To:
Head of Paediatric Medicines
European Medicines Agency
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): (1R, 4S, 5S, 6S)-4-[[(2s)-2-amino-4-(methylthio)-1-oxobutyl]amino]-2-thiabicyclo[3.1.0]hexane-4,6-dicarboxylic acid,2,2-dioxide, monohydrate (LY2140023)
Invented name: -

Latest Decision number(s): 1) P/253/2011 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000150-PIP02-10 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Treatment of schizophrenia

☒ has been discontinued
☐ has been suspended/put on long-term hold (with possible re-start at a later time)

for the following reason(s): *(tick all that apply)*

☒ (possible) lack of efficacy in adults
☐ (possible) lack of efficacy in children
☐ (possible) unsatisfactory safety profile in adults
☐ (possible) unsatisfactory safety profile in children
☐ commercial reasons (please specify:)
☐ manufacturing / quality problems
☐ other regulatory action (please specify:) *(e.g. suspension, revocation of M.A.)*
☐ other reason (please specify:)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:

On Aug 29th, 2012 Eli Lilly and Company announced the decision to stop ongoing clinical studies investigating pomaglumetad methionil for the treatment of patients suffering from schizophrenia. The decision was based on results from clinical studies which either did not, or were projected not to meet their primary endpoint. The decision was not based on any safety signals. No paediatric stuies have been conducted.

Name and signature of the PIP contact point: Dr. Carsten Rehn

Date: 10-Feb-2015

Contact for inquiries from interested parties:

Telephone:

Email: