Lilly plans donation of COVID-19 therapies to Direct Relief for use in low- and lower-middle-income countries

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- Donation builds upon Lilly's access principles for COVID-19 therapies

INDIANAPOLIS, May 4, 2021 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) is donating COVID-19 therapies to Direct Relief, enabling the humanitarian organization to provide COVID-19 therapies at no cost to low- and lower-middle-income countries most heavily impacted by the pandemic. This donation furthers both Lilly and Direct Relief's charitable goal of providing access to COVID-19 treatments to patients in need by providing these medicines free of charge to low- and lower-middle-income countries. Lilly will donate both baricitinib (4 mg tablet) as well as bamlanivimab (LY-CoV555) 700 mg and etesevimab (LY-CoV016) 1400 mg together – providing options to treat COVID-19 patients at different stages of the disease.

Direct Relief will allocate donations of baricitinib to low- and lower-middle-income countries (based on World Bank classification) for the treatment of hospitalized COVID-19 patients requiring supplemental oxygen, based on requests from these governments to Direct Relief. Donations of bamlanivimab and etesevimab together will be provided by Direct Relief to those countries for the treatment of mild to moderate COVID-19 patients at high risk of progressing to hospitalization or death in the outpatient setting.

"Direct Relief is deeply grateful for Lilly's decision to make its COVID-19 therapies available at no charge for people who otherwise would not have access to them. This is a wonderful example of each of us doing whatever we can to get through this pandemic," said Direct Relief president and CEO Thomas Tighe. "Lilly's action provides both important new options and potential resources for countries' health and regulatory leaders to consider for the care of COVID-19 patients, and Direct Relief will of course move with urgency upon receiving any such requests."

"Even as the world makes progress on vaccine roll-outs, it remains vital for treatments to be available that can make a meaningful difference for those fighting COVID-19," said David A. Ricks, Lilly chairman and CEO. "Both baricitinib as well as bamlanivimab with etesevimab together have saved the lives of COVID-19 patients at different stages of the disease. Bamlanivimab with etesevimab together reduces the risk of hospitalizations and death for high-risk patients in the outpatient setting, while recent data show baricitinib in addition to current standard of care reduces death in hospitalized patients."

The allocation of therapies will be based on the disease burden and hospitalization rates in each country. This initiative, which will commence immediately, subject to relevant local regulatory requirements, currently goes through December 2021 and will be continuously assessed based on the pandemic situation in these countries.

Ricks continued, "Today's announcement with Direct Relief will help ensure access to Lilly's COVID-19 therapies for patients around the world—no matter where they live."

The arrangement is part of Lilly's philanthropic efforts and supports Lilly 30x30, the company's goal to improve access to quality health care for 30 million people living in settings with limited resources, each year, by 2030.

Authorized Use Under the EUA and Important Safety Information for baricitinib (in the United States) for COVID-19
Baricitinib is authorized for use under an Emergency Use Authorization (EUA) in combination with remdesivir, for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults and pediatric patients 2 years of age or older, requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Baricitinib has not been approved for the treatment of COVID-19, but has been authorized for emergency use by the FDA. Baricitinib is authorized under an EUA only for the duration of the declaration that circumstances exist justifying the authorization of the EUA of baricitinib under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

For information on the authorized use of baricitinib and mandatory requirements under the EUA, please review the FDA Letter of Authorization, Fact Sheet for Healthcare Providers and Fact Sheet for Patients, Parents and Caregivers (English; Spanish).

Important Safety Information about baricitinib for COVID-19
The following provides essential safety information on the unapproved use of baricitinib under the Emergency Use Authorization.
Warnings
Serious Infections: Serious infections have occurred in patients receiving baricitinib. Avoid the use of baricitinib with known active tuberculosis. Consider if the potential benefits outweigh the potential risks of baricitinib treatment in patients with active serious infections other than COVID-19 or chronic/recurrent infections.
Thrombosis: In hospitalized patients with COVID-19, prophylaxis for venous thromboembolism is recommended unless contraindicated. If clinical features of deep vein thrombosis or pulmonary embolism occur, patients should be evaluated promptly and treated appropriately.
Abnormal Laboratory Values: Evaluate at baseline and thereafter according to local patient management practice. Monitor closely when treating patients with abnormal baseline and post-baseline laboratory values. Follow dose adjustments as recommended in the Fact Sheet for Healthcare Providers for patients with abnormal renal, hematological and hepatic laboratory values. Manage patients according to routine clinical guidelines.
Hypersensitivity: If a serious hypersensitivity occurs, discontinue baricitinib while evaluating the potential causes of the reaction.
See **Warnings and Precautions** in the FDA-approved full Prescribing Information for additional information on risks associated with longer-term treatment with baricitinib.
Serious Side Effects: Serious venous thrombosis, including pulmonary embolism, and serious infections have been observed in COVID-19 patients

treated with baricitinib and are known adverse drug reactions of baricitinib.
There are limited clinical data available for baricitinib use in coronavirus 2019 (COVID-19). Additional information regarding baricitinib for its FDA-approved indication, including safety information, may be found in the full Prescribing Information, including Boxed Warning about Serious Infections, Malignancies, and Thrombosis, and Medication Guide.
Use in Specific Populations
Pregnancy: Baricitinib should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.
Renal Impairment: There are limited data for baricitinib in patients with severe renal impairment. Baricitinib is not recommended for patients who are on dialysis, have end-stage renal disease, or have acute kidney injury.
Hepatic Impairment: Baricitinib has not been studied in patients with severe hepatic impairment. Baricitinib should only be used in patients with severe hepatic impairment if the potential benefit outweighs the potential risk.
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Click here for resources related to Lilly's COVID-19 efforts and here for baricitinib's EUA.

About OLUMIANT ® (baricitinib)
OLUMIANT, a once-daily, oral JAK inhibitor was discovered by Incyte and licensed to Lilly. It is approved in the U.S. and more than 70 countries as a treatment for adults with moderate to severe rheumatoid arthritis and was recently approved in the European Union and Japan for the treatment of adult patients with moderate to severe atopic dermatitis who are candidates for systemic therapy. Olumiant was recently approved in Japan for the treatment of pneumonia associated with COVID-19 in hospitalized adult patients. The U.S. FDA-approved labeling for Olumiant includes a Boxed Warning for Serious Infections, Malignancy, and Thrombosis. See the full Prescribing Information here. Baricitinib is also being investigated in alopecia areata (AA), juvenile idiopathic arthritis (JIA) and systematic lupus erythematosus (SLE).

In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of baricitinib and certain follow-on compounds for patients with inflammatory and autoimmune diseases.

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

Bamlanivimab and etesevimab together are authorized under Emergency Use Authorization only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use 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 etesevimab together 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) for bamlanivimab and etesevimab together.

Authorized Use and Important Safety Information
Bamlanivimab and etesevimab together are authorized for use under EUA for 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 progressing to severe COVID-19 and/or hospitalization.

Limitations of Authorized Use

- Bamlanivimab and etesevimab together are 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.
- Treatment with bamlanivimab and etesevimab together has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab and etesevimab, 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 bamlanivimab and etesevimab together. Serious and unexpected adverse events may occur that have not been previously reported with bamlanivimab and etesevimab together.

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions
Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of bamlanivimab with and without etesevimab. 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 and etesevimab together. 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, dizziness, and diaphoresis.

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

Clinical Worsening After Bamlanivimab Administration

Clinical worsening of COVID-19 after administration of bamlanivimab 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 bamlanivimab use or were due to progression of COVID-19.

Limitations of Benefit and Potential Risk in Patients with Severe COVID-19
Treatment with bamlanivimab and etesevimab together has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab and etesevimab, 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 Events
Based on Phase 2 data from BLAZE-1, nausea was the most commonly reported adverse event, reported by 4% of subjects in both bamlanivimab and etesevimab together and placebo groups. Pruritus and pyrexia were more frequently reported from subjects treated with both bamlanivimab and etesevimab (2% and 1%) compared to placebo (1% and 0%, respectively).

Based on Phase 3 data from BLAZE-1, the most common adverse events were nausea, dizziness, and rash. These events each occurred in 1% of subjects treated with bamlanivimab and etesevimab together and in 1% of placebo subjects.

Use in Specific Populations
Pregnancy
There are insufficient data on the use of bamlanivimab and etesevimab together during pregnancy. Bamlanivimab and etesevimab together 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 or etesevimab 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 2/3 study in people recently diagnosed with COVID-19 in the ambulatory setting (BLAZE-1, NCT04427501) is ongoing. Results from the Phase 2 cohorts of BLAZE-1 were published in the *New England Journal of Medicine* and *The Journal of the American Medical Association*. A Phase 3 study of bamlanivimab alone or bamlanivimab and etesevimab together 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 etesevimab
Etesevimab (LY-CoV016, also known as JS016) is a recombinant fully human monoclonal neutralizing antibody, which specifically binds to the SARS-CoV-2 surface spike protein receptor binding domain with high affinity and can block the binding of the virus to the ACE2 host cell surface receptor. Point mutations were introduced into the native human IgG1 antibody to mitigate effector function. Lilly licensed etesevimab from Junshi Biosciences after it was jointly developed by Junshi Biosciences and the Institute of Microbiology, Chinese Academy of Science (IMCAS). Junshi Biosciences leads development in Greater China, while Lilly leads development in the rest of the world.

Lilly has successfully completed a Phase 1 study (NCT04441931) of etesevimab in healthy U.S. volunteers to evaluate the safety, tolerability, pharmacokinetics and immunogenicity. A Phase 2/3 study in people recently diagnosed with COVID-19 in the ambulatory setting (BLAZE-1, NCT04427501) is ongoing. Results from the Phase 2 cohorts of BLAZE-1 were published in the *New England Journal of Medicine* and *The Journal of the American Medical Association*. Junshi Biosciences has completed a similar Phase 1 study in healthy volunteers in China and has initiated Phase 1b/2 trials in COVID-19 patients globally.

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 and develop novel antibody treatments for COVID-19. 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

About Lilly 30x30
Through investments in people, medicines and health systems, we aim to improve access to quality health care for 30 million people living in limited resource settings annually by 2030. We call this global effort Lilly 30x30. To achieve our goal, we have structured Lilly 30x30 as a company-wide effort in strategic collaboration with valued external partners. Lilly 30x30 initiatives include activities across three areas of impact: pipeline, programs and partnerships. In each of these areas, we are leading cross-functional teams to develop high-impact, scalable projects and solutions.

About Direct Relief
Direct Relief is active in all 50 states and U.S. territories, with a mission to improve the health and lives of people affected by poverty or emergencies – without regard to politics, religion, or ability to pay. Direct Relief now supports more than 1,500 nonprofit community health centers, free and charitable

clinics, public health departments, and other safety-net organizations through the U.S., who in turn operate more than 5,000 clinical sites and provide care to millions of people.

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 OLUMIANT (baricitinib), bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016) together as potential treatments for patients with COVID-19 and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of research, development and commercialization. Among other things, there can be no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with the results to date, that either OLUMIANT or bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016) together will receive additional regulatory approvals or authorizations or be commercially successful, or that OLUMIANT or bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016) together will prove to be safe and effective treatments or successful preventative therapies for COVID-19. For further discussion of these and other risks and uncertainties, see Lilly's most recent respective Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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