Lilly will supply up to 600,000 doses of bebtelovimab to U.S. government in ongoing effort to provide COVID-19 treatment options

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Bebtelovimab neutralizes Omicron as demonstrated by pseudovirus and authentic virus data
Patients will continue to have no out-of-pocket costs for the medication

INDIANAPOLIS, Feb. 10, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced an agreement with the U.S. government to supply up to 600,000 doses of investigational drug bebtelovimab for at least $720 million. The U.S. government will accept the doses of bebtelovimab if it is granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). Lilly has submitted a request for an EUA for bebtelovimab for the treatment of mild to moderate COVID-19 in certain high-risk patients to the FDA.

Pseudovirus and authentic virus testing demonstrate that bebtelovimab retains full neutralizing activity against Omicron – currently the predominant variant in the U.S. In addition, pseudovirus testing with bebtelovimab demonstrates that it retains neutralization against all other known variants of interest and concern, including BA.2.

The supply agreement calls for the delivery of up to 600,000 doses no later than March 31, 2022 with an option of 500,000 additional doses no later than July 31, 2022.

The 2022 estimated financial impact of this agreement is at least $720 million of revenue and approximately $0.20 of EPS.

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.

About bebtelovimab

Bebtelovimab (LY-CoV1404; LY3853113) is an investigational 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, including Omicron and BA.2. Bebtelovimab is being 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 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.

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 is a global health care 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 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.

Refer to: Allison Howell, howell_allison@lilly.com, 317-655-1106 (Media)

Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (Investors)

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