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Eli Lilly and Company Limited

07 December 2022

Dr Harald Enzmann
Chair of the CHMP
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Withdrawal of Extension of Indication Application for:
Olumiant (baritinib) 2 mg and 4 mg film-coated tablets
EMA Product Number: EMEA/H/C/004085

Dear Dr Enzmann,

We would like to inform you that, at this point in time, Eli Lilly & Company (Lilly) has taken the decision to withdraw the application for an extension of indication for Olumiant (baricitinib), for the treatment of COVID-19 in adult patients who require low-flow oxygen or non-invasive ventilation/high-flow oxygen.

This withdrawal is based on the following reason: Lilly believes that data from the clinical programme support a positive benefit-risk for this indication; however, feedback from the CHMP indicates that the available efficacy data do not allow the Committee to conclude on a positive benefit-risk balance for the proposed indication.

The withdrawal of this application has no impact on ongoing clinical trials with baricitinib.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the European Medicines Agency website.

Yours sincerely,