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): rolofylline

Invented name: -

Latest Decision number(s): 1) P/87/2009 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000275-PIP01-08 2) EMEA- 3) EMEA- 4) EMEA-

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

☒ 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:

Results for the pivotal Phase III study of rolofylline (MK-7418), an investigational medicine for the treatment of acute heart failure, show that rolofylline did not meet the primary or secondary efficacy endpoints. The primary hypothesis of the 2,033-patient pivotal Phase III study, PROTECT, was that rolofylline 30 mg would improve symptoms of acute heart failure compared to placebo. The secondary endpoints were that rolofylline 30 mg would reduce the risk of death or cardiovascular or renal re-hospitalization 60 days after treatment, and that rolofylline 30 mg would reduce the incidence of persistent kidney impairment.

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

Date: 14 Feb 2019

Contact for inquiries from interested parties:

Telephone:

Email: