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): quilizumab

Invented name: N/A

Latest Decision number(s): 1) P/0271/2013 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001395-PIP01-12 2) EMEA- 3) EMEA- 4) EMEA-

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:

Following review of the planned primary analysis of protocol GB27980, entitled "A Phase IIb, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Dosing Regimens of quilizumab in Adults with Allergic Asthma Who Are Inadequately Controlled on Inhaled Corticosteroids and a Second Controller (COSTA)", the Applicant has concluded that the insufficient evidence for a clinically meaningful treatment benefit from quilizumab in patients with allergic asthma does not support the continued development of quilizumab in the treatment of asthma at this time.

Name and signature of the PIP contact point: Lionel Spreng

Date: 07.03.2018

Contact for inquiries from interested parties: info.paediatrics@roche.com

Telephone:

Email: