

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): Recombinant human antibody against the respiratory syncytial virus fusion protein (REGN2222)

Invented name: Suptavumab

Latest Decision number(s): 1) P/0037/2016 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001747-PIP01-15 2) EMEA- 3) EMEA- 4) EMEA-

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

Prevention of respiratory syncytial virus (RSV) infection

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:

On 14 August 2017 it was announced that a Phase 3 study evaluating suptavumab (REGN2222), an antibody to respiratory syncytial virus (RSV), did not meet its primary endpoint of preventing medically-attended RSV infections in infants, and that Regeneron would discontinue further development of the antibody. The Applicant wishes to inform the EMA of discontinuation as a means to formally close the PIP.

Name and signature of the PIP contact point: Niamh Mooney

Regeneron Ireland U.C.

Date:

04 April 2018

Contact for inquiries from interested parties: contact details as below

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