From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, May 6, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know

Antibody News You Should Know

April 15 - May 1, 2019

Antibody-based therapeutics are entering clinical study at a rate of ~120 per year, and being approved in record numbers. Recent news about relevant events are summarized below. Follow the links to find more details.

New (or close!) to the clinic: Antibody-based therapeutics that recently entered clinical studies or will soon

Innovent Biologics, Inc., a world-class biopharmaceutical company that develops and commercializes high quality medicines, announced that the first patient in China has been successfully dosed in a **Phase I clinical trial of IBI318**.

- IBI318 is a recombinant fully human bispecific antibody targeting programmed cell death receptor-1 (PD-1) and programmed cell death ligand-1 (PD-L1).
- Innovent Biologics, is developing IBI318 in collaboration with Eli Lilly and Company.

Innovent Biologics, Inc. also announced that the first patient has been successfully dosed in a **Phase I clinical trial of IBI302** as a treatment of wet age-related macular degeneration (wet AMD).

- IBI302 is a novel recombinant fully human bispecific fusion protein targeting both vascular endothelium growth factor (VEGF) and complement proteins

GEMoaB Monoclonals GmbH has initiated a multicenter, open-label, dose-escalating, **Phase I trial with GEM3PSCA** in patients with progressive disease after standard systemic therapy in cancers with positive PSCA marker.

- GEM3PSCA is a prostate stem cell antigen-targeted bispecific antibody engaging T-cells

Harpoon Therapeutics, Inc., a clinical-stage immunotherapy company developing a novel class of T cell engagers, announced today that the first patient has been dosed with **HPN536 in a Phase 1/2a clinical trial initially focused on ovarian cancer**.

- HPN536 targets mesothelin, which is expressed on malignant cells of ovarian and pancreatic carcinoma, mesothelioma, non-small cell lung cancer and breast cancer.
- HPN536 is Harpoon's second product candidate to enter the clinic and is based on Harpoon's proprietary Tri-specific T cell Activating Construct (TriTAC™) platform.

Molecular Templates, Inc., a clinical stage biopharmaceutical company focused on the discovery and development of Engineered Toxin Bodies (ETBs), a new class of targeted biologic therapies that possess unique mechanisms of action in oncology, announced that the U.S. FDA has accepted its Investigational New Drug (IND) application for **MT-5111, an ETB targeting HER2**.

- Molecular Templates expects to start dosing in a Phase I study in relapsed/refractory patients with HER2-positive solid tumors in 3Q19.

New (or close!) to the market: Antibody-based therapeutics recently approved or that may be soon

The US **Food and Drug Administration (FDA) approved risankizumab-rzaa (SKYRIZI)** to treat moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

- More information about risankizumab-rzaa and other novel drugs approved by FDA's Center for Drug Evaluation and Research during 2019 can be found **here**.

The European Medicines Agency's human medicines committee (CHMP)

recommended 13 medicines for approval at its April 2019 meeting, including cemiplimab and ravulizumab. In the EU, approvals are granted by the European Commission. Summaries of CHMP's positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

- The CHMP recommended the granting of a conditional marketing authorisation for **Libtayo (cemiplimab)** for the treatment of advanced cutaneous squamous cell carcinoma.
- The EU orphan drug-designated medicine **Ultomiris (ravulizumab)** received a positive opinion from the CHMP for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria.

Novartis announced that the US FDA accepted the company's **biologics license application (BLA) for brolucizumab** (RTH258) for the treatment of wet age-related macular degeneration (AMD), also known as neovascular AMD, or nAMD. Seeking to make brolucizumab available as quickly as possible, Novartis used a priority review voucher to expedite FDA review.

- If approved by the FDA, Novartis anticipates launching brolucizumab by the end of 2019.

Alder announced its **BLA submission for eptinezumab**, the company's investigational monoclonal antibody for migraine prevention targeting the calcitonin gene-related peptide and lead commercial candidate, was accepted by the FDA.

- The FDA has set the Prescription Drug User Fee Act target action date of February 21, 2020. The BLA includes, and is supported by, positive data from Alder's PROMISE 1 and PROMISE 2 Phase 3 clinical trials, open-label safety study, pharmacokinetic comparability study and chemistry, manufacturing, and controls data packages.

Other news

FDA granted supplemental approvals to Benlysta, Praluent, and KEYTRUDA.

- GSK announced that the US FDA has approved, under priority review, the use of the intravenous (IV) formulation of **Benlysta (belimumab), a B-lymphocyte stimulator (BLyS)-specific inhibitor, in children with lupus** from as young as five years of age.
- The FDA has approved **Praluent® (alirocumab) to reduce the risk of heart attack, stroke, and unstable angina requiring hospitalization** in

adults with established cardiovascular disease.

- Merck, known as MSD outside the United States and Canada, announced that the U.S. FDA has approved **KEYTRUDA (pembrolizumab) in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma**. The approval is based on findings from the pivotal Phase 3 KEYNOTE-426 trial, which demonstrated significant improvements in overall survival, progression-free survival and objective response rate for KEYTRUDA in combination with axitinib (KEYTRUDA-axitinib combination) compared to sunitinib.

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From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, May 20, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know - May 1-15, 2019

Antibody News You Should Know

May 1 - 15, 2019

Antibody-based therapeutics are entering clinical study at a rate of ~120 per year, and being approved in record numbers. Recent news about relevant events are summarized below. Follow the links to find more details.

New (or close!) to the clinic: Antibody therapeutics that recently entered clinical studies or will soon

Merus N.V. announced that the first patient has been treated in its Phase 1 trial evaluating the safety, tolerability, and preliminary efficacy of MCLA-145 for the treatment of patients with advanced solid tumors. MCLA-145 is a full-length human IgG1 bispecific antibody that targets PD-L1 and CD137.

- MCLA-145 is being developed in collaboration with Incyte.

Xencor, Inc. announced that the first patient has been treated in a Phase 1 multiple-dose study (DUET-3) to evaluate the safety and tolerability of XmAb®23104 in patients with selected advanced solid tumors. XmAb®23104 is

a bispecific antibody that simultaneously targets the immune receptors PD-1 and ICOS.

Teneobio, Inc. and its affiliate TeneoOne, Inc. announced that their investigational new drug application for TNB-383B was cleared for the initiation of Phase 1 clinical studies by the US Food and Drug Administration. TNB-383B is a fully human bispecific antibody with two binding moieties for B-cell maturation antigen on one arm and a unique anti-CD3 on the other.

- The ongoing development of TNB-383B is being pursued in collaboration with AbbVie, Inc.

Antibody therapeutics in late-stage clinical studies

AstraZeneca and Daiichi Sankyo Company, Limited announced that the pivotal Phase 2 DESTINY-Breast01 trial (NCT03248492) of the anti-HER2 antibody-drug conjugate (ADC) trastuzumab deruxtecan (DS-8201) met its primary endpoint. The ADC was evaluated in patients with HER2-positive, unresectable and/or metastatic breast cancer previously treated with trastuzumab emtansine.

- The study results support a global regulatory submission plan to start in the second half of 2019.

MorphoSys AG and I-Mab Biopharma announced that the first patient has been dosed in a Phase 3 randomized and multi-center clinical study in Taiwan to evaluate MOR202/TJ202 in combination with lenalidomide in patients with relapsed or refractory multiple myeloma. MOR202 is an anti-CD38 human monoclonal antibody derived from MorphoSys's HuCAL antibody technology.

- I-Mab has exclusive rights for development and commercialization of MOR202/TJ202 in China, Taiwan, Hong Kong and Macao.

First approval for netakimab

On May 7, 2019, **BIOCAD announced the registration of netakimab (Efleira®, BCD-085) in Russia** for the treatment of moderate to iasis. Netakimab is a humanized IgG1 monoclonal antibod he VH domain is rep aced by a Lama glama VHH doma in complementarity-determining

egion (CDR-H3). The mAb n (IL)-17, a pro-inflammatory cytokine that plays a cr pathogenesis of psoriasis. The registration is the first for developed in Rus ia. The efficacy and safety of Efleira® in was confirmed in the Phase 3 BC -085-7/PLANETA study (NCT03 ducted in 22 certified study sites in Russi and 2 stu public of Belarus. After 12 weeks of the treatment, 83.3% of atients who received netakimab once a month after induction for the first 3 weeks achieved a 75% improvement in Psoriasis Area and Severity Index. The total duration of therapy and follow-up in this study is 3 years.

- BIOCAD, which is based in Moscow, is planning to start a pivotal clinical trial of netakimab in psoriasis in Europe later in 2019.

Other news

The US Food and Drug Administration granted ramucirumab (Cyramza®) approval as a monotherapy for hepatocellular carcinoma (HCC) in patients with alpha-fetoprotein levels of 400 nanograms per milliliter or higher who were previously treated with sorafenib. Cyramza is the first biomarker-driven therapy approved by the FDA as an HCC treatment. Approval was based on results of the REACH-2 study (NCT02435433). The trial's primary endpoint was overall survival (OS). The estimated median OS was 8.5 months (7.0, 10.6) for patients receiving ramucirumab and 7.3 months (5.4, 9.1) for those receiving placebo (HR 0.71; 95% CI: 0.53, 0.95; p=0.020).

- Cyramza was previously approved in the US for advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma; metastatic non-small cell lung cancer; and metastatic colorectal cancer.

The European Commission approved a new indication for Dupixent® (dupilumab) in asthma. Dupixent is now approved in the European Union (EU) for use in adults and adolescents 12 years and older as an add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised fractional exhaled nitric oxide, who are inadequately controlled with high dose inhaled corticosteroid plus another medicinal product for maintenance treatment.

- Dupixent was previously approved in the EU for moderate to severe atopic dermatitis.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, June 3, 2019 3:03 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: May 15 to June 1, 2019

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Antibody News You Should Know

May 15- June 1, 2019

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New to the clinic

A Phase 1 study (NCT03881488) of **CTX-471** monotherapy in patients with metastatic or locally advanced malignancies that have progressed while receiving an approved PD-1 or PD-L1 inhibitor started recruiting May 17, 2019.

- CTX-471 is a human, IgG4 agonist antibody of CD137 developed by Compass Therapeutics.

Antibodies in late-stage clinical studies

United BioPharma announced that the company plans to conduct a Phase 2/3 clinical trial (NCT03164447) with **UB-421** in the U.S., under the protocol entitled "A Multicenter, Single-Arm, 24-Week Study of UB-421 in Combination with Optimized Background Therapy (OBT) Regimen in Patients with Multi-Drug Resistant (MDR) HIV-1 Infection." The study's estimated start date is September 2019.

- UB-421 is an Fc-aglycosylated, non-T cell depleting and CD4-specific humanized IgG1 derived from the parent murine B4, which binds to discontinuous, conformational epitopes on the HIV-receptor complex, including CD4 (domain 1), and competitively blocks HIV entry.

Viela Bio, Inc. and Hansoh Pharmaceutical Group Company Limited announced a collaboration focused on development and commercialization of **inebilizumab** in China for neuromyelitis optica spectrum disorder, as well as other potential inflammation/autoimmune and hematologic malignancy indications. Viela expects to file for a Biologics License Application with the U.S. Food and Drug Administration in mid-2019.

- Inebilizumab is a humanized monoclonal antibody that binds with high affinity to CD19, a protein expressed on a broad range of B cells, including antibody-secreting plasmablasts and plasma cells.

Sesen Bio, a Cambridge, MA-based company developing **Vicinium®** for non-muscle invasive bladder cancer (NMIBC), announced that the Company has completed its Type C CMC meeting and has reached agreement with the U.S. Food and Drug Administration on the Analytical Comparability Plan, and that, subject to final comparability data to be provided in the BLA submission, no additional clinical trials to establish comparability are deemed necessary at this time. The on-going Phase 3 VISTA trial is designed to support the registration of Vicinium for the treatment of high-risk NMIBC in patients who have previously received a minimum of two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive.

- Vicinium (oportuzumab monatox) is composed of a humanized single-chain antibody variable fragment specific for the epithelial cell adhesion molecule antigen linked to ETA(252-608) Pseudomonas exotoxin

ImmunoGen announced the U.S. Food and Drug Administration has recommended that the Company conduct a new Phase 3 randomized trial to evaluate the safety and efficacy of **mirvetuximab soravtansine** in patients with high folate receptor alpha (FRα)-positive, platinum-resistant ovarian cancer as part of a Type C meeting. The agency advised that, because the Phase 3

FORWARD I study did not meet its primary endpoint under the pre-specified statistical analysis plan, the data generated assessing the secondary endpoints from the study could not be used to support an application for accelerated approval.

- Mirvetuximab soravtansine is an antibody-drug conjugate (ADC) composed of a humanized FRα-binding antibody and a potent anti-tumor agent, DM4, that kills targeted cancer cells.

AbbVie announced the Phase 3 INTELLANCE-1 study of the ADC **depatuxizumab mafodotin** in patients with newly diagnosed glioblastoma (GBM), whose tumors have epidermal growth factor receptor (EGFR) amplification, demonstrated no survival benefit for patients receiving the ADC at an interim analysis. An Independent Data Monitoring Committee recommended the study be stopped. No new safety findings were observed. Enrollment in all ongoing depatuxizumab mafodotin studies has been halted.

- Depatuxizumab mafodotin is composed of an anti-EGFR antibody and the drug monomethyl auristatin F.

Antibodies in regulatory review

Theratechnologies Inc. announced that the European Medicines Agency (EMA) has allowed the company an additional month to address new questions regarding the establishment of a post-approval registry to gather long-term data on patients taking **Trogarzo® (anti-CD4 ibalizumab**) in Europe.

- Theratechnologies will submit responses to the EMA by the end of June 2019, and their recommendation, either positive or negative, regarding the approval for the commercialization of Trogarzo® in Europe is expected within 30 days.

Other news

Zymeworks Inc. announced that the U.S. Food and Drug Administration granted Fast Track designation to **ZW25** for the first-line treatment of patients with HER2-overexpressing gastroesophageal adenocarcinoma in combination with standard of care chemotherapy. ZW25 was previously granted U.S. Orphan Drug designation for the treatment of both gastric and ovarian cancers.

- ZW25 a novel Azymetric™ bispecific antibody that binds two non-overlapping epitopes of human growth factor receptor 2.

Affimed N.V. announced a plan to focus its research and development investments on advancing on-going and previously announced clinical trials for its innate cell engager candidates, **AFM13 (CD30/CD16A) and AFM24 (EGFR/CD16A).** A Phase 2 registration-directed study of AFM13 as monotherapy in relapsed or refractory patients with peripheral T cell lymphoma and transformed mycosis fungoides is planned for H2 2019 pending agreement with the U.S. Food and Drug Administration on the final study protocol.

- Affimed will terminate the Phase 1 clinical program of AFM11, a CD19/CD3-targeting bispecific T cell engager.

Merrimack Pharmaceuticals announced an asset purchase agreement with 14ner Oncology, Inc., a newly formed biotechnology company backed by a prominent venture capital firm, to sell the Company's anti-HER3 monoclonal antibody programs, **MM-121 and MM-111**.

- Discovery efforts on Merrimack's remaining preclinical programs, MM-201 and MM-401, will be discontinued.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, June 17, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News June 1-15, 2019

Antibody News You Should Know

June 1-15, 2019

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Clinical studies expected to start soon

BioInvent International AB announced the submission to the U.S. Food and Drug Administration (FDA) of an investigational new drug application for a Phase 1/2a clinical trial of an immune-modulatory anti-FcγRIIB antibody in combination with an anti-programmed cell death 1 antibody in solid tumors.

Oncologie announced that it will initiate a global proof-of-concept gastric cancer study with its lead compound, bavituximab, in combination with pembrolizumab (Keytruda). In February 2018, **Avid Bioservices, Inc. and Oncologie, Inc.** announced that the companies had entered into an asset assignment and purchase agreement for Avid's phosphatidylserine (PS)-targeting program including bavituximab.

- Bavituximab is a chimeric IgG1 immune-modulatory monoclonal antibody targeting PS, a phospholipid that inhibits the ability of immune cells to recognize and fight tumors.

New to the clinic

Xencor, Inc. announced that the first patient has been dosed in a Phase 1 clinical study (**NCT03849469**) to evaluate the safety and tolerability of XmAb22841, both as a monotherapy and in combination with pembrolizumab, in patients with advanced solid tumors.

- XmAb22841 is a bispecific antibody that targets immune checkpoint receptors CTLA-4 and LAG-3 and is designed to promote tumor-selective T-cell activation. XmAb bispecific Fc domains have been engineered to eliminate FcγR binding, with the intent to prevent activation or depletion of T cells via engagement by FcγR-expressing cells.

Phase 2 studies started

Innate Pharma SA announced that it has enrolled the first patient in the TELLOMAK Phase 2 study (**NCT03902184**) of IPH4102. This open label, multicohort, multi-center study will evaluate the efficacy and safety of IPH4102 alone or in combination with chemotherapy in patients with different types of advanced T-cell lymphoma, including the cutaneous T-cell lymphoma (CTCL) subtype Sézary syndrome. FDA granted Innate Pharma Fast Track designation for IPH4102 for the treatment of adult patients with relapsed or refractory Sézary syndrome who have received at least two prior systemic therapies, and IPH4102 was granted orphan drug status in the European Union and in the United States for the treatment of CTCL.

- IPH4102 is a humanized anti-KIR3DL2, cytotoxicity-inducing antibody. KIR3DL2 is an inhibitory receptor of the KIR family, expressed by approximately 65% of patients across all CTCL subtypes and expressed by up to 85% of them with certain aggressive CTCL subtypes, in

particular, Sézary syndrome.

Corvidia Therapeutics Inc. announced the initiation of patient screening for a Phase 2b dose-finding study of ziltivekimab. The Phase 2b, randomized, double-blind, placebo-controlled trial (**NCT03926117**) will evaluate reduction in inflammation in patients with advanced chronic renal disease. The trial explores three doses (7.5 mg, 15 mg and 30 mg) of ziltivekimab administered subcutaneous monthly.

- Ziltivekimab is a human IgG1 anti-interleukin-6 ligand monoclonal antibody targeting residual inflammatory cardiovascular risk in patients living with advanced chronic kidney disease.

Biologics license application submission planned

Sesen Bio announced that that it completed a successful Type B Pre-Biologics License Application (BLA) meeting regarding the approval path for Vicinium® for the treatment of patients with high-risk, Bacillus Calmette-Guérin unresponsive, non-muscle invasive bladder cancer. The Company has reached alignment with the FDA on an Accelerated Approval Pathway for Vicinium along with Rolling Review, and the Company expects to initiate submission of the BLA in the fourth quarter of 2019. The FDA also indicated that the nonclinical data, the clinical pharmacology data, and the safety database are sufficient to support a BLA submission, and that no additional clinical trials are necessary for a BLA submission.

- Vicinium (oportuzumab monatox) is composed of a humanized single-chain antibody variable fragment specific for the epithelial cell adhesion molecule antigen linked to ETA(252-608) Pseudomonas exotoxin.

First FDA approval for ADC Polivy

On June 10, 2019, the **FDA granted accelerated approval to Polivy** (polatuzumab vedotin-piiq), in combination with the chemotherapy bendamustine and a rituximab product (BR), to treat adult patients with diffuse large B-cell lymphoma (DLBCL) that has progressed or returned after at least two prior therapies. The biologics license application for Polivy was granted FDA's Breakthrough Therapy and priority review designations. The drug also has European Medicines Agency (EMA)'s PRIME designation, and US and EU Orphan Drug designations for DLBCL. EMA is reviewing a marketing authorization application for Polivy.

- Polivy is composed of a humanized anti-CD79b IgG1 antibody conjugated to the antimitotic agent monomethyl auristatin E. The antibody's target is highly expressed on B cells of patients with lymphoma.

Other news

On June 4, 2019, **FDA approved Emgality®** (galcanezumab-gnlm) solution for injection for the treatment of episodic cluster headache in adults. The effectiveness of Emgality for the treatment of episodic cluster headache was demonstrated in a clinical trial that compared the drug to placebo in 106 patients. The trial measured the average number of cluster headaches per week for 3 weeks and compared the average changes from baseline in the Emgality and placebo groups. During the 3-week period, patients taking Emgality experienced 8.7 fewer weekly cluster headache attacks than they did at baseline, compared to 5.2 fewer attacks for patients on placebo.

- Emgality is a humanized IgG4 anti-calcitonin gene related peptide antibody that was first approved by the FDA in September 2018 for the preventive treatment of migraine in adults.

Genentech announced that FDA has accepted the company's supplemental BLA and granted Priority Review for the use of Rituxan® (rituximab), in combination with glucocorticoids, for the treatment of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in children two years of age and older. GPA and MPA are rare, potentially life-threatening diseases affecting small and medium sized blood vessels.

- Rituxan® is a chimeric anti-CD20 antibody therapeutic that was first approved by FDA in 1997. Rituxan is currently indicated for the treatment of 4 autoimmune indications. The FDA approved Rituxan for rheumatoid arthritis (RA) in 2006, for the treatment of adults with GPA and MPA in 2011, and for adults with pemphigus vulgaris in 2018.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, July 1, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News June 15-July 1, 2019

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Antibody News You Should Know

June 15-July 1, 2019

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First clinical studies expected soon

On June 27, 2019, **ImmunoGen announced** that it will advance two antibody-drug conjugates (ADCs): IMGC936, which is in co-development with MacroGenics with an Investigational New Drug (IND) application expected by the end of 2019; and the Company's next-generation anti-folate receptor alpha

(FRα) ADC, which is expected to enter development in mid-2020.

- **IMGC936** is an ADAM9-targeted, high-affinity humanized antibody site-specifically conjugated to DM21, a next-generation linker-payload that combines a maytansinoid microtubule disrupting payload with a stable peptide linker. The M252Y/S254T/T256E (YTE) mutation was introduced into the CH2 domain of the antibody to increase in vivo plasma half-life and exposure.

June 26, 2019 is the estimated start date for a **Phase 1/2 study of REGN5678** with cemiplimab (anti-PD-1) in patients with metastatic castration-resistant prostate cancer. The study is not yet recruiting patients.

- Regeneron's REGN5678 is a bispecific antibody targeting prostate-specific membrane antigen and CD28.

On June 18, 2019, **Alligator Bioscience announced** that the company has submitted a clinical trial authorization application to initiate a Phase 1 study of its fully owned anti-4-1BB antibody ATOR-1017 for the treatment of metastasizing cancer. The upcoming Phase 1 study will be conducted at 3 sites in Sweden.

- ATOR-1017 is an immunostimulatory IgG4 antibody that activates tumor-specific T cells and natural killer cells through the costimulatory receptor 4-1BB.

On June 17, 2019, **Molecular Templates, Inc. announced** that the U.S. Food and Drug Administration (FDA) has accepted the IND application for TAK-169. Molecular Templates and partner Takeda Pharmaceutical Company Limited are co-developing TAK-169 and plan to conduct an open label Phase 1 dose escalation and expansion study in relapsed/refractory multiple myeloma patients.

- TAK-169 is an Engineered Toxin Body comprising an anti-CD38 single-chain variable fragment conjugated to the enzymatically active, deimmunized Shiga-like toxin A subunit.

Supplemental approvals in the US

On June 27, 2019, **FDA approved anti-C5 antibody Soliris**® (eculizumab) injection for intravenous use for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody

positive. Soliris was first approved in the US in March 2007 for treatment of paroxysmal nocturnal hemoglobinuria to reduce hemolysis of red blood cells.

On June 27, 2019, **FDA approved anti-CD38 antibody DARZALEX®** (daratumumab) in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. DARZALEX® was first approved in the US in November 2015 for treatment of patients with multiple myeloma who have received at least 3 prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent or are double refractory to a proteasome inhibitor and an immunomodulatory agent.

- The application received approval through the U.S. FDA Oncology Center of Excellence's **Real-Time Oncology Review pilot program**. This program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality and balancing the review team's workload through data and analysis standardization, and early iterative engagement with the applicant.

On June 26, 2019, **FDA approved anti-IL-4 receptor alpha antibody Dupixent®** (dupilumab) to treat adults with nasal polyps accompanied by chronic rhinosinusitis, which is characterized by prolonged inflammation of the sinuses and nasal cavity. Dupixent was first approved in the US in March 2017 for patients 12 and older with atopic dermatitis that is not controlled adequately by topical therapies or when those therapies are not advisable.

On June 17, 2019, **FDA granted accelerated approval to anti-PD-1 KEYTRUDA®** (pembrolizumab) for patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy. Pembrolizumab was granted US orphan drug designation for SCLC in October 3, 2017. KEYTRUDA® was first approved in the US in September 2014 for treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.

Other news

On June 27, 2019, **ImmunoGen announced** that it will initiate a registration study for mirvetuximab soravtansine as a monotherapy for women with FRα-high, platinum-resistant ovarian cancer by the end of this year, complete

enrollment and continue follow up in the ongoing FORWARD II mirvetuximab combination cohorts, and reduce ongoing expenses through portfolio prioritization and restructuring initiatives, including:

- Discontinuation of the development of IMGN779 in adults with relapsed/refractory CD33-positive AML;
- Reduction of its workforce by approximately 220 employees

On June 25, 2019, Bayer Healthcare LLC was granted a US Orphan Drug designation for human monoclonal IgG2 antibody against tissue factor pathway inhibitor (TFPI) for treatment of hemophilia B. A US Orphan Drug designation for hemophilia A was granted on March 25, 2019.

- **BAY1093884** is a human IgG2 antibody with <10 pM binding affinity to human and murine TFPI derived from a human phage-displayed antibody library. It is undergoing evaluation in adults with hemophilia A or B with or without inhibitors.

On June 25, 2019, **AbbVie Inc. and Allergan announced** that the companies have entered into a definitive transaction agreement under which AbbVie will acquire Allergan in a cash and stock transaction for a transaction equity value of approximately $63 billion, based on the closing price of AbbVie's common stock of $78.45 on June 24, 2019.

- Allergan is currently developing brazikumab for moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis. A Phase 2/3 study (NCT03759288) in Crohn’s disease was started in December 2018; a Phase 3 open-label, long-term extension study of brazikumab in participants with Crohn's disease (NCT03961815) is not yet recruiting patients.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, July 15, 2019 3:11 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News July 1-15, 2019

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July 1-15, 2019

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New to the clinic

NGM Biopharmaceuticals, Inc. has started a Phase 1 study (**NCT04014777**) of NGM621 in patients with geographic atrophy secondary to age-related macular degeneration. The study will assess the safety, tolerability, and pharmacokinetics of single-dose and multiple-doses of intravitreal injections of

NGM621.

- NGM621 is a long-acting antibody binding an undisclosed target, designed to decrease levels of a protein implicated in the dry form of age-related macular degeneration.

Phase 2 study results

On July 5, 2019, safety and efficacy results from the randomized, placebo-controlled Phase 2 study (NCT01864148) of opicinumab (BIIB033) in patients with relapsing multiple sclerosis were **published online in The Lancet Neurology**. Cadavid et al. reported that their findings did not show a significant dose-linear improvement in disability compared with placebo in patients with relapsing multiple sclerosis.

- Opicinumab is a human aglycosyl IgG1 monoclonal antibody targeting LINGO-1, an inhibitor of oligodendrocyte differentiation and axonal regeneration.

Phase 3 program started

On July 3, 2019, **GSK announced the start of a Phase 3 clinical development program with otilimab** for patients with moderate to severe rheumatoid arthritis who have had an inadequate response to disease modifying antirheumatic drugs or targeted therapies. The program comprises three pivotal studies (contRAst-1, -2, -3 and -X) and a long-term extension study that will compare otilimab against two treatments with different modes of actions: tofacitinib (a Janus Kinase (JAK) inhibitor) and sarilumab (an anti-IL6 antibody).

- Otilimab is a human IgG1 antibody targeting granulocyte macrophage colony-stimulating factor.
- The contRAst-1 (**NCT03980483**; 201790) and contRAst-2 (**NCT03970837**; 201791) studies comparing otolimab to tofacitinib are recruiting patients.

Biological license applications submitted or expected soon

On July 8, 2019, **Y-mAbs announced the company had reached alignment with the US Food and Drug Administration (FDA) on an accelerated approval pathway for naxitamab** along with a rolling BLA submission for the

treatment of patients with relapsed/refractory high-risk neuroblastoma. The company expects to submit the clinical/safety and non-clinical portions of the BLA in November 2019. For the CMC portion, the Company believes it will have sufficient data from the process performance qualification batches to complete the CMC portion in early 2020.

- Naxitamab is a humanized IgG1 antibody that targets GD2.

On July 10, 2019, **Horizon Therapeutics plc announced that it has submitted a BLA to FDA for teprotumumab** for the treatment of active thyroid eye disease. Teprotumumab has Breakthrough Therapy, Orphan Drug and Fast Track designations from the FDA. Horizon requested priority review for the application, which, if granted, could result in a six-month review process. The FDA has a 60-day filing review period to determine whether the BLA is complete and acceptable for filing.

- Teprotumumab is a human IgG1 antibody that targets insulin-like growth factor 1 receptor.

On July 10, 2019, **Sanofi announced that the FDA has accepted for review the BLA for isatuximab** (SAR650984) for the treatment of patients with relapsed/refractory multiple myeloma (RRMM). The target action date for the FDA decision is April 30, 2020. Isatuximab received orphan designation for RRMM from both the FDA and the European Medicines Agency (EMA), and in the second quarter of 2019 the EMA accepted a marketing authorization application for evaluation.

- Isatuximab is a novel IgG1 antibody that binds selectively to a specific epitope on CD38.

Approvals in the European Union

On July 1, **Sanofi announced that the European Commission (EC) granted conditional marketing authorization for Libtayo®** (cemiplimab) for the treatment of adults with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation. The EC approval is based on data from the pivotal, open-label, multi-center, non-randomized Phase 2 EMPOWER-CSCC-1 trial (Study 1540) and supported by two advanced CSCC expansion cohorts from a multi-center, open-label, non-randomized Phase 1 trial (Study 1423). Libtayo® (cemiplimab-rwlc) was approved in the US for CSCC in September 2018.

- Libtayo is a human IgG4 antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1).

On July 3, 2019, **Alexion Pharmaceuticals, Inc. announced that the EC approved ULTOMIRIS®** (ravulizumab) for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) with hemolysis with clinical symptoms indicative of high disease activity, and also for adult patients who are clinically stable after having been treated with SOLIRIS® (eculizumab) for at least the past six months. The European Commission approval is based on comprehensive results from two Phase 3 studies, which were published in Blood in December 2018. FDA approved ULTOMIRIS® (ravulizumab-cwvz) for adults with PNH in December 2018.

- Ravulizumab is a humanized IgG2/4 antibody targeting the complement component 5 protein.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Friday, August 2, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: July 15 - Aug 1, 2019

Antibody News You Should Know

July 15 - August 1, 2019

Antibody-based therapeutics are advancing in clinical development at a rapid rate and being approved in record numbers. Recent news about antibody-related events are summarized below. Follow the links for more details.

New to the clinic

Patient recruitment has started for a Phase 1 study of Seattle Genetics' SGN-CD47M. **NCT03957096** is a safety study of SGN-CD47M administered intravenously (IV) to patients with solid tumors. Incidence of anti-drug antibodies is a secondary outcome measure of the study.

- As of August 1, 2019, SGN-CD47M's composition of matter has not been publicly disclosed.

Phase 2 study planned

On July 19, 2019, **Mereo BioPharma Group plc announced that it held a**

successful Type B meeting with the U.S. Food and Drug Administration (FDA) in which they discussed, and agreed in principle, an outline for the design of a Phase 2 clinical trial that could potentially support the accelerated approval of navicixizumab in patients with ovarian cancer (including peritoneal or fallopian tube cancer) who have become resistant to their prior therapies. Navicixizumab has completed a Phase 1a monotherapy study in patients with various types of refractory solid tumors and is currently being evaluated in an ongoing Phase 1b study in combination with paclitaxel in patients with advanced platinum-resistant ovarian cancer.

- Navicixizumab, an IgG2 bispecific antibody targeting DLL4 and VEGF, was acquired by Mereo through its April 2019 merger with OncoMed Pharmaceuticals, Inc.

Phase 3 studies planned or started

Patient recruitment is due to start soon for a Phase 2/ 3 study (NCT04031742) that will evaluate the safety and efficacy of IBI306, an anti- PCSK9 antibody, in Chinese patients with homozygous familial hypercholesterolemia. The estimated study start date is August 12, 2019.

- IBI306 is a human monoclonal antibody that binds proprotein convertase substilisin/kexin type 9, preventing its interaction with the low-density lipoprotein cholesterol receptor (LDL-R) and thereby restoring LDL-R recycling and low-density lipoprotein cholesterol uptake.

Patient recruitment is due to start soon for a Phase 3 study (NCT03938792) that will evaluate the efficacy and safety PF-06741086 in adult and teenage patients with severe hemophilia A or B. The estimated study start date is July 2019, although the study was listed as not yet recruiting as of July 30.

- PF-06741086 (marstacimab) is a human IgG1 antibody targeting tissue factor pathway inhibitor, which is a single-chain polypeptide that can reversibly inhibit Factor Xa.

On July 22, 2019, FibroGen, Inc. announced dosing of the first patient in the ZEPHYRUS Phase 3 clinical study (NCT03955146) of pamrevlumab in patients with idiopathic pulmonary fibrosis (IPF). This trial will evaluate the efficacy and safety of 30 mg/kg IV infusions of pamrevlumab administered every 3 weeks as compared to placebo in patients with IPF. Pamrevlumab was granted FDA's orphan drug and fast track designations for IPF.

- Pamrevlumab, a human IgG1 antibody targeting connective tissue growth factor, is also undergoing evaluation in a Phase 3 study of patients with locally advanced unresectable pancreatic cancer, and in a Phase 2 study of non-ambulatory patients with Duchenne muscular dystrophy.

Biological license applications submitted

On July 16, 2019, Seattle Genetics, Inc. and Astellas Pharma Inc. announced **submission of a biologics license application (BLA) for accelerated approval to the FDA for enfortumab vedotin** for the treatment of patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting. FDA granted enfortumab vedotin Breakthrough Therapy designation for patients with locally advanced or metastatic urothelial cancer whose disease has progressed during or following checkpoint inhibitor therapy.

- Enfortumab vedotin is an antibody-drug conjugate composed of an anti-Nectin-4 IgG1 antibody attached to a microtubule-disrupting agent, MMAE, using Seattle Genetics' proprietary linker technology.

On July 16, 2019, Novartis announced the **FDA accepted the BLA and granted Priority Review for crizanlizumab** (SEG101) for prevention of vaso-occlusive crises in patients with sickle cell disease.

- Crizanlizumab, a humanized IgG2 antibody, targets P-selectin on the surface of platelets and endothelium in the blood vessels and inhibits interactions between endothelial cells, platelets, red blood cells, sickled red blood cells, and leukocytes.

European Medicines Agency news

On July 26, 2019, Theratechnologies Inc. announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has given a **positive recommendation for the approval of Trogarzo®** (ibalizumab) for the treatment of multidrug resistant HIV-1. Summaries of CHMP's positive opinion are published without prejudice to the European Commission decision, which will normally be issued 67 days from adoption of the opinion.

- Trogarzo®, an anti-CD4 IgG4 antibody, was approved in the US in March

2018 for chronic HIV infection in patients who have not responded adequately to other treatments.

On July 26, 2019, **CHMP announced positive opinions on extensions of indications of 6 antibody therapeutics**:

- Novartis received a positive opinion for **Lucentis**® (ranibizumab) treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or aggressive posterior ROP disease.
- Roche received a positive opinion for **Tecentriq**® (atezolizumab) in combination with carboplatin and Abraxane® for the first-line treatment of adults with metastatic non-squamous non-small cell lung cancer (NSCLC) who do not have EGFR mutant or ALK-positive NSCLC, and for **Tecentriq**® in combination with carboplatin and etoposide for the first-line. treatment of adults with extensive-stage small cell lung cancer.
- Janssen received a positive opinion for **Stelara**® (ustekinumab) for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.
- Bristol-Myers Squibb received a positive opinion recommending approval of **Empliciti** (elotuzumab) in combination with pomalidomide and dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy.
- Merck Sharp & Dohme received a positive opinion recommending approval of **Keytruda** (pembrolizumab), in combination with axitinib, for the first-line treatment of advanced renal cell carcinoma in adults.
- Alexion received a positive opinion recommending approval of **Soliris**® (eculizumab) for treatment of neuromyelitis optica spectrum disorder in patients who are anti-aquaporin-4 (AQP4) antibody-positive with a relapsing course of the disease.

In June 2019, the European Medicines Agency recommended the refusal of the marketing authorization for Evenity (romosozumab), an antibody therapeutic intended for the treatment of osteoporosis. As a **July 25, 2019 update, the company that applied for authorization, UCB Pharma S.A., had requested a re-examination of the opinion**. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation.

- Romosozumab, a humanized IgG2 antibody targeting sclerostin, was approved by FDA in April 2019.

Another FDA approval for Keytruda

On July 30, 2019, the **FDA approved pembrolizumab (KEYTRUDA, Merck) for patients with recurrent, locally advanced or metastatic, squamous cell carcinoma of the esophagus** (ESCC) whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10), as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.

- Pembrolizumab is a programmed death receptor-1 (PD-1)-blocking antibody approved in the US for a total of 14 indications as of August 1, 2019. Prescribing information can be found **here**.

In other news...

A Phase 3 study (**NCT04034485**) of the Adnectin LIB003 is due to start soon. First posted on July 26, the estimated start date for the study, which will evaluate the efficacy and safety of LIB003 with evolocumab in homozygous familial hypercholesterolemia patients on stable lipid-lowering therapy, is August 12, 2019.

- **LIB003 is a 77 kDa recombinant fusion protein** consisting of an adnectin, derived from the 10th type III domain of human fibronectin and targeted with high affinity to proprotein convertase subtilisin/kexin type 9 (PCSK9), and human serum albumin.

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Antibody News You Should Know

August 1 - 15, 2019

Antibody-based therapeutics are advancing in clinical development at a rapid rate and being approved in record numbers. Recent news about antibody-related events are summarized below. Follow the links for more details.

Entering the clinic

On August 8, 2019 Agenus Inc. announced today that the US **Food and Drug Administration (FDA) accepted the company's investigational new drug (IND) filing for AGEN2373,** which represents a milestone in its partnership with Gilead Sciences, Inc.

- AGEN2373 is an anti-CD137 human monoclonal antibody (mAb) that boosts the immune response to cancer cells by enhancing CD137 cosymmetry signaling in activated immune cells, both adaptive T-cells and innate NK cells.

On August 7, 2019 Aevi Genomic Medicine announced that it has obtained the

right to exercise an exclusive global license for MEDI2338. The company plans to initially develop MEDI2338 for adult onset Still's disease, a serious rare and orphan rheumatological disease with no currently approved biologic therapies in the US.

- MEDI2338 is a Phase 2-ready human IgG1 mAb that targets interleukin (IL)-18. The safety of MEDI2338 was previously evaluated in subjects with chronic obstructive pulmonary disease (NCT01322594).

On August 01, 2019 I-Mab Biopharma and TRACON Pharmaceuticals jointly announced that TRACON has dosed the first patient in a U.S. **Phase 1 first-in-human clinical trial (NCT03835949) of I-Mab's proprietary CD73 antibody TJD5**, also known as TJ004309, in patients with advanced solid tumors. In this study, TJD5 will be dosed in the Phase 1 trial both as a single agent and in combination with TECENTRIQ® (atezolizumab), a PD-L1 antibody marketed by Roche.

- TJD5 is a humanized mAb targeting CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular adenosine monophosphate to adenosine, which is highly immunosuppressive.

Seattle Genetics will soon start a **Phase 1 study (NCT04042480) designed to evaluate the safety, tolerability, PK, and antitumor activity of the antibody-drug conjugate SGN-CD228A** in select advanced solid tumors. Study details were first posted on clinicaltrials.gov on August 2, 2019; the estimated study start date is September 2019.

- SGN-CD228A is a humanized anti-CD228 mAb conjugated to eight molecules of MMAE, a potent microtubule disrupting cytotoxic drug, via a β-glucuronidase-cleavable linker, which incorporates a PEG side chain and self-stabilizing maleimide.

Phase 2/3 study started

On August 1, 2019 Momenta Pharmaceuticals, Inc. announced the **launch of an adaptive Phase 2/3 clinical study for nipocalimab in warm autoimmune hemolytic anemia** (wAIHA). The FDA has granted Fast Track Designation for nipocalimab in wAIHA.

- Nipocalimab is a human aglycosylated IgG1 mAb that targets the IgG-binding site of the neonatal Fc receptor (FcRn). In preclinical models, nipocalimab potently antagonizes FcRn binding of IgGs and rapidly

diminishes circulating levels of IgG antibodies, the primary pathogenic agent in a number of autoimmune diseases.

Another approval for Dupixent in the European Union

On August 6, 2019 Sanofi announced that the European Commission **extended the marketing authorization for Dupixent® (dupilumab) in the European Union** (EU) to include 17 years of age with moderate-to-sever atopic dermatitis for systemic therapy. This approval in the EU expands the ixent, which is approved for use in adults with moderate-to-s titis who are can idates for systemic therapy. It is also ap or adults and adolescents 12 years a d older as an add-on main for severe asthma with type 2 inflammation characteri zed by raised blood eosinophils and/or raised fractional exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroid (ICS) plus another medicinal product for maintenance treatment.

- Dupixent® is an anti-IL-4Ra human mAb that inhibits the signaling of both IL-4 and IL-13.
- Outside of the EU, Dupixent® is approved for use in specific patients with moderate-to-severe atopic dermatitis and certain patients with asthma in a number of other countries around the world, including the U.S. and Japan. Dupixent® is also approved in the U.S. for use with other medicines to treat chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled and is currently under regulatory review for patients with CRSwNP in the EU.

In other news...

On August 5, 2019 Provention Bio, Inc. announced that the **FDA granted Breakthrough Therapy Designation to teplizumab** (PRV-031) for the prevention or delay of clinical type 1 diabetes in individuals at-risk of developing the disease. Provention Bio, Inc.'s Phase 3 study to evaluate efficacy and safety of teplizumab in children and adolescents with newly diagnosed type 1 diabetes was started in April 2019.

- Teplizumab, also called MGA031 and hOKT31(Ala-Ala), is a humanized, non-Fc receptor binding, anti-CD3 mAb. Teplizumab binds to an epitope of the CD3-epsilon chain expressed on mature T lymphocytes and, by doing so, may modulate the pathological immunologic responses underlying multiple autoimmune diseases.

On August 6, 2019 Molecular Partners AG announced that the **European Medicines Agency (EMA) has validated the marketing authorisation application of its strategic partner Allergan for abicipar,** a novel DARPin® therapy for the treatment of neovascular age-related macular degeneration. The validation of the application confirms that the submission by the EMA is sufficiently complete to begin the formal review process.

- Abicipar pegol is an engineered ankyrin repeat protein that targets VEGF-A.

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Sent: Monday, September 2, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Aug 15 - Sep 1, 2019

Antibody News You Should Know

August 15 - September 1, 2019

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Entering the clinic

On August 28, 2019 Agenus Inc. announced that the US Food and Drug Administration (FDA) accepted the company's **investigational new drug filing for AGEN1223**, a milestone in its partnership with Gilead Sciences, Inc. This milestone triggers a cash payment of $7.5M.

- AGEN1223 is a bispecific antibody designed to selectively deplete immunosuppressive T regulatory cells from the tumor microenvironment by taking advantage of co-expression of the target antigens specifically on tumor-infiltrating T regulatory cells. AGEN1223's targets have not yet been disclosed.

Phase 2 study in glioblastoma to start

On August 23, 2019 PharmAbcine, Inc. announced that the Austin Health Human Research Ethics Committee notified the company of their approval of a **Phase 2 clinical trial of olinvacimab** (TTAC-0001) in recurrent glioblastoma patients. **NCT03856099** is a multicenter, open-label, Phase 2 clinical trial to evaluate the safety and efficacy of TTAC-0001 in patients with recurrent glioblastoma progressed on bevacizumab including therapy.

- Olinvacimab is a human IgG1 monoclonal antibody targeting VEGFR-2.

Phase 2/3 study started

Details of a Phase 2/3 clinical study of M7824 (bintrafusp alfa) were posted on clinicaltrials.gov on August 26, 2019. **NCT04066491** is a multicenter, randomized, placebo-controlled study of gemcitabine plus cisplatin with or without M7824 as first-line treatment of biliary tract cancer. This study is not yet recruiting.

- Bintrafusp alfa is a human IgG1 monoclonal antibody against PD-L1 fused via a glycine-serine linker at the CH 3 -C terminus to the extracellular domain of human TGFβ receptor II, which functions as a TGFβ "trap."

Biological license applications planned or submitted

On August 23, 2019 GlaxoSmithKline announced **positive headline results from the pivotal DREAMM-2 study of belantamab mafodotin** (GSK2857916) for multiple myeloma. The two-arm study met its primary objective and demonstrated a clinically meaningful overall response rate with belantamab mafodotin in the patient population. The safety and tolerability profile was consistent with that observed in DREAMM-1, the first time in human study of belantamab mafodotin. Data from the DREAMM-2 study will be the basis for regulatory filings starting later this year.

- Belantamab mafodotin is a humanized anti-B-cell maturation antigen monoclonal antibody that is afucosylated and conjugated to the microtubule-disrupting agent monomethyl auristatin-F.

On August 27, 2019 Viela Bio announced that the **FDA has accepted for review its biologics license application for inebilizumab** for the treatment of patients with neuromyelitis optica spectrum disorder, a rare autoimmune

disease characterized by unpredictable attacks that often lead to severe, irreparable disability including blindness and paralysis.

- Inebilizumab is an affinity optimized, afucosylated, humanized IgG1 monoclonal antibody targeting human CD19 for B cell depletion.

In other news...

On August 28, 2019 HiFiBiO Therapeutics announced the **completion of a $67 Million Series C financing round**. The funding was led by new investor IDG Capital. HiFiBiO Therapeutics will use the proceeds from the financing to expand its platform efforts and accelerate the development of its novel antibody drug pipeline to treat cancer and autoimmune disorders.

- HiFiBiO Therapeutics expects to have multiple drug candidates advance to the clinical trial phase.

AbbVie announced that MERU (NCT03033511), a Phase 3 trial ev zumab t sirine (Rova-T) as a first-line maintenance therapy -cell lung cancer, demonstr ted no survival benefit at a pre nalysis for patients receiving Rova-T as comp ared with placebo. The overall safety profile was generally consistent with that observed in previous studies. The MERU trial is being closed, and the **Rova-T research and development program has been terminated**. AbbVie will move forward prioritizing other development programs within its oncology pipeline.

- Rovalpituzumab tesirine is an antibody-drug conjugate composed of a humanized monoclonal antibody, dipeptide linker, and pyrrolobenzodiazepine dimer toxin with a drug-to-antibody ratio of 2. The antibody component targets cancer-stem cell-associated delta-like protein 3.

On August 28, 2019 Sanofi and Regeneron Pharmaceuticals, Inc. announced that the U.S. District Court for the District of Delaware ruled in their favor and found as a matter of law that Amgen's asserted **patent claims for antibodies targeting PCSK9** (proprotein convertase subtilisin/kexin type 9) are invalid based on lack of enablement. The ruling overturned portions of an earlier jury verdict upholding the validity of three claims. On February 25, 2019, a jury previously found in Sanofi and Regeneron's favor that two other asserted Amgen patent claims are invalid. This means that Sanofi and Regeneron have successfully invalidated all five asserted Amgen patent claims.

- Anti-PCSK9 antibody products from Sanofi and Regeneron

Pharmaceuticals (Praluent®) and Amgen (Repatha®) were approved in the US in 2015.

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We hope our Career Center will help our members – both job seekers and employers – by matching the best talent with the perfect job.

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September 1 - 15, 2019

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New to the clinic

On September 12, 2019 GT Biopharma, Inc. announced that it notified the U.S. Food and Drug Administration (FDA) that it was **commencing enrollment in its first-in-human GTB-3550 Phase I/2 clinical trial.** The clinical trial is being conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota. NCT03214666 is a single center Phase 1/2 clinical trial of CD16/IL-15/CD33 (161533) tri-specific killer cell engager (TriKE™) for the treatment of CD33-expressing high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia or advanced systemic mastocytosis.

- GTB-3550 is a single-chain, tri-specific scFv recombinant fusion protein conjugate composed of the variable regions of the heavy and light chains

of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. The IL-15 portion of the molecule provides a self-sustaining signal that activates natural killer cells and enhances their ability to kill.

Biological license applications planned

On September 11, 2019 Omeros Corporation announced that the FDA agreed with the company's **proposed schedule for the rolling review of the biologics license application** (BLA) for narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Consistent with the agreed schedule, Omeros is on track to submit the BLA's first sections, which will include the nonclinical and clinical pharmacology data, in the first half of the next quarter.

- Narsoplimab is a human IgG4 antibody targeting mannan-binding lectin-associated serine protease-2.

On September 12, 2019 Chugai Pharmaceutical Co., Ltd. announced that positive results from the SAkuraStar Study (NCT02073279) were presented at the Congress of European Committee for Treatment and Research in Multiple Sclerosis. In this study, satralizumab significantly reduced the risk of relapse by 55% (hazard ratio=0.45 [95% confidence interval: 0.23-0.89], p=0.0184 [stratified log-rank test]) in the overall population, representative of neuromyelitis optica spectrum disorder (NMOSD) patients (including aquaporin-4 antibodies [AQP4-IgG] seropositive and seronegative patients). **Global regulatory filings for a proposed indication of treatment of NMOSD are planned this year**.

- Satralizumab is an anti-IL-6 receptor humanized IgG2 recycling antibody designed to have pH-dependent binding to soluble IL-6R.

Marketing applications recently submitted

On September 9, 2019 Daiichi Sankyo Company, Limited announced the **submission of a New Drug Application to Japan's Ministry of Health, Labour and Welfare (MHLW) for the use of [fam-] trastuzumab deruxtecan** for the treatment of patients with HER2+ metastatic breast cancer. [Fam-] trastuzumab deruxtecan is currently in development for the treatment of patients with a variety of HER2 expressing or HER2 mutant cancers, including gastric, colorectal and lung cancer, as well as in breast cancer with HER2 low expression.

- [fam-] trastuzumab deruxtecan (DS-8201) is an investigational HER2 targeting antibody drug conjugate.

On September 9, 2019 Allergan plc and Molecular Partners announced that the **FDA accepted a BLA and the European Medicines Agency has validated a marketing authorisation application (MAA) for abicipar pegol** in patients with neovascular (wet) age-related macular degeneration. The FDA is expected to take action on the BLA mid-2020. A decision from the European Commission is expected in the second half of 2020. The BLA and MAA filings are based on data from two Phase 3 trials, CEDAR and SEQUOIA, which supported the non-inferior efficacy of the abicipar quarterly dosing regimen to maintain vision gains with more than 50% fewer injections versus ranibizumab (13 vs. 6) dosed monthly in the first year.

- Abicipar pegol is a novel, investigational designed ankyrin repeat protein (DARPin®) targeting VEGF-A.

On September 9, 2019 Horizon Therapeutics plc announced that **FDA accepted the BLA for teprotumumab**, an investigational medicine for the treatment of active thyroid eye disease (TED), and granted it Priority Review designation. If approved, teprotumumab would be the first FDA-approved medicine for the treatment of active TED. The FDA is expected to take action on the BLA on March 8, 2020.

- Teprotumumab is a human IgG1 antibody targeting the insulin-like growth factor 1 receptor.

RabiMabs approved in India

On September 3, 2019, Zydus Cadila announced that it received **marketing authorization for TwinrabTM (RabiMabs) from the Drug Controller General of India**. The novel biologic is indicated in combination with rabies vaccine for rabies post-exposure prophylaxis. The FDA has granted an orphan drug status to this candidate.

- RabiMabs is a unique combination of two murine monoclonal antibodies, selected from a panel of five mAbs shortlisted by the World Health Organization from collaborating research centers around the world, that bind to two different epitopes on the G protein expressed on the surface of rabies virus.

In other news...

On September 3, 2019 Forty Seven, Inc. announced that the **FDA granted Fast Track designation to magrolimab** for yelodysplastic syndrome (MDS) an acute myeloid leukemia (as previously granted Fast Track desig ation by the FDA fo MDS and AML, and for the treatment of relapsed or refract -cell lymphoma (DLBCL) and follicular lymphoma. Based tyr Seven, Inc. belie es that single arm pivotal trial t to support registration of magrolimab in combination with azacitidine in untreated higher risk MDS and magrolimab in combination with rituximab in heavily pre-treated relapsed or refractory DLBCL patients, respectively.

- Magrolimab is a humanized IgG4 antibody targeting CD47, which is part of a signaling pathway used by cancer cells to avoid being ingested by macrophages.

On September 6, 2019 Ridgeback Biotherapeutics LP, a closely held biotechnology company, announced that the **FDA recently granted mAb114, an experimental treatment for Ebola, Breakthrough Therapy designation**. In December 2018 Ridgeback Biotherapeutics LP announced that it entered into a patent license agreement with the National Institute of Allergy and Infectious Diseases for intellectual property related to mAb114.

- mAb114 is a human IgG1 antibody that binds to a highly conserved region of amino acids in the receptor-binding domain of Ebola virus variants and prevents the interaction of the glycoprotein with the NPC1 receptor, thus blocking virus entry into the cytoplasm of the host cell.

On September 3, 2019 Aridis Pharmaceuticals, Inc. announced results from a Phase 2 clinical trial evaluating AR-105 for the treatment of ventilator-associated pneumonia caused by gram-negative *Pseudomonas aeruginosa*. The recently completed study did not meet its primary endpoint of demonstrating superiority in clinical cure rates on Day 21 compared to placebo. Furthermore, there was a statistically significant imbalance in all-cause mortality, as well as serious adverse event (SAE) rates between treatment groups that favored placebo. However, no SAE or mortality in the study was deemed to be drug related by the study investigators or the study's Data Monitoring Committee. At this point, **Aridis will no longer allocate further development resources to AR-105**.

- AR-105 is a human IgG1 antibody targeting *P. aeruginosa* alginate.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Tuesday, October 1, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Sep 15 - 30, 2019

Antibody News You Should Know

September 15 - 30, 2019

Antibody-based therapeutics are advancing in clinical development at a rapid rate and being approved in record numbers. Recent news about antibody-related events are summarized below. Follow the links for more details.

Attention members!
Our data for antibodies in late-stage clinical studies was updated in mid-September. This data is now available to you in the Members Only area of the Society's website. Log in to access data for 71 antibodies in late-stage studies and an additional 9 with studies pending on clinicaltrials.gov!

Clinical study of orally administered antibody to start

On September 16, 2019 Tiziana Life Sciences plc announced that the U.S. Food and Drug Administration (FDA) has allowed the initiation of a **Phase 1 clinical trial in healthy volunteers using a novel oral enteric-coated capsule formulation of foralumab** (TZLS-401, NI-0401). According to the proposed mechanism of action, oral or nasal administration of anti-CD3 mAb

induces mucosal tolerance to upregulate T regulatory cells capable of providing site-targeted immunomodulation to suppress inflammation. Foralumab may be a potential therapy for nonalcoholic steatohepatitis, Crohn's disease, and neurodegenerative diseases such as multiple sclerosis.

- Foralumab, a human monoclonal anti-CD3 antibody, was in-licensed from Novimmune SA. Point mutations in the Fc were introduced to minimize adverse immune responses.

Phase 3 study planned

On September 26, 2019 Innate Pharma SA announced that **AstraZeneca will advance monalizumab into a Phase 3 randomized clinical trial** evaluating monalizumab in combination with cetuximab in patients suffering from recurrent or metastatic squamous cell carcinoma of the head and neck, and the companies will co-fund the trial. The trial initiation is expected in 2020, subject to regulatory and compliance approvals.

- Monalizumab is a humanized IgG4 antibody targeting NKG2A receptors expressed on tumor infiltrating cytotoxic CD8+ T cells and NK cells.

Marketing application submission planned

On September 24, 2019 Provention Bio, Inc. reiterated its regulatory strategy regarding teplizumab (PRV-031) for the prevention or delay of clinical type 1 diabetes in individuals at-risk of developing the disease. Based on written communications from FDA and FDA's designation of teplizumab as a breakthrough therapy, the company believes that existing clinical and non-clinical data will be **sufficient to support a biologics license application (BLA) submission for teplizumab in the fourth quarter of 2020** for the at-risk indication. The company expects to meet with the FDA in the fourth quarter of 2019 to discuss this expedited development plan.

- Teplizumab, also called hOKT31(Ala-Ala), is a humanized, non-Fc receptor binding, anti-CD3 IgG1 antibody. Teplizumab binds to an epitope of the CD3-epsilon chain expressed on mature T lymphocytes and, by doing so, may modulate pathological immunologic responses.

BLA update

On September 16, 2019 Seattle Genetics, Inc. and Astellas Pharma Inc.

announced that their **BLA for enfortumab vedotin was accepted by FDA and granted Priority Review** for the treatment of patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting. The BLA includes results from the first cohort of patients in the **EV-201 pivotal Phase 2 clinical trial**, which were presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2019. FDA has set a target date of March 15, 2020 for a first action on the application.

- Enfortumab vedotin is an antibody-drug conjugate (ADC) composed of an anti-Nectin-4 monoclonal antibody attached to a microtubule-disrupting agent, MMAE, using Seattle Genetics' proprietary linker technology. Nectin-4, a cell adhesion molecule expressed on many solid tumors, was identified as an ADC target by Astellas.

Ibalizumab approved by European Commission

On September 26, 2019 **Theratechnologies Inc. announced that Trogarzo® (ibalizumab) was approved by the European Commission**. Trogarzo®, in combination with other antiretroviral(s), is indicated for the treatment of adults infected with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen.

- Trogarzo® (ibalizumab-uiyk), a humanized IgG4 antibody targeting CD4, was approved by FDA in March 2018 for treatment of chronic HIV infection in patients who have not responded adequately to other treatments.

FDA approves rituximab for new indication

On September 27, 2019 **FDA approved Rituxan (rituximab) injection to treat granulomatosis with polyangiitis and microscopic polyangiitis in children** 2 years of age and older in combination with glucocorticoids. It is the first approved treatment for children with these rare vasculitis diseases. The product is also approved in the US for treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies, granulomatosis with polyangiitis and microscopic polyangiitis in adult patients in combination with glucocorticoids, and moderate to severe pemphigus vulgaris in adult patients.

