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): Monoclonal IgG1

Invented name: Not Applicable

Latest Decision number(s): 1) P/0300/2016 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001831-PIP01-15 2) EMEA- 3) EMEA- 4) EMEA-

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

Treatment of influenza

☒ 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 decision to terminate development occurred following an interim analysis of Phase 2b study in adult patients hospitalised with severe influenza. Primary and key secondary endpoints did not support a clinical benefit in this patient population. SAEs were numerically higher in the treatment + oseltamivir arm compared with oseltamivir alone. The nature and pattern of SAEs was consistent with what might expected in this population, and did not suggest a clear drug-related cause.

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

Date: 16/02/18

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