Lilly announces proof of concept data for neutralizing antibody LY-CoV555 in the COVID-19 outpatient setting

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- Primary endpoint of viral load change from baseline at day 11 was met for one of three doses; consistent effects of viral reduction seen at earlier time points

- Rate of hospitalizations and ER visits was 1.7 percent (5/302) for LY-CoV555 versus 6 percent (9/150) for placebo--a 72 percent risk reduction in this limited population

- LY-CoV555 was well-tolerated across all doses with no drug-related serious adverse events reported

INDIANAPOLIS, Sept. 16, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced proof of concept data from an interim analysis of the BLAZE-1 clinical trial, showing a reduced rate of hospitalization for patients treated with LY-CoV555. The randomized, double-blind, placebo-controlled Phase 2 study evaluated LY-CoV555, a SARS-CoV-2 neutralizing antibody, for the treatment of symptomatic COVID-19 in the outpatient setting. The trial enrolled mild-to-moderate recently diagnosed COVID-19 patients across four groups (placebo, 700 mg, 2800 mg, and 7000 mg).

The prespecified primary endpoint, change from baseline in viral load at day 11, was met at the 2800 mg dose level, but not the others. Most patients, including those receiving placebo, demonstrated near complete viral clearance by day 11. Additional analyses of viral data demonstrated that LY-CoV555 improved viral clearance at an earlier time point (day 3) and reduced the proportion of patients with persistently high viral load at later time points.

These biomarker data correlated with LY-CoV555's positive impact on the prespecified endpoint of COVID-19-related hospitalization or ER visit. This endpoint occurred in 1.7 percent (5/302) of LY-CoV555 patients, pooled across dose groups, as compared to 6 percent (9/150) of placebo patients, which corresponds to a 72 percent risk reduction in this limited population. Most study hospitalizations occurred in patients with underlying risk factors (age or BMI), suggesting a more pronounced treatment effect for patients in these higher-risk groups. Ongoing studies will seek to confirm this finding. Across all treatment groups (including placebo), no patients progressed to mechanical ventilation or died. Exploratory analyses indicated a more rapid improvement in symptoms for patients treated with LY-CoV555 versus placebo, supporting the hospitalization effect.

LY-CoV555 was well-tolerated, with no drug-related serious adverse events reported. Treatment emergent adverse events were similar across all dose groups and comparable to placebo. Viral RNA sequencing revealed putative LY-CoV555-resistance variants in placebo and all treatment arms. The rate of resistance variants was numerically higher in treated patients (8 percent) versus placebo (6 percent).

"These interim data from the BLAZE-1 trial suggest that LY-CoV555, an antibody specifically directed against SARS-CoV-2, has a direct antiviral effect and may reduce COVID-related hospitalizations," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Laboratories. "The results reinforce our conviction that neutralizing antibodies can help in the fight against COVID-19."

Lilly intends to quickly publish the results of this interim analysis in a peer-reviewed journal and discuss appropriate next steps with global regulators. The BLAZE-1 clinical trial remains ongoing, testing LY-CoV555 in combination with a second Lilly antibody, LY-CoV016, which binds a different epitope in the SARS-CoV-2 spike region. The trial is currently enrolling a larger, confirmatory cohort of higher risk patients, testing the ability of the antibody combination to reduce the number of patients with persistently high viral load and reduce COVID-related hospitalizations.

"We are grateful to the patients, physicians, and staff that have participated in this trial," Skovronsky continued. "We look forward to continued data generation as this trial proceeds."

About BLAZE-1
BLAZE-1 (NCT04427501) is a randomized, double-blind, placebo-controlled Phase 2 study designed to assess the efficacy and safety of LY-CoV555 and LY-CoV016 for the treatment of symptomatic COVID-19 in the outpatient setting. Across all treatment arms, the trial will enroll an estimated 800 participants.

The monotherapy arms of the trial enrolled mild-to-moderate recently diagnosed COVID-19 patients across four groups (placebo, LY-CoV555 700 mg, LY-CoV555 2800 mg, and LY-CoV555 7000 mg). To be eligible, patients were required to have mild or moderate symptoms of COVID-19 as well as a positive SARS-CoV-2 test based on a sample collected no more than 3 days prior to drug infusion.

The primary outcome measure for the BLAZE-1 monotherapy arms was change from baseline to Day 11 in SARS-CoV-2 viral load. Additional endpoints include the percentage of participants who experience COVID-related hospitalization, ER visit or death from baseline through Day 29, as well as safety.

The study is ongoing with additional treatment arms.

About LY-CoV555
LY-CoV555 is a potent, neutralizing 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 preventing and treating COVID-19. LY-CoV555 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 tested by 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 enrollment and primary safety assessments of LY-CoV555 in a Phase 1 study of hospitalized patients with COVID-19 (NCT04411628) and long-term follow-up is ongoing. A Phase 2 study in people recently diagnosed with COVID-19 in the ambulatory setting (NCT04427501) is ongoing. Lilly recently initiated a Phase 3 study for the prevention of COVID-19 in residents and staff at long-term care facilities (NCT04497987). In addition, LY-CoV555 is being tested in the National Institutes of Health-led ACTIV-2 and ACTIV-3 studies of ambulatory and hospitalized COVID-19 patients.

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 now being studied to understand their potential in treating complications of COVID-19, and the company is collaborating with two partner companies to discover novel antibody treatments for COVID-19. Lilly intends to test both single antibody therapy as well as combinations of antibodies (sometimes known as antibody cocktails) as potential therapeutics for COVID-19. Click here for media 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 LY-CoV555 as a potential treatment for patients with or at risk of infection from COVID-19 and reflects Lilly's current beliefs. However, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there can be no guarantee that LY-CoV555 will prove to be a safe and effective treatment or preventative for COVID-19, that LY-CoV555 will receive regulatory approvals, or that we can provide an adequate supply of LY-CoV555 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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