

To:

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

Actives substances(s): Tralokinumab

Invented name: -

Latest Decision number(s): 1) P/280/2011 2) P/
0198/2014 3) P/0099/2016 4) P/0321/2017

Corresponding PIP number(s): 1) EMEA-000782-PIP01-09-M01 2) EMEA-
000782-PIP01-09-M02 3) EMEA-000782-PIP01-09-M03 4) EMEA-000782-PIP01-09-M04

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

Treatment of Asthma

- ☒ 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:

AstraZeneca decided to discontinue the development of tralokinumab, an investigational anti-IL-13 human immunoglobulin-G4 monoclonal antibody, in severe, uncontrolled asthma. The decision followed the publication of the high level results of the Phase III programme, in which the primary endpoint of a significant reduction in the annual asthma exacerbation rate was not met in the two pivotal trials, STRATOS 1 and STRATOS 2. In an OCS-sparing trial, TROPOS, tralokinumab did not achieve a statistically-significant reduction in OCS use when added to the standard of care, in patients dependent on OCS.

Name and signature of the PIP contact point: Signature on file

Date: 5 February 2018

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