed to activate the lymphotoxin beta receptor (LTβR) and induce tertiary lymphoid structure formation and maturation.

On June 12, 2024, Zumutor Biologics Inc. announced that the first patient was dosed in its Phase 1 clinical trial of ZM008. The dose escalation trial is evaluating ZM008 in patients with advanced solid tumors, as a single agent and in combination with pembrolizumab. The ZM008-001 trial is an open-label, first-in-human, multicenter, Phase 1 dose escalation trial of ZM008 administered alone or combined with pembrolizumab. The trial will assess the safety, pharmacokinetics, and establish the maximum tolerated dose, pharmacodynamic biomarkers, and initial antitumour activity of ZM008.

- ZM008 is a fully human IgG1 monoclonal antibody against LLT1 (CLEC2D), which disrupts the interaction of LLT1-CD161 between natural killer (NK) cells and tumor cells. ZM008-mediated NK cell activation and subsequent T cell activation will modify the immune infiltrate in the tumor microenvironment driving eventual antitumor effects.

Regulatory Agency News

On June 4, 2024, Philogen S.p.A. and Sun Pharmaceutical Industries Limited announced the submission of a marketing authorization application to the European Medicines Agency for the approval of Nidlegy™, an investigational treatment for neoadjuvant locally advanced fully resectable melanoma. The completed submission was based on clinical data from the Phase 3 PIVOTAL study (PHL19IL2TNF-02/15), whose primary results were presented at ASCO 2024, and on the Phase 2 trial (PHL19IL2TNF-02/12). If approved, Nidlegy™ would become the first immunocytokine product to gain marketing authorization.

- Nidlegy™ is a mixture of two immunocytokines, L19IL2 and L19TNF, manufactured independently and mixed prior to intralesional administration. L19IL2 (bifikafusp alpha) and L19TNF (onfekafusp alfa) are composed of the L19 single-chain variable fragments targeting fibronectin extra-domain B fused with the pro-inflammatory cytokine IL-2 and tumor necrosis factor, respectively.

On June 10, 2024, the FDA's Peripheral and Central Nervous System Drugs Advisory Committee voted 11-0 to recommend the approval of Eli Lilly's donanemab for early Alzheimer's disease, ruling that the treatment's ability to slow the cognitive decline in patients outweighed its safety risks. The unanimous outcome of the advisory panel suggests the FDA will approve donanemab for a broad population of people diagnosed with mild cognitive impairment due to Alzheimer's. A decision by FDA is expected later this year. Committee meeting documents can be downloaded here.

- Donanemab is a humanized immunoglobulin G1 monoclonal antibody that specifically targets N-terminally truncated pyroglutamate-modified amyloid.

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of antibody therapeutics and those that are approved or in regulatory review in any country can be found in our searchable online tables.

Antibody News You Should Know | June 15 - July 1, 2024

Topics

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Business News

On June 20, 2024, **Yellowstone Biosciences launched** to unlock a new class of therapeutically targetable, frequently expressed antigens with potential to significantly transform patient lives. Syncona Limited committed £16.5 million to fund the Company in progressing its operational build, lead program in acute myeloid leukemia, and exploration into expanding its pipeline.
Spun out of the University of Oxford with the support of Oxford University Innovation, Yellowstone is built around the pioneering research of Professor Paresh Vyas. Yellowstone has been formed to develop soluble bispecific TCR-based therapeutics targeting HLA Class II presented peptides on the surface of cancer cells in a number of cancers with high unmet need.

On June 25, 2024, IPA (ImmunoPrecise Antibodies) announced that its subsidiary, BioStrand, is collaborating with PGxAI to leverage BioStrand's Foundation AI Model, LENSai. This collaboration advances the precision medicine field of pharmacogenomics and supports LENSai Application Programming Interface commercial rollout through expanding LENSai features and market reach. Integrating pharmacogenomics with Electronic Health Records and AI offers significant potential to personalize treatments and enhance patient outcomes. A robust AI model in this field has the potential to revolutionize the $400 billion prescription drug market, significantly improving patient outcomes and driving innovation in precision medicine.

On June 27, 2024, AbbVie announced the acquisition of Celsius Therapeutics, Inc., a privately held biotechnology company pioneering new therapies for patients with inflammatory disease. Celsius' lead investigational asset is CEL383, a potential first-in-class anti-TREM1 antibody that has completed a Phase 1 clinical study for the treatment of IBD. TREM1 has been identified as a key disease driver gene in IBD, where it is expressed on inflammatory monocytes and neutrophils. In these cell types and others,

TREM1 is upstream of multiple known inflammatory pathways and acts as an amplifier of inflammation.

Event News You Should Know

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Reserve your spot now!

Register now

Phase 1 Studies Planned or Started

On June 17, 2024, Zymeworks Inc. **announced** that the United States Food and Drug Administration (FDA) cleared the investigational new drug application for ZW171, which

was engineered and optimized using the company's Azymetric™ and EFECT™4 technologies. Zymeworks expects to file applications seeking regulatory permission to commence clinical studies for ZW171 in other jurisdictions in the second half of 2024.

