Lilly's neutralizing antibody bamlanivimab (LY-CoV555) prevented COVID-19 at nursing homes in the BLAZE-2 trial, reducing risk by up to 80 percent for residents

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INDIANAPOLIS, Jan. 21, 2021 /PRNewswire/ -- Bamlanivimab (LY-CoV555) significantly reduced the risk of contracting symptomatic COVID-19 among residents and staff of long-term care facilities, Eli Lilly and Company (NYSE: LLY) announced. The Phase 3 BLAZE-2 COVID-19 prevention trial – conducted in partnership with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the COVID-19 Prevention Network (CoVPN) – enrolled residents and staff at skilled nursing and assisted living facilities, commonly referred to as nursing homes, across the U.S.

The 965 participants who tested negative for the SARS-CoV-2 virus at baseline (299 residents and 666 staff) were included in the analysis of primary and key secondary endpoints for assessing prevention, while the 132 participants (41 residents and 91 staff) who tested positive for the virus at baseline were included in exploratory analyses for assessing treatment, adding to the growing body of evidence for treatment with bamlanivimab. All participants were randomized to receive either 4,200 mg of bamlanivimab or placebo.

After all participants reached 8 weeks of follow-up, there was a significantly lower frequency of symptomatic COVID-19 (the primary endpoint) in the bamlanivimab treatment arm versus placebo (odds ratio 0.43, p=0.00021). Results for all key secondary endpoints also reached statistical significance in both the overall and resident populations.

For the pre-specified subgroup of nursing home residents, there was also a significantly lower frequency of symptomatic COVID-19 in those treated with bamlanivimab versus placebo in this important population (odds ratio 0.20; p=0.00026). These results suggest that residents randomized to bamlanivimab have up to an 80 percent lower risk of contracting COVID-19 versus residents in the same facility randomized to placebo.

Results from exploratory analyses of viral load in the treatment group were consistent with previously disclosed data from BLAZE-1 evaluating bamlanivimab as an outpatient treatment for recently diagnosed COVID-19.

Among the 299 residents in the prevention group, there were 4 deaths attributed to COVID-19 at the time of death, and all occurred in the placebo arm. There were no COVID-19 attributed deaths in the bamlanivimab arm. Among the 41 residents in the treatment group, there were 4 deaths, and all occurred in the placebo arm with none in the bamlanivimab arm. Over the entire trial, there were a total of 16 deaths reported, including deaths not related to COVID-19, and all deaths were residents (11 deaths in placebo arm and 5 in bamlanivimab arm).

"We are exceptionally pleased with these positive results, which showed bamlanivimab was able to help prevent COVID-19, substantially reducing symptomatic disease among nursing home residents, some of the most vulnerable members of our society," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Laboratories. "These data provide important additional clinical evidence regarding the use of bamlanivimab to fight COVID-19 and strengthen our conviction that monoclonal antibodies such as bamlanivimab can play a critical role in turning the tide of this pandemic. We're glad bamlanivimab is already available as a treatment for patients at high risk for progressing to severe COVID-19 illness or hospitalization, including those in nursing homes, and look forward to working with regulators to explore expanding the emergency use authorization to prevent the spread of COVID-19 in these facilities."

An independent data and safety monitoring board oversaw the BLAZE-2 trial. In the trial, the safety profile of bamlanivimab was consistent with observations from the Phase 1 and Phase 2 trials. Serious adverse events were reported at a similar frequency in the bamlanivimab and placebo groups. Across multiple clinical trials, Lilly now has collected safety and efficacy data in more than 4,000 patients treated with bamlanivimab, either alone or administered together with another antibody.

"The results of this innovative study further support the belief that bamlanivimab – and potentially other monoclonal antibodies – can reduce symptoms and may even prevent COVID-19," said Myron S. Cohen, M.D., CoVPN co-principal investigator and director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill. "The antiviral activity seen with bamlanivimab treatment emphasizes the importance of early intervention to help counter the devastating impact the virus has had in this vulnerable population and other high-risk patients."

BLAZE-2 is a first-of-its-kind COVID-19 trial designed to evaluate this vulnerable population by addressing the challenging aspects of running a clinical trial in long-term care facilities, which normally do not conduct clinical trials. The study is sponsored by Lilly and conducted in partnership with NIAID, part of the NIH, along with the CoVPN and numerous long-term care facility networks across the country. BLAZE-2 is ongoing as an open-label trial evaluating bamlanivimab alone or administered together with another antibody as a treatment for high-risk individuals (residents and staff) diagnosed with COVID-19 at these long-term care facilities. The full results from BLAZE-2 will be presented at a future medical congress and submitted for publication in a peer-reviewed clinical journal.

Bamlanivimab is authorized for emergency use by the U.S. Food and Drug Administration for the treatment of mild to moderate COVID-19 in high-risk patients. For more information about the use of bamlanivimab, contact Lilly's 24-hour support line at 1-855-LillyC19 (1-855-545-5921). Patients and physicians can visit covid.infusioncenter.org or the HHS Therapeutics Distribution locator to find a potential treatment location near you. Visit combatcovid.hhs.gov to find out more about antibody therapy.

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 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 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 2/3 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 ongoing. In addition, bamlanivimab is being tested in the National Institutes of Health-led ACTIV-2 study in ambulatory COVID-19 patients.

Bamlanivimab is authorized in the U.S. for the treatment of mild to moderate COVID-19 in adults and pediatric patients 12 years and older with a positive COVID-19 test, who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab should be administered as soon as possible after a positive COVID-19 test and within 10 days of symptom onset.

About BLAZE-2
BLAZE-2, (NCT04497987) is a randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of bamlanivimab 4200 mg versus placebo for the prevention of SARS-CoV-2 infection and COVID-19 in skilled nursing and assisted living facility residents and staff. To be eligible, there must be at least one confirmed case of SARS-CoV-2 infection among residents or facility staff based on a sample collection no more than seven days prior to randomization.

The primary outcome measure for the completed arms of the BLAZE-2 trial was cumulative incidence of COVID-19 defined as the detection of SARS-CoV-2 by RT-PCR and mild or worse disease severity within 21 days of detection. Additional endpoints include cumulative incidence of SARS-CoV-2 infection, moderate or worse disease severity within 21 days of detection, as well as safety.

Residents and staff were tested for SARS-CoV-2 weekly – whether or not they exhibited symptoms – providing robust surveillance data regarding the impact of bamlanivimab on infection rates and symptomatic COVID-19 diagnoses in this population.

The study is ongoing as an open-label trial evaluating bamlanivimab alone or administered together with another antibody as a treatment for high-risk individuals (residents and staff) diagnosed with COVID-19 at long-term care facilities.

Across all treatment arms, the trial will enroll up to 5,000 participants.

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 collection of data regarding its effectiveness, 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 bamlanivimab will receive regulatory approvals or additional authorizations, that patients will volunteer to participate in the study or achieve positive outcomes 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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