Lilly announces agreement with U.S. government to supply 300,000 vials of investigational neutralizing antibody bamlanivimab (LY-CoV555) in an effort to fight COVID-19

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- Initial agreement for 300,000 vials with potential for purchase of an additional 650,000 vials

- Patients will have no out-of-pocket costs for the medication

INDIANAPOLIS, Oct. 28, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today an initial agreement with the U.S. government to supply 300,000 vials of bamlanivimab (LY-CoV555) 700 mg, an investigational neutralizing antibody, for $375 million. The U.S. government will accept the vials of bamlanivimab if it is granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). Lilly submitted a request for an EUA for bamlanivimab for the treatment of mild to moderate COVID-19 in high-risk patients to the FDA in early October. The initial agreement is for delivery over the two months following an EUA and also provides the option for the U.S. government to purchase up to an additional 650,000 vials through June 30, 2021, under the same terms as the base agreement and subject to agreement from Lilly, product availability and the medical need in the U.S.

"Lilly has leveraged our deep scientific capability to fight this pandemic and we are proud of our efforts to develop potential medicines to combat COVID-19. Supply agreements with governments – such as this one with the U.S. government to meet Operation Warp Speed goals – are fundamental to enable the most widespread and equitable access to our potential therapy," said David A. Ricks, Lilly's chairman and CEO. "The U.S. is experiencing a surge in COVID-19 cases and associated hospitalizations, and we believe bamlanivimab could be an important therapeutic option that can bring value to the overall healthcare system, as it has shown a potential benefit in clinical outcomes with a reduction in viral load and rates of symptoms and hospitalizations."

If an EUA is granted, the U.S. government has committed that patients will have no out-of-pocket costs for the medicine, although healthcare facilities may charge a fee for the product's administration. The federal government, in partnership with state health departments, is developing a government allocation program for bamlanivimab. As part of this government program, Lilly is partnering with Operation Warp Speed and a national distributor to finalize distribution plans and shipping preparations, should an EUA be granted. The intravenous administration of therapeutics to patients with confirmed mild to moderate COVID-19 presents unique challenges to the healthcare system. Lilly is also working closely with Operation Warp Speed to assist U.S. federal and state agencies in the identification and creation of options for locations where patients can receive this medication that are accessible and minimize infection transmission.

Lilly anticipates manufacturing up to one million doses of bamlanivimab 700 mg by the end of 2020 – with 100,000 doses ready to ship within days of authorization – for use around the world. The supply of Lilly's antibody therapy is expected to increase substantially beginning in Q1 2021, as additional manufacturing resources come online throughout the year. Lilly has a robust, global supply chain in place to produce bamlanivimab, with five active pharmaceutical ingredients (API) manufacturing sites worldwide. To ensure rapid access of this treatment to patients around the world, Lilly has invested in large-scale manufacturing of bamlanivimab at risk – even before data demonstrated its potential to become a meaningful therapeutic option for COVID-19.

Discussions with global regulators are ongoing. Global allocation will be made based on Lilly's guiding principles that aim to ensure access for patients with high unmet need, no matter where they live. Read more about Lilly's global pricing and access principles for its antibody therapies at lilly.com.

"We are also partnering with governments and philanthropic organizations around the world to ensure a fair and transparent allocation of the limited supply of our antibody therapies to those who need it most, based on a global methodology using data from trusted research centers," Ricks continued.

About bamlanivimab
Bamlanivimab 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. 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 of ambulatory COVID-19 patients.

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 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, as well as its supply, cost and potential regulatory approval. This press release 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.

Refer to:
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