- Rituximab is a chimeric IgG1 antibody targeting CD20 first approved in

1997.

In other news...

On September 17, 2019 **Glenmark Pharmaceuticals announced that the FDA granted Orphan Drug Designation to its bispecific antibody candidate GBR 1342** for the treatment of patients with multiple myeloma who have received prior therapies. A Phase 1 study of GBR 1342 in multiple myeloma is ongoing.

- **GBR 1342** includes a single chain, variable fragment arm with anti-CD38 specificity and a fragment antigen binding (Fab) arm that targets CD3ε on T cells. Fcγ receptor binding is engineered to reduce effector functions.

On September 23, 2019 **Annexon Biosciences announced that FDA granted Fast Track designation for ANX005** for the treatment of Guillain-Barré Syndrome (GBS), a rare, acute, antibody-mediated autoimmune disease affecting the peripheral nervous system for which there are currently no approved therapies in the United States. The FDA had previously granted Orphan Drug designation for ANX005 for the treatment of GBS. Annexon has completed a Phase 1b clinical trial of ANX005 and plans to advance ANX005 into later-stage clinical trials in GBS.

- ANX005 is a humanized anti-C1q IgG4 antibody.

Biogen has stopped the Phase 2 SPIRIT (NCT03573505) study, a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of BG00011 in patients with idiopathic pulmonary fibrosis because of safety concerns. End-of-study and safety follow-up visits are in progress.

- BG00011 is a humanized IgG1 antibody targeting av/b6 integrin, which is upregulated on alveolar epithelial cells in IPF patients and drives the activation of TGF-beta.

Considering your career options?

From: The Antibody Society <membership@antibodysociety.org>
Sent: Wednesday, October 16, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Oct 1 - 15, 2019

Antibody News You Should Know

October 1 - 15, 2019

Antibody-based therapeutics are advancing in clinical development at a rapid rate and being approved in record numbers. Recent news about antibody-related events are summarized below. Follow the links for more details.

New to the clinic

On October 10, 2019, Alder BioPharmaceuticals, Inc. announced dosing of the first patient in a double-blind, placebo-controlled **Phase 1 clinical study to evaluate ALD1910** as a preventive treatment for migraine. The Phase 1 study of ALD1910 will enroll approximately 100 healthy men and women between the ages of 18 and 55 and will assess the safety, tolerability and pharmacokinetic profile of ALD1910 at various doses. Initial results are expected in the second half of 2020.

- ALD1910 is a humanized antibody that inhibits pituitary adenylate cyclase-activating polypeptide, an important signaling molecule in the pathophysiology of migraine.

Tomopath Inc., with collaborators Invicro and Janssen Research & Development, LLC, has initiated an **early Phase 1 study (NCT04116164) of 111In-DOTA-h11B6**. This imaging trial will be conducted to confirm the safety and estimate the mass amount of antibody h11B6, and confirm in vivo tumor targeting of the antibody, using Indium-111 (111In) radiolabeled h11B6 in subjects with advanced prostate cancer. The companies intend to develop h11B6 as a therapeutic radiopharmaceutical for men with metastatic castration-resistant prostate cancer.

- h11B6 is a novel radiolabeled antibody targeting human kallikrein-2.

Alector Inc. plans to initiate a **Phase 1 study (NCT04111666) of AL101** in mid-December 2019. First posted on clinicaltrials.gov on October 1, 2019, NCT04111666 is a first in human phase 1 study in healthy volunteers to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and bioavailability of IV and SC AL101.

- **AL101, which targets SORT1, is intended as a treatment for neurodegenerative disorders** such as Alzheimer's disease and Parkinson's disease.

Amgen plans to initiate a **Phase 1 study (NCT04117958) of AMG 199**. First posted on clinicaltrials.gov on October 7, 2019, NCT04117958 is a global Phase 1 study evaluating the safety, tolerability, pharmacokinetics, and efficacy of the half-life extended bispecific T-cell engager (BiTE®) AMG 199 in patients with MUC17-positive gastric and gastroesophageal junction cancer.

- AMG 199 is a BiTE® molecule designed to direct T cells towards MUC17-expressing cells.

Agenus Inc. plans to initiate a **Phase 1 study (NCT04121676) of AGEN2373**. First posted on clinicaltrials.gov on October 10, 2019, NCT04121676 is an open-label, dose escalation study of AGEN2373 as monotherapy in patients with solid tumors.

- AGEN2373 is an human antibody targeting CD137. Also known as 4-1BB, CD137 is a positive regulator of the immune system that is highly upregulated on activated T cells and natural killer cells.

Late-stage clinical studies started

On October 9, 2019, Dermira, Inc. announced dosing of the first patient in a

Phase 3 study evaluating the safety and efficacy of lebrikizumab in adult and adolescent patients ages 12 and older with moderate-to-severe atopic dermatitis. The lebrikizumab Phase 3 program includes two identical, randomized, double-blind, placebo-controlled, parallel-group Phase 3 studies designed to confirm the safety and efficacy of lebrikizumab as monotherapy in patients with this disease.

- Lebrikizumab is a humanized IgG4 antibody that binds IL-13 with very high affinity, specifically preventing the formation of the IL-13Rα1/IL-4Rα heterodimer complex and subsequent signaling.

On October 10, 2019, Kodiak Sciences Inc. announced that the first patients have been treated in the double-masked, active comparator-controlled **pivotal Phase 2 DAZZLE study (NCT04049266) of KSI-301** in patients with treatment-naïve wet (neovascular) age-related macular degeneration.

- KSI-301 is an antibody-biopolymer conjugate targeting vascular endothelial growth factor (VEGF).

Satralizumab marketing application submitted in EU

On October 9, 2019, the European Medicines Agency (EMA) provided information on applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use in a list compiled on October 3, 2019. This list only includes information for medicines whose applications have been validated at the time the report was compiled. **Satralizumab was newly included on this list, with a note that the application is being reviewed under EMA's accelerated assessment program**.

- Satralizumab, a humanized IgG2 antibody designed to have pH-dependent binding to soluble IL-6 receptor, has been evaluated in Phase 3 studies of patients with neuromyelitis optica spectrum disorder.

FDA approves brolucizumab-dbll

On October 7, 2019, the US **Food and Drug Administration (FDA) approved brolucizumab-dbll (BEOVU®)** for the treatment of neovascular age-related macular degeneration (nAMD). BEOVU is administered by intravitreal injection, and the recommended dose is 6 mg monthly for the first three doses, followed by one dose of 6 mg every 8-12 weeks. A marketing application for brolucizumab is undergoing review by EMA.

- Brolucizumab is a humanized antibody single-chain variable fragment that binds to the 3 major isoforms of human VEGF, thereby interfering with their interaction with receptors VEGFR-1 and VEGFR-2 and suppressing endothelial cell proliferation, neovascularization and vascular permeability.

In other news...

On October 7, 2019, Mereo BioPharma Group plc announced that FDA granted **Fast Track designation to navicixizumab** for the treatment of high grade ovarian, primary peritoneal or fallopian tube cancer in patients who have received at least 3 prior therapies and/or prior bevacizumab. candidates Mereo acquired navicixizumab through its April 2019 merger with OncoMed Pharmaceuticals, Inc.

- Navicixizumab is a bispecific antibody targeting delta-like ligand and VEGF currently being evaluated in an ongoing Phase 1b study in combination with paclitaxel in patients with advanced heavily pretreated ovarian cancer.

On October 3, 2019, Aptevo Therapeutics Inc. announced its decision to **discontinue further development of APVO210**, a bispecific antibody candidate under development for the treatment of autoimmune diseases. The decision followed the review of data from the Phase 1 multiple ascending dose (MAD) clinical study of APVO210 in healthy volunteers that suggests that APVO210 would not meet the desired target product profile for future commercialization. Specifically, the clinical data showed evidence of increasing titers of anti-drug antibodies (ADA) with repeated doses of APVO210, which had varying impact on APVO210 drug levels in subjects' blood.

- APVO210 is an ADAPTIR™ molecule containing an anti-CD86 single-chain Fv coupled to an engineered monomeric form of the human IL-10. The central portion of the protein is an engineered immunoglobulin Fc domain that provides extended in vivo half-life and lacks effector function.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, November 4, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Oct 15 - Nov 1, 2019

Antibody News You Should Know

October 15 - Nov 1, 2019

Antibody-based therapeutics are advancing in clinical development at a rapid rate and being approved in record numbers. Recent news about antibody-related events are summarized below. Follow the links for more details.

Attention, Antibodies to Watch readers! *The data for "Antibodies to Watch in 2020" is currently being compiled, and we are planning for online publication in December 2019. You can access our most recent data for antibodies in late-stage studies in the Members Only section of the Society's website.* ***Log in*** *to download it in Excel format.*

New to the clinic

On October 15, 2019, Affimed N.V. announced the submission of an Investigational New Drug application to the U.S. Food and Drug Administration (FDA) to **initiate a first-in-human Phase 1/2a study of AFM24**. The initial goal of the study is to determine the maximum tolerated dose and recommended Phase 2 dose of AFM24, as well as to evaluate the safety,

pharmacokinetics, pharmacodynamics, and preliminary efficacy in patients with advanced cancers known to express the epidermal growth factor receptor (EGFR).

- AFM24 is a tetravalent, bispecific EGFR- and CD16A-binding innate cell engager from Affimed's fit-for-purpose ROCK® platform.

On October 16, 2019, AL-S Pharma AG, a biotech company jointly founded and financed by Neurimmune and TVM Capital Life Science, announced **enrollment of the first patient in a multicenter Phase 1 clinical trial to evaluate AP-101** in patients with amyotrophic lateral sclerosis (ALS). The antibody was discovered by translating genetic information of human memory B cells through Neurimmune's Reverse Translational MedicineTM technology. AP-101 has Orphan Drug Designation from FDA, European Medicines Agency (EMA) and Swissmedic. In the initiated study, safety, tolerability and pharmacokinetics of AP-101 will be assessed in patients with ALS.

- AP-101 is a human antibody directed against misfolded superoxide dismutase 1.

Late-stage clinical study started

On October 17, 2019, **ADC Therapeutics SA announced that the first patients have been dosed in a 100-patient pivotal Phase 2 clinical trial (NCT04052997) evaluating the efficacy and safety of ADCT-301** (camidanlumab tesirine) in patients with relapsed or refractory Hodgkin lymphoma. The trial is intended to support the submission of a biologics license application (BLA) for possible accelerated approval to the FDA in 2022.

- Camidanlumab tesirine is an antibody-drug conjugate (ADC) composed of a human anti-CD25 monoclonal antibody that binds to CD25 (HuMax®-TAC, licensed from Genmab A/S), conjugated to a pyrrolobenzodiazepine dimer payload.

BLA planned

On October 22, 2019, **Biogen announced that, after consulting with FDA, Biogen plans to pursue regulatory approval for aducanumab** (BIIB037) based on the results of two Phase 3 studies of patients with early Alzheimer's disease, EMERGE (NCT02484547) and ENGAGE (NCT02477800). These studies were designed to evaluate the efficacy and safety of two dosing

regimens of aducanumab, but they were discontinued on March 21, 2019 because a pre-specified futility analysis based on data available as of December 26, 2018, from 1,748 patients who had the opportunity to complete the 18-month study period, predicted that both studies were unlikely to meet their primary endpoint. However, later analysis of data from a total of 3,285 patients, 2,066 of whom had the opportunity to complete the full 18 months of treatment, indicated the EMERGE study had met its primary endpoint.

- Aducanumab, a human anti-amyloid beta (Aβ) IgG1 antibody binds a linear epitope formed by amino acids 3–7 of the Aβ peptide and discriminates between monomers and oligomeric or fibrillar aggregates.

Marketing application news

On October 17, 2019, AstraZeneca and Daiichi Sankyo Company, Limited announced that the **FDA has accepted for review the BLA for [fam-] trastuzumab deruxtecan (DS-8201) for HER2+ breast cancer and granted Priority Review**. FDA's first action date on the application is set for Q2 2020.

