Antibody News You Should Know

June 15 - July 1, 2020

Updates on non-COVID-19 interventions

Preclinical development

On June 17, 2020, **Lassen Therapeutics announced it has secured $31 million in Series A financing to develop antibodies** as potential treatments for fibrosis, rare diseases and oncology. Lassen acquired human anti-IL-11R monoclonal antibodies from CSL Limited and is working in partnership with FUJIFILM Diosynth Biotechnologies to accelerate its anti-IL-11R program.

- The lead candidate is LASN01, a monoclonal antibody targeting IL-11 receptor alpha.

First clinical studies

On June 18, 2020, **Seattle Genetics, Inc. announced dosing of the first patient** in a Phase 1 clinical trial (NCT04254107) evaluating SEA-TGT, also known as SGN-TGT, for patients with solid tumors and lymphomas. They also announced the dosing of the first patient in a Phase 1 clinical trial (NCT04389632) evaluating SGN-B6A in patients with advanced solid tumors.

- SEA-TGT/ SGN-TGT is a nonfucosylated human IgG1 antibody targeting T-cell immune receptor with Ig and ITIM domains (TIGIT), an inhibitory immune receptor.
- SGN-B6A is an antibody-drug conjugate (ADC) targeting integrin beta-6, which is overexpressed in numerous solid tumors and has been demonstrated to be a negative prognostic indicator across a diverse range of cancers.

Details for a **first-in-human, Phase 1/2 study (NCT04441099) of NBE-002**, an anti-ROR1 ADC, in patients with advanced solid tumors were posted on June 22, 2020. The study will evaluate the recommended dose for further clinical development, safety, tolerability, anti-tumor activity, immunogenicity, pharmacokinetics and pharmacodynamics of NBE-002. This study is not yet recruiting patients.

- Developed by NBE-Therapeutics AG, NBE-002 is an anthracycline-based immune-stimulatory ADC targeting ROR1.

Details for a **first-in-human, open-label, multi-center, Phase 1/2, dose-escalation study (NCT04442126) with expansion cohorts to evaluate NM21-1480** for safety and immunogenicity, to determine the maximal tolerated dose and recommended Phase 2 dose,

define the pharmacokinetics, to explore the pharmacodynamics, and to obtain preliminary evidence of the clinical activity in adult patients with selected advanced solid tumors were posted on June 22, 2020. This study is not yet recruiting patients.

- Developed by Numab Therapeutics AG, NM21-1480 is a trispecific anti-PD-L1/anti-4-1BB/anti-human serum albumin single-chain Fv fusion protein.

On June 22, 2020, **Heat Biologics, Inc. announced that the first patient has been treated in their first-in-human Phase 1 clinical trial evaluating PTX-35**, the first antibody product candidate developed by Heat Biologics' Pelican Therapeutics subsidiary. NCT04430348 is a Phase I, first-in-human, dose-escalation study to evaluate the safety of PTX-35 in patients with advanced solid tumors refractory to standard of care.

- PTX-35 is a humanized monoclonal antibody that is a functional agonist of human T-cell co-stimulator, TNFRSF25.

On June 24, 2020, **Grid Therapeutics, LLC announced that the first patient has been dosed in a Phase 1/2 study (NCT04314089) of GT103** in patients with refractory non-small cell lung cancer. The study will enroll an estimated 24 patients and has an estimated primary completion date of June 2022.

- GT103 is an IgG3 therapeutic antibody derived from single B cells of cancer patients.

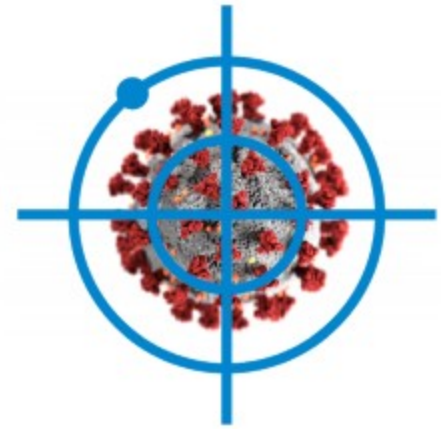
On June 25, 2020, **Tizona Therapeutics, Inc. announced today that its Investigational New Drug application for the anti-HLA-G antibody TTX-080** has been cleared by the U.S. Food and Drug Administration (FDA). The first clinical study of TTX-080 will be initiated in advanced cancers in Q3 2020.

- By blocking the interaction of HLA-G with its receptors, TTX-080 prevents the suppression of both innate and adaptive immune activity and has the potential to enhance anti-tumor responses.

Regulatory review update

On June 19, 2020, **GlaxoSmithKline plc announced the US FDA will convene a meeting of the Oncologic Drugs Advisory Committee (ODAC) to review data supporting the company's Biologics License Application) for belantamab mafodotin** for the potential treatment of patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody. The ODAC will meet virtually on July 14, 2020.

- Belantamab mafodotin is a humanized ADC targeting B-cell maturation antigen.



New developments in COVID-19 interventions

The Antibody Society, in partnership with the Chinese Antibody Society, is closely tracking over 140 programs involving the development of recombinant protein therapeutics, mostly monoclonal antibodies, as COVID-19 interventions. While some are intended to ameliorate symptoms of the disease, such as elevated levels of cytokines or abnormal clotting, more than 80 directly target SARS-CoV-2 and block its entry into cells.

Details can be found in our **online searchable Tracker**.

News announced during June 15 - July 1, 2020 include:

On June 16, 2020, **YUMAB announced the first financing round of its spin-off CORAT Therapeutics GmbH** to advance the development of anti-SARS-CoV-2 antibody drug candidates. CORAT Therapeutics will continue the pre-clinical development of the lead antibody drug candidate to potentially begin clinical development by the end of 2020.

- The candidates are human anti-SARS-CoV-2 antibodies with neutralizing activity against live SARS-CoV-2.

On June 29, 2020, **IMMUNOPRECISE ANTIBODIES LTD. announced the discovery of functional anti-SARS-CoV-2 antibodies** from humans and llama, which were identified using the company's phage display technology. Numerous lead candidate antibodies with highly potent

neutralizing activity in vitro were identified. The company anticipates pre-clinical studies will begin summer 2020.

- Additional anti-SARS-CoV-2 antibodies derived from rabbit and OmniAb® rat campaigns are also undergoing functional screens.

On June 16, 2020, **Monopar Therapeutics Inc. and NorthStar Medical Radioisotopes, LLC announced a 50/50 collaboration to develop potential radio-immuno-therapeutics to treat the symptoms of severe COVID-19** caused by aberrantly activated immune cells that release pro-inflammatory cytokines. The companies aim to develop Monopar Therapeutics Inc.'s MNPR-101 monoclonal antibody, along with a proprietary portfolio of related monoclonal antibodies. MNPR-101 will be coupled to a therapeutic radioisotope supplied by NorthStar.

- MNPR-101 is a preclinical stage, humanized antibody targeting urokinase plasminogen activator receptor.

On June 15, 2020, **Edesa Biotech, Inc. announced they received expedited approval from Health Canada to begin a Phase 2/3 clinical study that will evaluate EB05** as a potential treatment for moderate to severe COVID-19 patients. The company is seeking government grants to accelerate the initiation and rollout of the study. The randomized, double-blind, placebo-controlled Phase 2/3 Study (NCT04401475) will evaluate the safety and efficacy of EB05 + standard of care (SOC) vs. placebo + SOC in adult hospitalized patients with moderate to severe covid-19 pneumonia.

- EB05 is a humanized IgG1 antibody targeting toll-like receptor 4. As NI-0101, the mAb was originally developed by NovImmune SA as a potential treatment for rheumatoid arthritis.

Details of a **Phase 3 randomized, double-blind, placebo-controlled study (NCT04452318) assessing the efficacy and safety of REGN10933+REGN10987** in preventing SARS-CoV-2 infection in household contacts of individuals infected with SARS-CoV-2 were first posted on June 30, 2020. An estimated 2000 patients will receive subcutaneous administration of the mixture of antibodies. The estimated study primary completion date is April 11, 2021.

- REGN10933+REGN10987 are anti-Spike SARS-CoV-2 monoclonal antibodies.