Antibody News You Should Know

June 1 - 15, 2020

COVID-19 Biologics Tracker is now online!

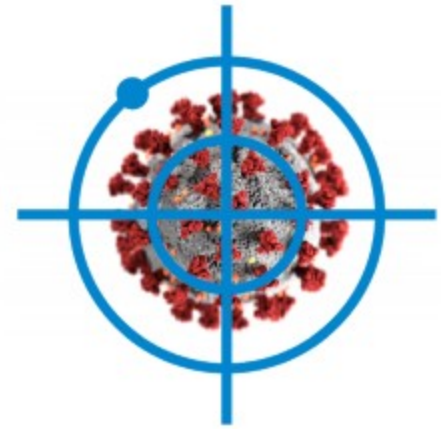
The Antibody Society, in collaboration with the Chinese Antibody Society, is tracking over 140 recombinant protein-based COVID-19 interventions in preclinical and clinical development. Our ongoing collaboration is designed to provide data, analysis and commentary relating to COVID-19 interventions to the scientific community.

Our **COVID-19 Antibody Therapeutics Tracker** includes data relating to COVID-19 biologics discovery programs and specific molecules in preclinical and clinical development. The database includes:

- Drug code and other names
- Target and format
- Development status
- Sponsoring organization and partners

Detailed information about the clinical studies of the anti-SARS-CoV-2 antibodies, including results when available, can be found here.

The "**Coronavirus in the Crosshairs**" series provides analyses and commentary on the ongoing discovery and development of COVID-19 interventions for broad use, including small molecule and biologic drugs, and vaccines.



Special Issue on COVID-19 interventions

The 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.

During June 1-15, 2020, 4 companies announced that their anti-SARS-CoV-2 antibodies entered a first-in-humans study:

On June 1, 2020, **Eli Lilly and Company announced LY-CoV555, an anti-SARS-CoV2 IgG1 antibody, has been administered to COVID-19 patients**. LY-CoV555 is the first antibody specifically targeting SARS-COV-2 to enter clinical study.

- The antibody was developed via a collaboration between Lilly and AbCellera. AbCellera, with the Vaccine Research Center at the National Institute of Allergy and Infectious Diseases, isolated single B cells from convalescent patients, identified a pool of ~500 candidate antibodies against the virus' spike protein and selected leads from this pool. Lilly scientists further developed LY-CoV555 in just three months.
- The placebo-controlled study (**NCT04411628**) will assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of LY-CoV555 following a single dose in patients hospitalized with COVID-19. Results are anticipated by the end of June 2020. The company intends to test LY-CoV555 and other neutralizing antibodies against SARS-CoV-2 over the next several months as monotherapy or antibody cocktails for COVID-19.

- The start of a Phase 2 (**NCT04427501**), randomized, double-blind, placebo-controlled, Phase 2 study to evaluate the efficacy and safety of LY3819253 in participants with mild to moderate COVID-19 illness is pending.

On June 7, 2020, **Junshi Biosciences announced that a Phase 1 clinical study of JS016 in healthy volunteers had started in China**.

- JS016 is a human monoclonal antibody that targets the SARS-CoV-2 spike protein and blocks binding of the virus to host cells. The antibody was identified by screening B cells from convalescent COVID-19 patients, and engineered to introduce LALA mutations to silence the Fc portion. JS016 was shown to provide protection from SARS-CoV-2 infection when administered to rhesus monkeys (**Shi et al. Nature 2020**).
- The clinical study will evaluate the tolerability, safety, pharmacokinetics and immunogenicity of JS016 in healthy volunteers. If the Phase 1 study shows the antibody can be administered safely, Junshi Biosciences intends to start another clinical study in that will assess JS016's ability to prevent and treat COVID-19.
- Junshi and Eli Lilly and Company are collaborating to co-develop JS016, with Junshi leading clinical development in China and Lilly leading clinical development in the rest of the world. The antibody was jointly developed by Junshi Biosciences and the Institute of Microbiology, Chinese Academy of Sciences.

On June 9, 2020 Singapore-based biotechnology company **Tychan Pte Ltd. initiated a Phase 1 study (NCT04429529) to evaluate TY027**, a monoclonal antibody that specifically targets SARS-CoV-2, in healthy volunteers.

- The safety of the antibody will be assessed in this time lagged, randomized, placebo controlled, double blind, single ascending dose (0.5 - 20 mg) study.

On June 11, 2020, **Regeneron Pharmaceuticals, Inc. announced the start of the first clinical trial of REGN-COV2 for the prevention and treatment of COVID-19**.

- REGN-COV2 is a cocktail of the human antibodies REGN10933 and REGN10987, which were derived from Regeneron's parallel efforts using both humanized VelocImmune® mice and blood samples from recovered COVID-19 patients to generate a large and diverse collection of antibodies targeting multiple different regions of the receptor-binding domain of the SARS-CoV-2 spike protein. Two papers describing the creation of REGN-COV2 and its anti-viral activity have been accepted for publication in Science.
- The REGN-COV2 clinical program will consist of four separate study populations: hospitalized COVID-19 patients, non-hospitalized symptomatic COVID-19 patients,

uninfected people in groups that are at high-risk of exposure and uninfected people with close exposure to a COVID-19 patient. The placebo-controlled trials will be conducted at multiple sites. The first two adaptive Phase 1/2/3 studies are evaluating REGN-COV2 as a treatment for hospitalized and non-hospitalized patients with COVID-19. The Phase 1 portion will focus on virologic and safety endpoints, and the Phase 2 portion will focus on virologic and clinical endpoints. Data from the Phase 1 and Phase 2 studies will be used to refine the endpoints and determine size for the Phase 3 studies.

- **NCT04425629** is a master protocol assessing the safety, tolerability, and efficacy of anti-spike (S) SARS-CoV-2 monoclonal antibodies for the treatment of ambulatory patients with COVID-19.
- **NCT04426695** is a master protocol assessing the safety, tolerability, and efficacy of anti-spike (S) SARS-CoV-2 monoclonal antibodies for the treatment of hospitalized patients with COVID-19.

In other news about COVID-19 interventions:

On June 5, 2020, **AbbVie, Harbour BioMed, Utrecht University and Erasmus Medical Center announced they entered into a collaboration** to develop a novel antibody therapeutic to prevent and treat COVID-19.

- The collaboration will focus on developing 47D11, a human, neutralizing antibody 47D11 targeting the conserved domain of the SARS-CoV-2 spike protein that was recently **reported in Nature Communications**.

On June 9, 2020, **AstraZeneca announced they have licensed coronavirus-neutralizing antibodies from Vanderbilt University**, and plan to advance a pair of these mAbs into clinical development as a potential combination therapy for the prevention and treatment of COVID-19. This agreement builds on the Company's collaboration agreement with Vanderbilt, announced in April 2020.

On June 9, 2020, it was reported that the **Ministry of Health of the Russian Federation registered anti-IL-6R levilimab** (BCD-089, trade name Ilsira), intended for the treatment of severe COVID-19. Developed by Biocab, levilimab received state approval in Russia through a fast-track mechanism.