Lilly and UnitedHealth Group partner on pragmatic study of neutralizing antibody bamlanivimab (LY-CoV555) for COVID-19

December 4, 2020

The study brings together symptom tracking, in-home testing and in-home infusions to detect, intercept and treat COVID-19 early

INDIANAPOLIS and MINNETONKA, Minn., Dec. 4, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and UnitedHealth Group (NYSE: UNH) today announced a partnership to conduct a pragmatic study of bamlanivimab (LY-CoV555) in high-risk, COVID-19 infected individuals.

Bamlanivimab recently received Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration for the treatment of mild to moderate COVID-19 patients who are at high risk for progressing to severe COVID-19 and/or hospitalization. The trial will evaluate the efficacy and safety of bamlanivimab versus a propensity-matched control in individuals that meet the EUA criteria.

The study will identify and treat a large, diverse population of high-risk individuals for COVID-19 with bamlanivimab under real-world conditions with a goal of reducing the severity of illness and hospitalizations. It will draw upon both UnitedHealth Group's UnitedHealthcare health benefits business as well as its Optum health services business to detect and treat high-risk symptomatic patients who test positive for COVID-19, including daily symptom tracking, in-home SARS-CoV-2 testing and in-home infusion services.

Delivering bamlanivimab to patients through home infusions allows them to stay quarantined and at home, minimizing the potential spread of COVID-19.

"While bamlanivimab is authorized for emergency use based on the efficacy and safety data accumulated to date, larger pragmatic studies in diverse populations can help us further understand the efficacy and safety of SARS-CoV-2 neutralizing antibodies in real world settings," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Laboratories. "Lilly is excited to partner with UnitedHealth Group to study our antibody therapy using a care delivery model that will allow rapid diagnosis and in-home treatment of patients at a high risk of complications."

Under the study design, UnitedHealthcare Medicare Advantage members who meet the FDA-authorized criteria for treatment will be invited to volunteer for the study through United in Research, a UnitedHealth Group virtual community and technology platform for citizen scientists.

Those who volunteer and are in an area where they can receive treatment will be directed to download Optum's symptom-checking ProtectWell app and complete a daily questionnaire. Participants experiencing symptoms of COVID-19 will take an in-home SARS-CoV-2 test which they will self-administer and return. Those that are COVID-19 positive will receive outreach from an Optum Infusion Pharmacy nurse to schedule a home infusion treatment of bamlanivimab. The study will enroll up to 500,000 people, with at least 5,000 people expected to receive bamlanivimab therapy.

"Treatments like bamlanivimab offer a crucial early intervention against COVID-19 until vaccines are widely available," said Ken Ehlert, chief scientific officer, UnitedHealth Group and chief executive officer, OptumLabs. "Intercepting the disease before it escalates may help to keep people out of the hospital and reduce the overwhelming burden on the healthcare system. By bringing together UnitedHealth Group's expertise in science, clinical research, and technology, with Lilly's expertise in pharmaceutical development, we can responsibly and safely accelerate research on this new potential COVID-19 treatment."

This study is part of a collaborative partnership between OptumLabs, the scientific research arm of UnitedHealth Group, and Lilly to advance cutting-edge science, research, and solutions that will accelerate the progression of validated therapies into real world applications.

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 700 mg injection 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, testing bamlanivimab alone and in combination with a second antibody. Data from the monotherapy arms of BLAZE-1 were published in the *New England Journal of Medicine*. 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 the UNITED Trial
UNITED (NCT04639479) is an open-label, pragmatic study designed to assess the efficacy and safety of bamlanivimab versus a propensity matched cohort for the treatment of symptomatic COVID-19 in the outpatient setting. To be eligible, patients must meet the criteria in the Emergency Use Authorization for bamlanivimab. Trial participants will track for symptom development and upon reporting symptoms be tested for COVID-19. If positive, they will receive a one-time at-home infusion of 700 mg bamlanivimab. The primary objective is to determine the incidence of COVID-related hospitalization at day 28 among bamlanivimab-treated participants relative to external, propensity-matched controls. Additional endpoints include the incidence of COVID-related mortality at day 28, as well as safety. The study will enroll up to 500,000 people, with at least 5,000 expected to receive bamlanivimab therapy.

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

About UnitedHealth Group
UnitedHealth Group (NYSE: UNH) is a diversified health care company dedicated to helping people live healthier lives and helping to make the health system work better for everyone. UnitedHealth Group offers a broad spectrum of products and services through two distinct platforms: UnitedHealthcare, which provides health care coverage and benefits services; and Optum, which provides information and technology-enabled health services. For more information, visit UnitedHealth Group at www.unitedhealthgroup.com or follow @UnitedHealthGrp on Twitter.

About OptumLabs
OptumLabs brings together experts in the fields of research science, clinical research, data analytics and technology to solve health care's greatest challenges and achieve our mission of preventing, detecting, and intercepting disease. Our work is enhanced through substantive engagement with partners, including academic, clinical, and policy leaders from across health care, working together to create a health care system that is personalized, convenient, and affordable for everyone.

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 and delivery, 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 patients will volunteer to participate in the study or achieve positive outcomes, that bamlanivimab will receive regulatory approvals or additional 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.

UnitedHealth Group Forward-Looking Statements

This press release contains statements, estimates, projections, guidance or outlook that constitute "forward-looking" statements as defined under U.S. federal securities laws. We caution that actual results could differ materially from those that management expects, depending on the outcome of certain factors. A list and description of some of these risks and uncertainties can be found in our reports filed with the Securities and Exchange Commission from time to time, including the cautionary statements in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. Any or all forward-looking statements we make may turn out to be wrong. 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, or that an adequate supply of bamlanivimab can be provided to patients in all circumstances. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. We do not undertake to update or revise any forward-looking statements, except as required by applicable securities laws.

Refer to:Molly McCully; mccully_molly@lilly.com; (317) 478-5423 (Lilly Media)
Kevin Hern; hern_kevin_r@lilly.com; (317) 277-1838 (Lilly Investors)
Lauren Mihajlov; lauren.mihajlov@uhg.com (952) 205-6312 (UnitedHealth Group Media)
Brett Manderfeld; brett_manderfeld@uhg.com (952) 936-7216 (UnitedHealth Group Investors)

View original content to download multimedia:http://www.prnewswire.com/news-releases/lilly-and-unitedhealth-group-partner-on-pragmatic-study-of-neutralizing-antibody-bamlanivimab-ly-cov555-for-covid-19-301186265.html

SOURCE Eli Lilly and Company