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): Lebrikizumab

Invented name: N/A

Latest Decision number(s): 1) P/0011/2012 2) P/0279/2012 3) P/0258/2013 4) P/0281/2015

Corresponding PIP number(s): 1) EMEA-001053-PIP01-10 2) EMEA-001053-PIP01-10-M01 3) EMEA-001053-PIP01-10-M02 4) EMEA-001053-PIP01-10-M03

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:

The applicant had previously communicated via press release (dated 29 February 2016) that only one of the two pivotal Phase III clinical trials of lebrikizumab in the treatment of asthma in adult patients had met its primary endpoint. Furthermore, the observed efficacy was lower than anticipated based on the Phase II data. After conducting additional analyses and further review of the data, the Applicant has concluded that the limited efficacy does not support the continued development of lebrikizumab in the treatment of asthma at this time.

Name and signature of the PIP contact point:

Date:	20 October 2016
Contact for inquiries from interested parties:	info.paediatrics@roche.com
Telephone:	
Email:	