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Eli Lilly European Regulatory Team

29 October 2021

Dr Enzmann, CHMP chair
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Bamlanivimab(EMEA/H/C/005836/0000) and Etesevimab (EMEA/H/C/005837/0000)

Dear Dr Enzmann,
Subject: **Withdrawal of rolling review for bamlanivimab (EMEA/H/C/005836/0000) and etesevimab (EMEA/H/C/005837/0000)**

Eli Lilly Netherlands BV (Lilly) would like to inform you of the decision to no longer continue with the ongoing submissions and responses under rolling review for an eventual marketing authorisation application for bamlanivimab and etesevimab for the treatment of confirmed COVID-19 in patients aged 12 years and older that do not require supplemental oxygen for COVID-19 and who are at increased risk of progressing to severe COVID-19.

The decision to no longer pursue a marketing authorisation application is based on the following reason:

- CHMP has determined that prospective concurrent validation is required for submission of a formal marketing authorisation application. Given the current demand from EU member states, Lilly forecasts that no additional / new drug substance manufacturing campaigns will be needed for the foreseeable future. Therefore, at this point Lilly is not in a position to generate the additional data required by the CHMP to progress to a formal marketing authorization application.

Lilly would like to thank the Rapporteurs, EMA, and the scientific committees involved for the time dedicated to assessing the rolling review, and the valuable support and helpful guidance provided during this novel process.

Yours sincerely,

Senior Advisor-Global Regulatory Affairs - International