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): anacetrapib

Invented name:

Latest Decision number(s): 1) P/0068/2013 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001100-PIP01-10 2) EMEA- 3) EMEA- 4) EMEA-

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

Prevention of cardiovascular events in patients with hypercholesterolaemia - Treatment of hypercholesterolaemia

☒ 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: decision not to file)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:

After comprehensive evaluation, MSD has concluded that the clinical profile for anacetrapib does not support regulatory filing. Anacetrapib has never been registered in the EU Members States or any countries in the EEA.

Name and signature of the PIP contact point: Ann Debbaudt

Date: 23 October 2017

Contact for inquiries from interested parties: Merck Sharp & Dohme Europe

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