



2215 Yukon St .
Vancouver, BC
Canada, V5Y 0A1
T 1. 604.559.9005
abcellera.com

NEWS RELEASE

Emergency Use Authorization of AbCellera-Discovered Bamlanivimab Administered with Etesevimab Expanded by the FDA to Include Post-Exposure Prophylaxis for the Prevention of COVID-19

9/16/2021

Emergency use authorization now includes post-exposure prophylaxis to prevent COVID-19 in certain people who have been exposed to someone infected with SARS-CoV-2 or who are at high risk of exposure in an institutional setting

VANCOUVER, British Columbia--(BUSINESS WIRE)-- **AbCellera** (Nasdaq: ABCL) today announced the U.S. Food and Drug Administration (FDA) has expanded the Emergency Use Authorization (EUA) for bamlanivimab (LY-CoV555) 700 mg administered with etesevimab (LY-CoV016) 1400 mg to include post-exposure prophylaxis (PEP) to prevent SARS-CoV-2 infection or symptomatic COVID-19. The neutralizing antibodies, which were authorized together by the FDA in February 2021 to treat early COVID-19 infection, can now also be used together to treat high-risk individuals 12 years of age and older who have not been fully vaccinated against COVID-19 or are not expected to mount an adequate immune response to complete vaccination, and have been exposed to someone infected with SARS-CoV-2 or who are at high risk of exposure in an institutional setting, including a nursing home or prison.

"The expanded use authorization for bamlanivimab together with etesevimab provides a way to protect the significant number of people who, because of their situational exposure risk or medical condition, remain vulnerable to COVID-19," said Carl Hansen, Ph.D., CEO and President of AbCellera. "More than 535,000 patients have been treated with bamlanivimab alone or together with etesevimab, potentially keeping more than 25,000

patients out of the hospital and saving more than 10,000 lives. With this expanded authorization, these antibodies, which have been shown to be effective against the highly contagious Delta variant, can now be used to protect some of the most at-risk people exposed to the virus.”

The expanded EUA is based on data from the Phase 3 BLAZE-2 trial that showed bamlanivimab prevented COVID-19 in nursing homes, reducing the risk of contracting the disease by up to 80 percent in nursing home residents and up to 57 percent among residents and staff of long-term care facilities. Eli Lilly and Company’s (Lilly) study was conducted in partnership with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the COVID-19 Prevention Network (CoVPN).

Pseudovirus and authentic virus studies demonstrate that bamlanivimab and etesevimab together retain neutralization activity against the Alpha and Delta variants. On September 2nd, the Office of the Assistant Secretary for Preparedness and Response (ASPR), alongside the FDA, resumed the shipment and distribution of bamlanivimab and etesevimab administered together.

For information about the use of bamlanivimab and etesevimab together for the treatment and prevention of mild to moderate COVID-19 in high-risk patients under the FDA’s emergency use authorization, please click [here](#) or contact Lilly’s 24-hour support line at 1-855-LillyC19 (1-855-545-5921).

About AbCellera’s Response to COVID-19

AbCellera initially mobilized its pandemic response platform against COVID-19 in March of 2020, resulting in the discovery of bamlanivimab, the first monoclonal antibody therapy for COVID-19 to reach human testing and to be authorized for emergency use by the FDA. Bamlanivimab alone and together with other antibodies has treated hundreds of thousands of patients, preventing COVID-19-related hospitalizations and death.

AbCellera’s ongoing efforts to respond to the COVID-19 pandemic have identified thousands of unique anti-SARS-CoV-2 human antibodies. These include bamlanivimab, bebtelovimab, and other antibodies that are in various stages of testing by AbCellera and its partners.

AbCellera’s pandemic response capabilities were developed over the past three 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. Bamlanivimab was developed from an antibody that was discovered from the blood of a recovered COVID-19 patient using AbCellera’s pandemic response platform, in partnership with the Vaccine Research Center (VRC) at NIAID. Within one week of receiving the sample, AbCellera screened over five million antibody-producing cells to identify and isolate approximately 500 unique antibodies that bind to SARS-CoV-2, the virus that causes COVID-19. The binding antibodies were then tested by AbCellera, the VRC, and Lilly to find those most effective in neutralizing

the virus. Bamlanivimab was selected as the lead candidate from this group of antibodies and was both the first therapeutic candidate specifically developed against SARS-CoV-2 to enter human clinical trials in North America, and to receive EUA from the FDA. Bamlanivimab alone and/or administered with etesevimab are authorized under special use pathways in more than 22 countries, spanning four continents. In the U.S., bamlanivimab is currently only authorized for emergency use with etesevimab.

Results from a Phase 2/3 study in people recently diagnosed with COVID-19 in the ambulatory setting (BLAZE-1, [NCT04427501](#)) were published in the [New England Journal of Medicine](#). Results from a Phase 3 study of bamlanivimab in residents and staff at long-term care facilities (BLAZE-2, [NCT04497987](#)) were published in the [Journal of American Medical Association](#). A Phase 2 study assessing the efficacy and safety of bamlanivimab alone, and bamlanivimab with other neutralizing antibodies versus placebo for the treatment of symptomatic low-risk COVID-19 in the outpatient setting (BLAZE-4, [NCT04634409](#)) has completed enrollment.

About AbCellera Biologics Inc.

AbCellera is a technology company that searches, decodes, and analyzes natural immune systems to find antibodies that its partners can develop into drugs to prevent and treat disease. AbCellera partners with drug developers of all sizes, from large pharmaceutical to small biotechnology companies, empowering them to move quickly, reduce cost, and tackle the toughest problems in drug development. For more information, please visit www.abcellera.com.

AbCellera Forward-looking Statements

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements are based on management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize and achieve market acceptance of our current and planned products and services, our research and development efforts, and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the Securities and Exchange Commission from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

Source: AbCellera Biologics Inc.

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20210916005867/en/>

Inquiries

Media: Jessica Yingling, Ph.D.; media@abcellera.com, +1(236)521-6774

Business Development: Neil Berkley; bd@abcellera.com, +1(604)559-9005

Investor Relations: Melanie Solomon; ir@abcellera.com, +1(778)729-9116

Source: AbCellera Biologics Inc.