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): Proteinase, metallo- (synthetic nociceptin receptor-binding) 1290102-81-6 (also referred to as AGN-214868 or senrebotase)

Invented name: Not Available

Latest Decision number(s): 1) P/0030/2013 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001200-PIP01-11 2) EMEA- 3) EMEA- 4) EMEA-

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

overactive bladder and post-herpetic neuralgia

☒ 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 overall results of study AGN 214868-004 in adult OAB patients demonstrated that a single administration of AGN-214868 at doses ranging from 60,000 ng to 500 ng into the detrusor walls of the bladder is safe and well-tolerated in adults with OAB. Although greater numerical improvements from baseline were observed only for the primary efficacy variable in the AGN-214868 groups compared with the placebo group at week 12 (primary timepoint), these differences were not statistically significant and were no longer observed at week 24. In addition, no dose-response among the AGN-214868 groups for efficacy was observed at any timepoint.

Similar results were also observed between the AGN-214868 and placebo groups for other

efficacy variables at all timepoints and no apparent dose-response was observed. Furthermore, there was a marked placebo response in all OAB symptoms, the TBS, and the ICIQ-OAB.

Based on results from this study, further development of AGN-214868 in OAB is not planned in adults or paediatric patients.

In addition, AGN-214868 is no longer being developed for the post-herpetic neuralgia indication, for which a waiver in all subsets of the paediatric population was granted..

Name and signature of the PIP contact point:	Signature on file
Date:	24 March 2016

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