Lilly will supply an additional 150,000 doses of bebtelovimab to U.S. government in ongoing effort to provide COVID-19 treatment options

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Bebtelovimab continues to maintain neutralization against all known variants of interest and concern

INDIANAPOLIS, June 29, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced a modified purchase agreement with the U.S. government to supply an additional 150,000 doses of bebtelovimab for approximately $275 million. The existing U.S. government supply of bebtelovimab, including the new purchase, is expected to meet present demand through late August 2022. Bebtelovimab continues to maintain neutralization activity against the most common, and fastest growing, Omicron variants (BA.2.12.1 and BA.4/BA.5) in the United States, in addition to all known variants of interest and concern.

"Lilly and its collaborators have partnered closely with the federal government throughout the pandemic to ensure broad and equitable access to our monoclonal antibodies," said David A. Ricks, Lilly's chair and CEO. "While Congress works toward additional COVID-19 funding, Lilly and the U.S. government will continue to work together to support the availability of bebtelovimab to maximize equity and accessibility in the U.S. market."

Delivery of doses will begin immediately and complete no later than August 5, 2022. The 2022 estimated financial impact of this agreement is approximately $275 million of revenue and approximately $0.08 of EPS. An option for an additional 350,000 doses to be exercised no later than September 14, 2022 will remain in the agreement.

This purchase has been supported in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number W58P0522C0012.

Important Information about bebtelovimab

Bebtelovimab has not been approved, but has been authorized for emergency use by the FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

The emergency use of bebtelovimab is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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

Authorized Use and Important Safety Information

Bebtelovimab is authorized for use under Emergency Use Authorization (EUA) for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg):

- with positive results of direct SARS-CoV-2 viral testing, **and**
- who are at high risk[i] for progression to severe COVID-19, including hospitalization or death, **and**
- for whom alternate COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

LIMITATIONS OF AUTHORIZED USE

Bebtelovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to this drug and regional variant frequency.

- FDA will monitor conditions to determine whether use in a geographic region is consistent with this scope of authorization, referring to available information, including information on variant susceptibility, and CDC regional variant frequency data available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions.
- FDA's determination and any updates will be available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs

Bebtelovimab is not authorized for use in patients who:

- are hospitalized due to COVID-19, OR
- require oxygen therapy and/or respiratory support due to COVID-19, OR
- require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity.

Treatment with bebtelovimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bebtelovimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

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

WARNINGS
Hypersensitivity Including Anaphylaxis and Infusion-Related Reaction
Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of other SARS-CoV-2 monoclonal antibodies and could occur with administration of bebtelovimab. 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, which may occur up to 24 hours after the injection, have been observed in clinical trials of bebtelovimab when administered with other monoclonal antibodies and may occur with use of bebtelovimab alone. These reactions may be severe or life threatening. Signs and symptoms of infusion-related reactions may include:

- fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g. atrial fibrillation, sinus tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vasovagal reactions (e.g. pre-syncope, syncope), dizziness, and diaphoresis.

Administer appropriate medications and/or supportive care if an infusion-related reaction occurs. Hypersensitivity reactions occurring more than 24 hours after the injection have also been reported with the use of SARS-CoV-2 monoclonal antibodies under Emergency Use Authorization.

Clinical Worsening After Monoclonal Antibody Administration
Clinical worsening of COVID-19 after administration of SARS-CoV-2 monoclonal antibody treatment has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (e.g., atrial fibrillation, sinus tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to SARS-CoV-2 monoclonal antibody use or were due to progression of COVID-19.

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

Adverse Reactions
Adverse reactions observed in those who have received bebtelovimab alone or in combination with bamlanivimab and etesevimab, at the authorized dose or higher are infusion-related reactions (n=2, 0.3%), pruritus (n=2, 0.3%) and rash (n=5, 0.8%). The most common treatment-emergent adverse events observed in subjects treated with bebtelovimab, alone or in combination with bamlanivimab and etesevimab, at the authorized dose or higher included nausea (0.8%) and vomiting (0.7%).

USE IN SPECIFIC POPULATIONS
Pregnancy
Severe hypersensitivity reactions and infusion-related reactions, have been observed with administration of bebtelovimab, including in pregnant patients. Pregnant patients who develop severe hypersensitivity and infusion-related reactions should be managed appropriately, including obstetrical care. There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Bebtelovimab 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 bebtelovimab 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 bebtelovimab
Bebtelovimab (LY-CoV1404; LY3853113) is a neutralizing IgG1 monoclonal antibody (mAb) directed against the spike protein of SARS-CoV-2 that maintains binding and neutralizing activity across currently known and reported variants of concern. Bebtelovimab has been studied for the treatment of mild-to-moderate COVID-19 both as a monotherapy and together with other mAbs. Lilly has licensed and developed bebtelovimab after it was discovered by AbCellera and the scientists at the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center.

About BLAZE-4
BLAZE-4 is a Phase 2, randomized clinical trial evaluating treatment of subjects with mild-to-moderate COVID-19 (subjects with COVID-19 symptoms who are not hospitalized). The data supporting this EUA for treatment of mild-to-moderate COVID-19 are primarily based on analyses of data from the Phase 2 BLAZE-4 trial (NCT04634409), treatment arms 9-14. This trial evaluated the clinical safety and efficacy from subjects receiving 175 mg bebtelovimab, alone and together with 700 mg bamlanivimab and 1,400 mg of etesevimab. The authorized dosage of bebtelovimab is 175 mg given as an intravenous injection over at least 30 seconds. Clinical data confirm the neutralizing ability of bebtelovimab. The trial enrolled subjects who were not hospitalized and had 1 or more COVID-19 symptoms that were at least mild in severity.

About Lilly's COVID-19 Efforts
Lilly has utilized the full force of its expertise to develop the first monoclonal antibody authorized for Emergency Use (EUA) by the U.S. Food and Drug Administration (FDA) – bamlanivimab, followed by the authorization of bamlanivimab with etesevimab and, most recently, bebtelovimab. The authorized dose of bebtelovimab is 175 mg given as an intravenous injection over at least 30 seconds.

While bamlanivimab together with etesevimab are not authorized for use in the U.S., at this time, the FDA will monitor conditions to determine whether

use in a geographic region is medically appropriate, referring to available information, including information on variant susceptibility, and CDC regional variant frequency data available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions.

To date, over 700,000 patients have been treated with Lilly's monoclonal antibodies in the U.S., potentially preventing more than 35,000 hospitalizations and at least 14,000 deaths during the worst of the pandemic. Click here for resources related to Lilly's COVID-19 efforts.

About Eli Lilly and Company
Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 47 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn. 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 bebtelovimab as a potential therapy for patients with COVID-19, the supply, distribution and contracts with governments relating to bebtelovimab, and Lilly's development plans, 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 bebtelovimab will prove to be a safe and effective treatment for COVID-19, that bebtelovimab will receive regulatory approvals or additional authorizations, that patients will volunteer to participate in clinical trials or achieve positive outcomes, that Lilly will obtain any additional purchase orders or supply contracts, or that Lilly can provide an adequate supply of bebtelovimab 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.

For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the Centers for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider the benefit-risk for an individual patient.

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