- [fam-] trastuzumab deruxtecan is anti-HER2 ADC being evaluated in the DESTINY-Breast01 (NCT03248492) study, a pivotal Phase 2 trial assessing the safety and efficacy of trastuzumab deruxtecan in patients with HER2-positive unresectable and/or metastatic breast cancer previously treated with trastuzumab emtansine.

On October 17, 2019, the EMA's **Committee for Medicinal Products for Human Use adopted a positive opinion following a re-examination procedure, recommending the granting of a marketing authorization for the medicinal product Evenity** (romosozumab), intended for the treatment of severe postmenopausal osteoporosis. The applicant for this medicinal product is UCB Pharma S.A.

- Evenity is a humanized anti-sclerostin IgG2 antibody approved by FDA in April 2019 for treatment of osteoporosis in postmenopausal women at high risk for fracture.

On October 28, 2019, Omeros Corporation announced they submitted the first sections of the **rolling submission of its BLA to the FDA for narsoplimab** for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Narsoplimab has FDA's breakthrough therapy and orphan drug designations for this indication.

- Narsoplimab is a human IgG4 antibody targeting mannan-binding lectin-associated serine protease-2, a pro-inflammatory protein critical to activation of the lectin complement pathway of the immune system.

On October 29, 2019, MorphoSys announced that they started a **rolling submission of a BLA for tafasitamab** to the FDA, and plan to complete the submission by the end of 2019. The BLA submission is based in the the pivotal, single-arm Phase 2 L-MIND trial (NCT02399085) is evaluating tafasitamab in combination with lenalidomine for the treatment of relapsed / refractory diffuse large B-cell lymphoma (DLBCL). MorphoSys reported that a statistically significant superior best objective response rate was seen in combination treatment of tafasitamab with lenalidomide (L-MIND study) compared to a real-world data matched control cohort of lenalidomide alone (Re-MIND).

- Tafasitamab is an Fc-engineered IgG1 antibody targeting CD19, which is expressed in B cell malignancies such as DLBCL. Fc engineering enhances binding of tafasitamab's Fc domain to activating Fcgamma-receptors, which enhances cytotoxicity.

On October 30, 2019, Chugai Pharmaceutical Co., Ltd. announced that **EMA has accepted the Marketing Authorization Application for satralizumab** (SA237) for the treatment of adult and adolescent patients with neuromyelitis optica spectrum disorder. EMA has granted Accelerated Assessment status for satralizumab. The **FDA has also accepted a BLA for satralizumab.** The applications are based on the results from Phase 3 studies in patients with NMOSD: SAkuraStar Study (NCT02073279) evaluating satralizumab monotherapy, and SAkuraSky Study (NCT02028884) evaluating satralizumab added to baseline treatment.

- Satralizumab is an anti-interleukin-6 receptor humanized recycling antibody.

In other news...

On October 24, 2019, Provention Bio, Inc. announced that **EMA granted teplizumab (PRV-031) PRIority MEdicines (PRIME) designation** for the prevention or delay of clinical type 1 diabetes (T1D) in individuals at-risk of developing the disease. PRIME designation is granted to promising medicines that demonstrate the potential to address substantial unmet medical need based on clinical data. Teplizumab was previously granted Breakthrough Therapy designation from FDA for T1D. Provention Bio plans to meet with FDA in Q4 2019 to discuss a possible BLA submission in Q4 2020.

- Teplizumab is an anti-CD3 IgG1 antibody currently being evaluating in patients with newly diagnosed T1D in the Phase 3 PROTECT study (NCT03875729).

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- Search our resume database and contact qualified candidates proactively
- Expose your job postings to a wider audience through our diverse membership and social networks

We hope our Career Center will help our members – both job seekers and employers – by matching the best talent with the perfect job.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, November 18, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Nov 1 - 15, 2019

View this email in your browser

Antibody News You Should Know

November 1 - 15, 2019

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Log in *to download it in Excel format.*

New to the clinic

On November 4, 2019, Compugen Ltd. announced that the U.S. Food and Drug Administration (FDA) cleared its **investigational new drug application for COM902**. A Phase 1 trial in patients with advanced malignancies is expected to begin in early 2020. COM902 is being developed for combination treatment with COM701, which target PVRIG, a novel B7/CD28-like immune checkpoint

target candidate discovered by Compugen. Parallel inhibition of TIGIT and PVRIG results in synergistic effects on effector T cell function and tumor growth inhibition in various model systems.

- COM902 is a high affinity, human antibody targeting TIGIT, an antigen also known as T cell immunoreceptor with Ig and ITIM domains.

On November 4, 2019, Harbour BioMed announced the **start of the first clinical trial of HBM4003** for the treatment of patients with advanced solid tumors. HBM4003 has shown potential for increased anti-tumor activity based on enhanced antibody-dependent Treg depletion and a favorable safety profile resulting from reduced half-life.

- HBM4003 is human anti-CTLA-4 antibody derived from a heavy chain only antibody (HCAb) transgenic mouse platform.

Phase 2 clinical study started

On November 7, 2019, AVEO Oncology and Biodesix, Inc. announced the initiation of the CyFi-2 study, a randomized **Phase 2 clinical study evaluating ficlatuzumab** in combination with high-dose cytarabine vs. high-dose cytarabine alone in patients with relapsed and refractory acute myeloid leukemia. AVEO and Biodesix, Inc. have a worldwide agreement to develop and commercialize ficlatuzumab, which is also being evaluated in patients with squamous cell carcinoma of the head and neck and metastatic pancreatic ductal cancer.

- Ficlatuzumab is a humanized IgG1 antibody that potently inhibits hepatocyte growth factor.

BLA submission started

Released November 5, 2019, Regeneron's 3rd quarter 2019 report revealed that the FDA granted Breakthrough Therapy designation to REGN-EB3 for the treatment of Ebola virus infection, and that a **rolling biologics license application submission for REGN-EB3 had been initiated**. In August 2019, Regeneron announced that a randomized, controlled trial evaluating 4 investigational therapies for Ebola virus infection was stopped early because REGN-EB3 demonstrated superiority over ZMapp, the standard-of-care control arm of the trial, in preventing death.

- REGN-EB3 is composed of a mixture of 3 human IgG1 antibodies that target the Ebola virus.

EMA recommends approval for Polivy

On November 14, 2019, the European Medicines Agency's human medicines committee **recommended granting a conditional marketing authorization for Polivy** (polatuzumab vedotin) for the treatment of relapsed/refractory diffuse large B-cell lymphoma, a rare type of cancer of the white blood cells.

- Polatuzumab vedotin is composed of a humanized anti-CD79b IgG1 antibody conjugated to the antimitotic agent monomethyl auristatin E.

FDA approval for crizanlizumab

On November 15, 2019, **FDA approved crizanlizumab-tmca (Adakveo)**, a treatment to reduce the frequency of vaso-occlusive crisis, which occurs when blood circulation is obstructed by sickled red blood cells, for patients age 16 years and older. Developed by Novartis, crizanlizumab was granted Orphan Drug designation in the US and EU for the treatment of VOC in patients with sickle cell disease, as well as FDA's Breakthrough Therapy designation for prevention of VOCs in patients of all genotypes with sickle cell disease. A marketing application for crizanlizumab is undergoing review by the European Medicines Agency.

- Crizanlizumab is a humanized antibody directed against P-selectin, which contributes to the pathogenesis of sickle cell disease, including vaso-occlusive events and hemolytic anemia.

In other news...

On November 6, 2019, Teneobio, Inc. announced that **TNB-383B has received orphan drug designation by the FDA** for the treatment of multiple myeloma. A multicenter, Phase 1, open-label, dose-escalation and expansion study (NCT03933735) of TNB-383B in subjects with relapsed or refractory multiple myeloma is on-going.

- TNB-383B, a bispecific antibody that simultaneously targets BCMA and CD3, was derived from Teneobio's unique anti-CD3 platform.

On November 11, 2019, **BIOCAD announced plans to introduce netakimab (BCD-085) and prolgolimab (BCD-100) to the European market** and start of

the clinical trials in Europe. Netakimab is approved in Russia for the treatment of moderate to severe plaque psoriasis, while prolgolimab is being evaluated in late-stage clinical studies as a treatment for non-small cell lung cancer. To date, the clinical study sites involved in the evaluation of these antibodies have been located in Russia or Belarus.

- Netakimab is a humanized IgG1 antibody targeting IL-17.
- Prolgolimab is a human IgG1 antibody targeting PD-1.

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- Search our resume database and contact qualified candidates proactively
- Expose your job postings to a wider audience through our diverse membership and social networks

We hope our Career Center will help our members – both job seekers and employers – by matching the best talent with the perfect job.

From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, December 2, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Nov 15 - Dec 1, 2019

Antibody News You Should Know

November 15 - December 1, 2019

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New to the clinic

On November 18, 2019 Surface Oncology announced that it submitted an Investigational New Drug application to the U.S. Food and Drug Administration (FDA) to support the initiation of a **Phase 1/1b clinical study of SRF617**.

- SRF617 is a human anti-CD39 antibody designed to promote anti-tumor immunity through a dual mechanism of reducing immunosuppressive adenosine and driving the extracellular accumulation of immunostimulatory ATP within the tumor microenvironment.

On November 27, 2019 Innovent Biologics, Inc. jointly announced with Beijing Hanmi Pharmaceutical Co., Ltd. that the first patient has been successfully dosed in a **Phase 1 clinical trial (CIBI315A101) of IBI315**, an innovative antibody co-developed by both companies.

- IBI315 is a recombinant human bispecific antibody targeting programmed cell death receptor-1 and human epidermal growth factor receptor 2. Preclinical studies have shown that the bridging effects between T cells and tumor cells introduced by IBI315 may enhance anti-tumor activity.

BLA submission started

On November 29, 2019 Y-mAbs Therapeutics, Inc. announced that it submitted the first portions of its **Biologics License Application for naxitamab** for the treatment of patients with relapsed/refractory high-risk neuroblastoma under the FDA's Rolling Review process. Naxitamab received FDA's Breakthrough Therapy Designation.

- Naxitamab is an anti-GD2 monoclonal antibody.

In other news...

On November 18, 2019 3SBio Inc. and Verseau Therapeutics, Inc. announced the **selection of VTX0811** as the first licensed program under their partnership agreement focused on the development and commercialization of novel monoclonal antibodies in the field of immuno-oncology for a broad range of cancers.

- VTX0811 is a monoclonal antibody targeting PSGL-1. By binding the antigen, VTX0811 reprograms macrophages to a pro-inflammatory state, activates T cells and attracts other immune cells to generate a coordinated and powerful antitumor response.

On November 21, 2019 ViiV Healthcare announced that the company will be **developing the investigational broadly neutralizing antibody N6LS** for the treatment and prevention of HIV-1 infection, as part of an exclusive licensing agreement between parent company GlaxoSmithKline and the National Institute of Allergy and Infectious Diseases. A Phase 1 dose-escalation study (NCT03538626) of N6LS administered intravenously or subcutaneously to healthy adults was started in June 2018.

- N6LS is a human antibody that binds gp120 on the surface of HIV, thereby preventing its entry into uninfected immune system cells (CD4+ T-cells). N6LS contains a methionine to leucine and asparagine to serine change within the C-terminus of the heavy chain constant region to increase its binding affinity for the neonatal Fc receptor.

On November 21, 2019 **Immunitas Therapeutics announced a $39 million Series A financing** led by Leaps by Bayer and Novartis Venture Fund. The funding will be used to advance its first programs, monoclonal antibody therapeutics with single agent activity in preclinical models of oncology, to clinical studies. Scientific founders of the new company are:

- Kai Wucherpfennig M.D. Ph.D., Professor and Chair of the Department of Cancer Immunology and Virology at the Dana-Farber Cancer Institute and Professor of Neurology at Harvard Medical School,
- Mario Suvà M.D., Ph.D., an Associate Professor in the Department of Pathology at Massachusetts General Hospital and at the Broad Institute of MIT and Harvard, and
- Dane Wittrup, Ph.D., the Carbon P. Dubbs Professor of Chemical Engineering and Biological Engineering at the Massachusetts Institute of Technology.