- ZW171 is a novel 2+1 T cell-targeting bispecific antibody for mesothelin-expressing cancers.

On June 18, 2024, details were posted on clinicaltrials.gov for a **Phase 1 study of LY4052031** in participants with advanced or metastatic urothelial carcinoma or other solid tumors. Sponsored by Eli Lilly and Company, the study will enroll an estimated 220 patients and has an estimated start date in June 2024.

- LY4052031 is an antibody-drug conjugate (ADC) composed of a human anti-Nectin-4 antibody conjugated to a novel topoisomerase 1 inhibitor by a cleavable peptide linker at a homogeneous drug-to-antibody ratio of 8:1.

On June 20, 2024, details were posted on clinicaltrials.gov for a **Phase 1 study of SGN-MesoC2** Sponsored by Seagen, which was acquired by Pfizer in 2023, the study will assess the safety, tolerability, pharmacokinetics (PK), and antitumor activity of SGN-MesoC2 in subjects with advanced solid tumors. The study will enroll an estimated 365 patients and has an estimated start date in Aug 2024.

- SGN-MesoC2 (PF-08052666) is an ADC composed of an anti-mesothelin antibody conjugated to a topoisomerase 1 inhibitor.

On June 21, 2024, details were posted on clinicaltrials.gov for a **first-in-human study of AZD5148** administered by intramuscular injection to healthy adults. Sponsored by AstraZeneca, the study will enroll an estimated 84 patients and has an estimated start date in June 2024.

- AZD5148 is an anti-Clostridioides difficile toxin B monoclonal antibody targeting a region within the glucosyltransferase domain.

On June 28, 2024, details were posted on clinicaltrials.gov for a **Phase 1 study of TEV-56278** as a monotherapy and in combination with pembrolizumab in participants with selected locally advanced or metastatic solid tumors. Sponsored by Teva Pharmaceuticals, the study will enroll an estimated 240 participants and has an estimated start date in July 2024.

- TEV-56278 is reported to be an anti-PD1-IL2 drug derived from Teva's Attenukine technology, which utilizes an attenuated form of interferon-alpha.

On June 18, 2024, Spyre Therapeutics, Inc. **announced** that it has initiated dosing of healthy volunteers in its first clinical trial of SPY001. The SPY001 Phase 1 trial (**NCT06448247**) is a double blind, placebo-controlled study in healthy volunteers and consists of a single-ascending dose (SAD) component and a multi-ascending dose (MAD) component. The study is expected to enroll approximately 48 healthy adult participants into four SAD cohorts and two MAD cohorts. The primary endpoint is safety, with PK serving as a secondary endpoint. Interim safety and PK data from this trial is expected by year-end 2024.

- SPY001 is an investigational, half-life extended, anti-α4β7 monoclonal antibody.

On June 20, 2024, Tubulis GmbH announced that the first patient has been treated in its first Phase 1/2a trial (NAPISTAR 1-01, **NCT06303505**). The study is evaluating Tubulis' next-generation ADC TUB-040 in patients with platinum-resistant high-grade ovarian cancer or relapsed/refractory adenocarcinoma non-small cell lung cancer, who have exhausted other available treatment options. The study aims to investigate the safety, tolerability, PK, and efficacy of TUB-040 as a monotherapy.

- TUB-040 is composed of a humanized, Fc-silenced IgG1 antibody targeting Napi2b conjugated to the topoisomerase I inhibitor exatecan using a cleavable linker

system.

Phase 3 Study News

On June 17, 2024, **iTeos Therapeutics, Inc. and its development partner GSK announced** that they initiated the first, global Phase 3 registration study of belrestotug + dostarlimab doublet versus placebo + pembrolizumab in patients with previously untreated, unresectable, locally advanced or metastatic PD-L1 selected non-small cell lung cancer (NSCLC). The trial will enroll approximately 1,000 patients with previously untreated, unresectable, locally advanced or metastatic PD-L1 selected NSCLC in North America, South America, Europe, and Asia.

- Belrestotug (EOS-448) is a human IgG1 mAb against the TIGIT receptor.

On June 23, 2024, Novo Nordisk **announced** results from the Phase 3 FRONTIER2 trial of 254 adults and adolescents aged 12 years and over with hemophilia A, with and without inhibitors. The trial assessed both once-weekly and once-monthly prophylactic treatment with the investigational treatment Mim8. Mim8 demonstrated superior reductions in annualized bleeding rate compared to on-demand and prior prophylaxis treatment in people with hemophilia A. Contingent on regulatory interactions, Novo Nordisk aims to submit Mim8 for the first regulatory approval towards the end of 2024.

- Mim8 is a bispecific FVIII mimetic antibody that bridges FIXa and FX on platelets, enhancing FX activation and thereby coagulation. Development of Mim8 utilized Genmab's Duobody® platform to initially screen for compatible anti-FIXa and anti-FX antibodies followed by several iterations of systematic mutational optimization.

Regulatory Agency News

Fast track designations granted

On June 24, 2024, BioNTech SE and Duality Biologics announced that the FDA granted Fast Track designation for BNT324/DB-1311 for the treatment of patients with advanced/unresectable, or metastatic castration-resistant prostate cancer who have progressed on or after standard systemic regimens. BNT324/DB-1311 is currently being evaluated in an ongoing Phase 1/2 study (**NCT05914116**) in patients with advanced solid tumors.

- BNT324/DB-1311 is a next-generation ADC candidate targeting the transmembrane glycoprotein B7-H3, an immune checkpoint protein which is overexpressed in a range of tumor types and has been associated with disease progression and poor prognosis for patients.

On June 26, 2024, Vir Biotechnology, Inc. **announced** that the FDA granted Fast Track designation for the combination of tobevibart and elebsiran for the treatment of chronic hepatitis delta infection. Tobevibart and elebsiran, an investigational small interfering ribonucleic acid, are currently being evaluated in the Phase 2 SOLSTICE hepatitis delta clinical trial, with complete 24-week treatment data on track to be reported in the fourth quarter.

- Tobevibart (VIR-3434) is an HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes, and also to reduce the level of virions and subviral particles in the blood. It has been Fc engineered to include the XX2 “vaccinal mutation,” for which Vir has licensed exclusive rights for all infectious diseases. The vaccinal mutations incorporated into the Fc domain of VIR-3434 act in concert to potentially trigger the correct Fc gamma receptors on dendritic cells, resulting in their maturation.

On June 27, 2024, Abdera Therapeutics **announced** that the FDA granted Fast Track designation to ABD-147 for the treatment of patients with extensive stage small cell lung cancer (SCLC) who have progressed on or after platinum-based chemotherapy. In the second half of 2024, Abdera plans to initiate a first-in-human Phase 1 clinical trial with ABD-147 in patients with SCLC or large cell neuroendocrine carcinoma who previously received platinum-based therapy.

- ABD-147 is a next-generation precision radiopharmaceutical biologic therapy designed to deliver Actinium-225 to solid tumors expressing DLL3, a protein found on the surface of neuroendocrine tumors, but rarely expressed on the surface of normal cells or tissues.

Regulatory agency actions

On June 26, 2024, **Daiichi Sankyo announced** that the FDA issued a Complete Response Letter (CRL) for the Biologics License Application seeking accelerated approval of Daiichi Sankyo and Merck's (known as MSD outside of the United States and Canada) patritumab deruxtecan for the treatment of adult patients with locally advanced or metastatic EGFR-mutated NSCLC previously treated with two or more systemic therapies. The CRL results from findings pertaining to an inspection of a third-party manufacturing facility. The CRL did not identify any issues with the efficacy or safety data submitted.

- Patritumab deruxtecan is a specifically engineered potential first-in-class HER3-directed DXd ADC discovered by Daiichi Sankyo and being jointly developed by Daiichi Sankyo and Merck.

On June 20, 2024, the **FDA approved** Roche's PIASKY (crovalimab-akkz), a complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria and body weight of at least 40 kg. Developed by Chugai Pharmaceutical Co., Ltd., PIASKY is manufactured by Genentech.

- Crovalimab is an anti-C5 recycling monoclonal antibody designed to block the complement system.

On June 21, 2024, **argenx SE announced** that the FDA approved VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo is approved for CIDP as a once weekly 30-to-90 second subcutaneous injection. It is the first and only neonatal Fc receptor (FcRn) blocker approved for the treatment of CIDP. VYVGART and VYVGART Hytrulo were previously approved by FDA for treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive.

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

On June 28, 2024, Regeneron Pharmaceuticals, Inc. **announced** that the European Medicines Agency's Committee for Medicinal Products for Human Use has adopted a positive opinion recommending conditional marketing authorization of odronextamab to treat adults with relapsed/refractory (R/R) follicular lymphoma or R/R diffuse large B-cell lymphoma, after two or more lines of systemic therapy. Summaries of positive opinion are published without prejudice to the European Commission decision, which will normally be issued 67 days from adoption of the opinion.

- Odronextamab is an CD20xCD3 bispecific antibody designed to bridge CD20 on cancer cells with CD3-expressing T cells to facilitate local T-cell activation and cancer-cell killing.

On July 1, 2024 AstraZeneca **announced** that their Marketing Authorisation Application for anti-SARS-CoV-2 sipavibart has been accepted under an accelerated assessment procedure by the European Medicines Agency, for the pre-exposure prophylaxis (prevention) of COVID-19 in immunocompromised patients. The submission was based on positive SUPERNOVA Phase 3 trial data, which demonstrated a statistically significant

reduction in the incidence of COVID-19 in an immunocompromised patient population. Sipavibart was discovered by RQ Biotechnology, then licensed and further developed by AstraZeneca as AZD3152,

- Sipavibart, which was isolated from vaccinated volunteers after they had an Omicron-BA.1 infection, has broad and potent neutralizing activity across all known SARS-CoV-2 variants.

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.