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Lilly Statement Regarding NIH's ACTIV-3 Clinical Trial

Eli Lilly and Company | October 26, 2020

Tags | COVID19, Clinical Research, Clinical Trials









The ACTIV-3 clinical trial is being run by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and is the only study evaluating the efficacy of bamlanivimab in hospitalized COVID-19 patients. Based on an updated dataset from the trial reviewed on October 26, no additional COVID-19 patients in this hospitalized setting will receive bamlanivimab. This recommendation was based on trial data suggesting that bamlanivimab is unlikely to help hospitalized COVID-19 patients recover from this advanced stage of their disease. In this updated dataset, differences in safety outcomes between the groups were not significant.

All other studies of bamlanivimab remain ongoing, including ACTIV-2, the NIH-sponsored study in recently diagnosed mild to moderate COVID-19 patients; BLAZE-1, Lilly's ongoing Phase 2 trial in people recently diagnosed with COVID-19 in the ambulatory (non-hospitalized) setting, studying bamlanivimab as monotherapy and in combination with etesevimab; and BLAZE-2, Lilly's Phase 3 study of bamlanivimab for the prevention (prophylaxis) of COVID-19 in residents and staff at long-term care facilities. Based on data from BLAZE-1, Lilly submitted a request for EUA for bamlanivimab for the treatment of recently diagnosed mild to moderate COVID-19 illness in high-risk patients to the U.S. FDA in early October.

While there was insufficient evidence that bamlanivimab improved clinical outcomes when added to other treatments in hospitalized patients with COVID-19, we remain confident based on data from Lilly's BLAZE-1 study that bamlanivimab monotherapy may prevent progression of disease for those earlier in the course of COVID-19.

We thank the patients, physicians, and staff participating in all clinical trials of bamlanivimab, including ACTIV-3.

Read Lilly's previous statement on NIAID's ACTIV-3 trial.

Lilly Cautionary Statement Regarding Forward-Looking Statements

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and etesevimab 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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