

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): (S)-1-{5-Phenyl-4-[(pyridin-2-ylmethyl)-amino]-thieno[2,3-d]pyrimidin-2-yl}-piperidine-3-carboxylic acid (2-hydroxy-ethyl)-amide

Invented name: Xention - D0103_UPI 732162

Latest Decision number(s): 1) P/0179/2015 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001752-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 supraventricular arrhythmias

☒ 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 of the request for a waiver has decided to terminate the development of the active substance for the treatment of paroxysmal atrial fibrillation as a precautionary safety measure based on findings of pulmonary toxicity in toxicology studies in the monkey and the lack of efficacy in adults.

Name and signature of the PIP contact point: Mike Jarvill

Date: 27 April 2016

Contact for inquiries from interested parties: Dr P Round

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