On November 26, 2019 **APVO436 was granted Orphan Drug designation by the FDA** for treatment of acute myelogenous leukemia. APVO436 is sponsored by Aptevo Research and Development. A Phase 1/1B open-label, dose-escalation study (NCT03647800) of APVO436 in patients with relapsed or refractory acute myeloid leukemia or high-grade myelodysplastic syndrome was started in December 2018.

- APVO436 is tetravalent, recombinant bispecific antibody targeting CD123 and CD3. The anti-CD123 binding domain is a fully human single chain variable fragment (scFv) that binds human and non-human primate (NHP) CD123. The anti-CD3 binding domain is a humanized scFv derived from a murine antibody that binds human and NHP CD3. The Fc region was engineered to minimize complement fixation and interaction with Fc receptors. APVO436 was discovered in part with the OmniAb platform technology (anti-CD123 portion).

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From: The Antibody Society <membership@antibodysociety.org>
Sent: Monday, December 16, 2019 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Dec 1-15, 2019

Antibody News You Should Know

December 1 - 15, 2019

Antibody-based therapeutics are advancing in clinical development at a rapid rate and being approved in record numbers. Recent news about antibody-related events are summarized below. Follow the links for more details.

First clinical study to start soon

On December 9, 2019 IBC Generium announced that they received approval from the Russian Health Authorities to **initiate clinical trials with GNR-084**, a bispecific T-cell engaging antibody, for the treatment of B-cell acute lymphoblastic leukemia. IBC Generium and IONTAS Limited, a leader in the discovery and optimization of fully human antibodies, worked together to generate the anti-CD3 component of the bispecific molecule.

- GNR-084 is a bispecific antibody that targets CD19 and CD3.

On December 9, 2019 CARsgen Therapeutics announced that its drug candidate **AB011 has received Investigational New Drug clearance** from the National Medical Products Administration in China. AB011 will be evaluated as a treatment for patients with advanced gastric and pancreatic adenocarcinoma.

- AB011 is a humanized antibody targeting claudin18.2.

New to the clinic

On December 6, 2019 Innovent Biologics, Inc. announced that the first patient was successfully dosed in a **Phase 1 clinical study (NCT04085185; CIBI110A101) of IBI110** in China. This study will evaluate several dose levels of IBI110 administered as a single agent and in combination with anti-PD-1 sintilimab in patients with advanced malignant tumors.

- IBI110 is a human IgG4κ antibody that targets anti-lymphocyte activation gene 3.

On December 9, 2019 Immunocore Limited announced the start of the **first-in-human clinical trial of IMC-C103C**, the third bispecific developed using the company's ImmTAC ® technology platform. ImmTAC ® molecules combine a T cell receptor-targeting system with an anti-CD3 effector function to activate a highly potent and specific T cell response to cancer cells. IMC-C103C is being developed in partnership with Genentech.

- IMC-C103C targets melanoma-associated antigen A4 (MAGE-A4) expressed on tumor cells and CD3 on T cells.

Regulatory review news

On December 3, 2019 **Immunomedics, Inc. announced the resubmission of its Biologics License Application** (BLA) to the U.S. Food and Drug Administration (FDA) seeking accelerated approval of sacituzumab govitecan for the treatment of patients with metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease.

- Sacituzumab govitecan is an antibody-drug conjugate comprising SN38 (active metabolite of the topoisomerase I inhibitor irinotecan) conjugated to an anti-Trop 2 antibody.

On December 9, 2019 Sesen Bio announced that on December 6, 2019 they **initiated the submission of its BLA for oportuzumab monatox** (Vicinium) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer under Rolling Review to the FDA. Vicinium was granted Fast Track designation by the FDA in 2018. Completed non-clinical and clinical modules, and a partially completed Chemistry, Manufacturing and Controls (CMC) module have been submitted. Sesen Bio anticipates completing the BLA submission with the finalization of the CMC module in 2020 and may request a Priority Review.

- Oportuzumab monatox is a recombinant fusion protein composed of a humanized single-chain variable fragment targeting epithelial cell adhesion molecule (EpCAM) fused to *Pseudomonas* exotoxin A.

The briefing document for an **FDA Advisory Committee meeting held on December 13, 2019 to discuss teprotumumab** for injection is now available. Teprotumumab was developed to address a significant unmet need in patients with thyroid eye disease (TED), a progressive, vision-threatening autoimmune disease. Teprotumumab was effective in two randomized, double-masked, placebo-controlled studies, clinical studies, NCT01868997 and NCT03298867.

- Teprotumumab is a human immunoglobin IgG1 antibody that binds insulin-like growth factor-1 receptor, a tyrosine kinase cell surface receptor that is overexpressed in the orbital fibroblasts of TED patients.

EU approval for romosozumab

On December 11, 2019 Amgen and UCB announced that the **European Commission granted marketing authorization for EVENITY® (romosozumab)** for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture. The European Commission marketing authorization approval is valid in all EU and EEA-European Free Trade Association states (Norway, Iceland and Liechtenstein). EVENITY is now approved in 37 countries, including the US, Japan, Canada and Australia.

- Romosozumab is a humanized IgG2κ antibody that targets sclerostin.

In other news...

On December 9, 2019 Galderma announced that the **FDA granted Breakthrough Therapy Designation to nemolizumab** for the treatment of pruritus associated with prurigo nodularis. Galderma is now actively preparing for the initiation of a Phase 3 pivotal program with nemolizumab in adult patients with prurigo nodularis in 2020. Nemolizumab is currently undergoing evaluation in a Phase 3 study (NCT03985943) in patients with moderate-to-severe atopic dermatitis.

- Nemolizumab is a humanized IgG2κ antibody targeting interleukin (IL)-31 receptor alpha.

On December 10, 2019 Dermira, Inc. announced that the **FDA granted Fast Track designation for lebrikizumab**. Lebrikizumab is currently being evaluated in two Phase 3 studies, ADvocate 1 (NCT04146363) and ADvocate 2

(NCT04178967), to confirm its safety and efficacy in adolescent and adult patients, ages 12 years and older, with moderate-to-severe atopic dermatitis.

- Lebrikizumab is a humanized IgG4κ antibody that targets IL-13.

On December 7, 2019 XBiotech Inc. announced today that it has entered into a definitive agreement with Janssen Biotech, Inc., a Janssen Pharmaceutical Company of Johnson & Johnson, to sell XBiotech's bermekimab. **Janssen will acquire all rights to bermekimab** under the terms of the agreement, and XBiotech will be free to use its True Human Antibody discovery program to develop new antibody therapeutics that target IL-1α to treat non-dermatological diseases. Bermekimab is currently being evaluated in Phase 2 clinical studies in patients with hidradenitis suppurativa and systemic scleroderma, and a Phase 2 study in atopic dermatitis (NCT04021862) is not yet recruiting patients.

- Bermekimab is a human IgG1κ antibody that targets IL-1α.

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From: The Antibody Society <membership@antibodysociety.org>
Sent: Friday, January 3, 2020 3:00 AM
To: janice.reichert@antibodysociety.org
Subject: Antibody News You Should Know: Dec 15, 2019 - January 1, 2020

Antibody News You Should Know

December 15, 2019 - January 1, 2020

The Antibody Society wishes you a happy, prosperous, and productive new year!

Attention fans of 'Antibodies to watch': The 2020 installment has been published and can be downloaded here! This version of the annual 'Antibodies to Watch' series documents the antibody therapeutics approved in 2019 and in regulatory review in the United States or European Union, as well as those in late-stage clinical studies, as of November 2019. The December 1-15, 2019 and this 'Antibody News You Should Know' alerts include the following updates relevant to 'Antibodies to Watch in 2020' that occurred in December 2019:

1) The US Food and Drug Administration (FDA) granted accelerated approval to [fam-]trastuzumab deruxtecan (Enhertu) on December 20, 2019;
2) FDA granted accelerated approval to enfortumab vedotin-ejfv (Padcev) on December 18, 2019, bringing the total number of novel antibody therapeutics granted a first approval in either the US or EU during 2019 to 7;

3) The European Commission approved romosozumab on December 9, 2019;
4) The European Medicines Agency issued a positive opinion for brolucizumab;
5) Sesen Bio initiated a rolling biologics license application (BLA) for oportuzumab monatox on December 6, 2019;
6) As announced December 16, GlaxoSmithKline submitted a BLA for belantamab mafodotin;
7) As announced December 19, Macrogenics submitted a BLA for margetuximab; and
8) The status of the Phase 3 study (NCT04128696) of GSK3359609 in patients with head and neck squamous cell carcinoma was updated to recruiting from not yet recruiting.

News about antibody-related events announced December 15, 2019 to January 1, 2020 are summarized below. Follow the links for more details.

BLAs submitted for 2 mAbs

On December 16, 2019 **GlaxoSmithKline confirmed submission of a BLA to the FDA seeking approval of belantamab mafodotin** (GSK2857916) for the treatment of patients with relapsed or refractory multiple myeloma whose prior therapy included an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody. In the pivotal DREAMM-2 study, treatment with single-agent belantamab mafodotin resulted in a clinically meaningful 31% overall response rate with the 2.5 mg/kg regimen in patients with heavily pre-treated multiple myeloma. Patients in the trial received a median of seven prior lines of treatment, were refractory to an immunomodulatory drug and a proteasome inhibitor and were refractory and/or intolerant to an anti-CD38 antibody. In 2017, GSK2857916 was granted Breakthrough Therapy designation from the US FDA and PRIME designation from the European Medicines Agency.

- Belantamab mafodotin is an antibody-drug conjugate (ADC) comprising a humanized anti-B cell maturation antigen monoclonal antibody conjugated to the cytotoxic agent auristatin F via non-cleavable linker. The drug linker technology is licensed from Seattle Genetics; the antibody is produced using POTELLIGENT Technology licensed from BioWa.

On December 19, 2019 **MacroGenics, Inc. announced that they submitted a BLA for margetuximab** for the treatment of patients with metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer in combination with chemotherapy. The submission is based on the safety and efficacy results of the Phase 3 SOPHIA study, which evaluated margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in patients

with HER2-positive metastatic breast cancer, who had previously been treated with anti-HER2-targeted therapies, including trastuzumab, pertuzumab, and ado-trastuzumab emtansine.

- Margetuximab is an Fc-engineered monoclonal antibody that targets HER2.

FDA approves 2 mAbs

On December 18, 2019 **FDA granted accelerated approval to Enhertu** (fam-trastuzumab deruxtecan-nxki) for the treatment of adults with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

- Enhertu is an ADC composed of a HER2-directed antibody conjugated to a topoisomerase inhibitor.

On December 20, 2019 **FDA granted accelerated approval to Padcev** (enfortumab vedotin-ejfv) for the treatment of adult patients with locally or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and a platinum-containing chemotherapy. Platinum-containing chemotherapy, PD-1 and PD-L1 inhibitors are standard treatments for patients with bladder cancer, the sixth most common cancer in the U.S.

- Padcev is an ADC composed of a Nectin-4-directed antibody and a microtubule inhibitor (monomethyl auristatin E).

In other news...

On December 26, 2019 OBI Pharma, Inc. announced that the **FDA has granted Orphan Drug Designation for OBI-999** for the treatment of pancreatic cancer. A Phase 1/2 clinical trial of OBI-999 has commenced enrollment of patients with locally advanced or metastatic solid tumors, including pancreatic, gastric, colorectal and esophageal cancers (ClinicalTrials.gov Identifier: NCT04084366).

- OBI-999 is an ADC targeting Globo H, a glycolipid antigen, conjugated with monomethyl auristatin E.
