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NEWS RELEASE

AbCellera-Discovered Antibody Receives U.S. FDA Emergency Use Authorization as a Monotherapy for the Treatment of COVID-19

11/9/2020

AbCellera's partner, Eli Lilly and Company, will supply the U.S. government with 300,000 doses of bamlanivimab for allocation to high-risk patients

VANCOUVER, British Columbia, November 9, 2020 – AbCellera today announced that bamlanivimab (LY-CoV555) 700 mg, a human antibody developed through AbCellera's collaboration with Eli Lilly and Company (Lilly), has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA). Bamlanivimab is authorized for the treatment of mild to moderate COVID-19 in adults and pediatric patients 12 years and older with a positive COVID-19 test, who are at high risk for progressing to severe COVID-19 and/or hospitalization. The EUA is based on data from BLAZE-1, a randomized, double-blind placebo-controlled Phase 2 study in patients with recently diagnosed mild to moderate COVID-19 in the outpatient setting. Patients treated with bamlanivimab showed reduced viral load and rates of symptoms and hospitalization. Details regarding the EUA and Lilly's plans to make COVID-19 therapies broadly available to patients, including its agreement to provide the U.S. government with 300,000 doses, can be found [here](#).

"We commend the Lilly team for their tireless efforts to combat COVID-19 and for starting antibody manufacturing at risk in advance of clinical results. Because of this, there is now an opportunity to have a near-term impact against COVID-19, manufacturing up to one million doses of bamlanivimab for patients before the end of the year," said Carl Hansen, Ph.D., CEO of AbCellera.

Bamlanivimab was the first monoclonal antibody therapy for COVID-19 to enter human testing in the United States

and is currently undergoing multiple Phase 1, 2 and 3 clinical trials. Bamlanivimab was discovered from the blood of a recovered COVID-19 patient by AbCellera, scientists at the Vaccine Research Center at National Institute of Allergy and Infectious Diseases (NIAID) and Lilly.

AbCellera's COVID-19 response was based on capabilities developed over the past two years **as part of the Defense Advanced Research Projects Agency (DARPA) Pandemic Prevention Platform (P3) program**. The goal of the P3 program is to establish a robust technology platform for pandemic response capable of developing field-ready medical countermeasures within 60 days of isolation of an unknown viral pathogen.

About bamlanivimab

Bamlanivimab is a recombinant, neutralizing human IgG1 monoclonal antibody (mAb) directed against the spike protein of SARS-CoV-2. It is designed to block viral attachment and entry into human cells, thus neutralizing the virus, potentially treating COVID-19. Bamlanivimab emerged from the collaboration between Lilly and AbCellera to create antibody therapies for the prevention and treatment of COVID-19. Lilly scientists rapidly developed the antibody in less than three months after it was discovered by AbCellera and the scientists at the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center. It was identified from a blood sample taken from one of the first U.S. patients who recovered from COVID-19.

Lilly has successfully completed a Phase 1 study of bamlanivimab in hospitalized patients with COVID-19 (**NCT04411628**). A Phase 2 study in people recently diagnosed with COVID-19 in the ambulatory setting (BLAZE-1, **NCT04427501**) is ongoing. A Phase 3 study of bamlanivimab for the prevention of COVID-19 in residents and staff at long-term care facilities (BLAZE-2, **NCT04497987**) is also ongoing. In addition, bamlanivimab is being tested in the National Institutes of Health-led ACTIV-2 study in ambulatory COVID-19 patients.

About BLAZE-1

BLAZE-1 (**NCT04427501**) is a randomized, double-blind, placebo-controlled Phase 2 study designed to assess the efficacy and safety of bamlanivimab alone or in combination with a second antibody for the treatment of symptomatic COVID-19 in the outpatient setting. To be eligible, patients were required to have mild or moderate symptoms of COVID-19 as well as a positive SARS-CoV-2 test based on a sample collected no more than three days prior to drug infusion.

The monotherapy arms of the trial enrolled mild to moderate recently diagnosed COVID-19 patients, studying three doses of bamlanivimab (700 mg, 2800 mg, and 7000 mg) versus placebo.

The primary outcome measure for the completed arms of the BLAZE-1 trial was change from baseline to day 11 in SARS-CoV-2 viral load. Additional endpoints include the percentage of participants who experience COVID-related hospitalization, ER visit or death from baseline through day 29, as well as safety.

The study is ongoing with additional treatment arms. Across all treatment arms, the trial will enroll over 800 participants.

Data from the monotherapy arms of BLAZE-1 were published in the **New England Journal of Medicine**.

About AbCellera Biologics Inc.

AbCellera is a privately held technology company with an antibody discovery platform that searches and analyzes natural immune systems to find antibodies that can be used to prevent and treat disease. AbCellera's technology, which combines high-throughput microfluidics, hyper-scale data science, machine learning, bioinformatics, and genomics, identifies new drug candidates and aims to reduce the time it takes to bring treatments to the clinic. AbCellera's partners include leading biotechnology companies, global health organizations, and many of the top 10 biopharmaceutical companies. For more information, visit www.abcellera.com.

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