Lilly announces 650,000 additional doses of neutralizing antibody bamlanivimab (LY-CoV555) purchased by U.S. government to treat COVID-19

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INDIANAPOLIS, Dec. 2, 2020 /PRNewswire/ -- The U.S. government has purchased 650,000 additional doses of Eli Lilly and Company's (NYSE: LLY) neutralizing antibody bamlanivimab (LY-CoV555) 700 mg. The purchase agreement is for $812.5 million and the doses will be delivered through January 31, 2021, with at least 350,000 of the additional doses delivered in December 2020. Bamlanivimab recently received emergency use authorization for the treatment of mild to moderate COVID-19 in patients who are at high risk for progressing to severe COVID-19 and/or hospitalization.

"Given the significant increase in COVID-19 cases and hospitalizations in the U.S., we are doing everything possible to quickly provide more bamlanivimab doses to Americans," said David A. Ricks, Lilly's chairman and CEO. "We are proud of our work to deploy significant manufacturing capacity and remain committed to enabling widespread and equitable access to bamlanivimab. The U.S. government's effort to allocate bamlanivimab around the country is critical to ensuring it reaches patients who need it the most."

This purchase brings the total doses purchased by the U.S. government to 950,000. As previously announced by the U.S. government, Americans 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 is responsible for the allocation of bamlanivimab. Weekly allocation decisions will be proportionally based on confirmed COVID-19 cases in each state and territory over the previous seven days, based on data from the U.S. Department of Health and Human Services' Protect data collection platform. Weekly allocations can be viewed at this online federal dashboard. State and territorial health departments determine which sites of care receive the allocated doses.

Lilly has a robust, global supply chain in place to produce bamlanivimab, with numerous manufacturing sites worldwide. Lilly continues to manufacture bamlanivimab for use around the world, and the supply is expected to increase substantially in 2021. Global allocations will be made based on Lilly's guiding principles, which aim to ensure access for patients with high unmet need, no matter where they live.

For more information about the use of bamlanivimab in COVID-19, contact Lilly's 24-hour support line at 1-855-LillyC19 (1-855-545-5921). For media resources, including product images and fact sheets, please click here.

In 2020, the estimated impact of the updated purchase agreement to the guidance range provided in Lilly's earnings release on October 27, 2020 is approximately $500 million of additional revenue and approximately 25 cents of additional earnings per share.

Important Information about bamlanivimab
Bamlanivimab has not been approved by the FDA for any use. It is not known if bamlanivimab is safe and effective for the treatment of COVID-19.

Bamlanivimab is authorized under an Emergency Use Authorization only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of bamlanivimab under Section 564(b)(1) of the Act, 21 U.S.C § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Healthcare providers should review the Fact Sheet for information on the authorized use of bamlanivimab and mandatory requirements of the EUA. Please see the FDA Letter of Authorization, Fact Sheet for Healthcare Providers, and Fact Sheet for Patients, Parents, and Caregivers (English) (Spanish).

Authorized Use and Important Safety Information
Bamlanivimab is authorized for use under an EUA for treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Limitations of Authorized Use

- Bamlanivimab is not authorized for use in patients:
  - who are hospitalized due to COVID-19, OR
  - who require oxygen therapy due to COVID-19, OR
  - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19.

Important Safety Information
There are limited clinical data available for bamlanivimab. Serious and unexpected adverse events may occur that have not been previously reported with bamlanivimab use.

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of bamlanivimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care.

Infusion-related reactions have been observed with administration of bamlanivimab. Signs and symptoms of infusion-related reactions may include:

- fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.

If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.

Limitations of Benefit and Potential Risk in Patients with Severe COVID-19
Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19. See Limitations of Authorized Use.

Adverse Events
Adverse events reported in at least 1% of BLAZE-1 clinical trial participants on bamlanivimab 700 mg and placebo were Nausea (3% vs 4%), Diarrhea (1% vs 5%), Dizziness (3% vs 2%), Headache (3% vs 2%), Pruritus (2% vs 1%) and Vomiting (1% vs 3%).

Use in Specific Populations
Pregnancy
There are insufficient data on the use of bamlanivimab during pregnancy. Bamlanivimab should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Breastfeeding
There are no available data on the presence of bamlanivimab in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

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 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 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 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, delivery, additional contracts with the U.S. government and impact on Lilly's revenue and earnings per share, and reflects Lilly's current beliefs and expectations. However, as with any such undertaking, there are substantial risks and uncertainties in the process of drug research, development and commercialization. Among other things, there can be no guarantee 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 additional authorizations, that any negotiations with the U.S. government will result in additional supply contracts, that revenue or earnings per share will increase 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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