Data for Lilly's bamlanivimab (LY-CoV555) in COVID-19 outpatients published in New England Journal of Medicine

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INDIANAPOLIS, Oct. 28, 2020 /PRNewswire/ -- The *New England Journal of Medicine* has published data from the monotherapy arms of BLAZE-1, a Phase 2 study assessing the efficacy and safety of Eli Lilly and Company's (NYSE: LLY) bamlanivimab (LY-CoV555) – a neutralizing antibody – in the COVID-19 outpatient setting. This study focused on ambulatory COVID-19 patients being treated in the outpatient setting, whose symptoms did not require hospitalization at the time of enrollment. The publication, which can be found here, follows Lilly's proof-of-concept data announcement for bamlanivimab as monotherapy in September 2020.

"The publication of these data in a peer-reviewed journal adds to the growing body of evidence for the potential utility for neutralizing antibodies as therapeutics for people recently diagnosed with mild to moderate COVID-19, particularly high-risk patients," said Ajay Nirula, M.D., Ph.D., vice president of immunology at Lilly and co-first author of the study. "These data show bamlanivimab may be effective in treating COVID-19 by reducing viral load, symptoms and the risk of hospitalization in outpatients."

"It is important to treat people with COVID-19 as soon as possible after diagnosis in order to forestall development of more severe disease," said Peter Chen, M.D., director of Pulmonary and Critical Care Medicine at Cedars-Sinai and co-first author of the study. "Our findings indicate that neutralizing antibodies may have the potential to be useful in this early-stage intervention."

These data were submitted as part of Lilly's request for an emergency use authorization from the U.S. Food and Drug Administration for bamlanivimab in higher-risk patients who have been recently diagnosed with mild to moderate COVID-19.

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 BLAZE-1 study show bamlanivimab may be effective in treating COVID-19 by reducing viral load, symptoms and the risk of hospitalization in patients recently diagnosed with mild to moderate COVID-19. In the BLAZE-1 trial, rates and types of adverse events were similar between bamlanivimab and placebo, with the majority being mild to moderate in severity and with no drug-related serious adverse events reported thus far. In other bamlanivimab studies, there have been isolated drug-related infusion reactions or hypersensitivity that were generally mild (two reported as serious infusion reactions, both patients recovered).

About bamlanivimab (LY-CoV555)

LY-CoV555 is a potent, neutralizing 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 preventing and treating COVID-19. LY-CoV555 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 of ambulatory COVID-19 patients.

About Lilly's COVID-19 Efforts

Lilly is bringing the full force of its scientific and medical expertise to attack the coronavirus pandemic around the world. Existing Lilly medicines are now being studied to understand their potential in treating complications of COVID-19, and the company is collaborating with partner companies to discover novel antibody treatments for COVID-19. Lilly is testing both single antibody therapy as well as combinations of antibodies as potential therapeutics for COVID-19. Click here for media resources related to Lilly's COVID-19 efforts.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and www.lilly.com/news. P-LLY

Lilly Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about bamlanivimab (LY-CoV555) as a potential treatment for patients with or at risk of infection from COVID-19 and reflects Lilly's current beliefs. However, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there can be no guarantee that studies will complete as planned, that future study results will be consistent with the results to date, that bamlanivimab will prove to be a safe and effective treatment or preventative for COVID-19, that bamlanivimab will receive regulatory approvals or authorizations, or that we can provide an adequate supply of bamlanivimab in all circumstances. For a further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see Lilly's most recent Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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