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): Gevokizumab

Invented name: not yet assigned

Latest Decision number(s): 1) P/0148/2014 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001487-PIP01-13 2) EMEA- 3) EMEA- 4) EMEA-

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

Condition: Treatment of chronic non-infectious uveitis/ Indication(s) targeted by the PIP:Treatment of chronic non-infectious uveitis

☒ 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:

Three phase III studies, well-controlled trials (CL3-78989-002 sponsored by SERVIER, and X052130/CL3-78989-005 & X052131/ CL3-78989-006, sponsored both by XOMA US LLC) were intended to support a label indication for the treatment of chronic noninfectious uveitis including Behçet's disease uveitis. The EYEGUARD™-B study (CL3-78989-002) aimed to demonstrate the treatment effect of gevokizumab versus placebo on the reduction of risk of exacerbation in subjects having experienced an acute uveitis attack in the preceding four months and tapered from their high dose corticosteroids. Preliminary results of the EYEGUARD™-B core part of the study revealed that the primary endpoint (time to first acute ocular exacerbation) was not achieved. Consequently, the trial, sponsored by Servier, was terminated in September 2015. Gevokizumab was well tolerated in the trial. Adverse events were comparable between gevokizumab and placebo treated groups.

Name and signature of the PIP contact point:	Signature on file
Date:	19 September 2018

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