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): serelaxin

Invented name: Reasanz

Latest Decision number(s): 1) P/0292/2016 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001168-PIP01-11-M03 2) EMEA- 3) EMEA- 4) EMEA-

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

Treatment of acute heart failure

☒ 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 discontinuation of the pediatric development of serelaxin for the treatment of acute heart failure (AHF) follows the results of the global Phase III RELAX-AHF-2 study in adult patients with acute heart failure. This study did not meet either of its primary endpoints of reduction in cardiovascular death through Day 180 or reduced worsening heart failure through Day 5.

No new safety concerns associated with serelaxin were observed.

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

Date: 25-Aug-17

Contact for inquiries from interested parties:

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