Eli Lilly European Regulatory Team
Eli Lilly and Company Limited
Lilly Research Centre, Erl Wood Manor
Sunninghill Road, Windlesham,
Surrey, GU20 6PH
United Kingdom
Tel: +44 (0) 1276 483000
Fax: +44 (0) 1276 474390
www.lilly.co.uk

Eli Lilly European Regulatory Team

Phone: +44 (0)1276 483398

14 October 2015

Dr Paolo Tomasi, Head of Paediatric Medicines
European Medicines Agency
30 Churchill Place
Canary Wharf
London
E14 5EU

Re: Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision
Evacetrapib - EMEA-001180-PIP01-11

Actives substances(s): evacetrapib

Invented name:

Latest Decision number(s): 1) P/0155/2013

Corresponding PIP number(s): 1) EMEA-001180-PIP01-11

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

Treatment of hypercholesterolaemia

Treatment of hypo-HDL-cholesterolaemia

☒ 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:

Lilly announced in a press release on 12 October 2015 that development of evacetrapib will be discontinued due to insufficient efficacy.

The single pivotal registration study in adults (Study I1V-MC-EIAN, ACCELERATE) was designed to support an indication for evacetrapib in combination with optimised statin therapy for the prevention of cardiovascular events in adult patients with atheroscelerotic cardiovascular disease. The primary endpoint was a composite of cardiovascular death, myocardian infarction, stroke, coronary revascularisation or hospitalisation for unstable angina.

Lilly and the ACCELERATE study's academic leadership accepted the recommendation of the independent Data Monitoring Committee (DMC) to terminate the Phase 3 trial due to insufficient efficacy. The independent DMC based its recommendation on data from periodic data reviews, which suggested there was a low probability the study would achieve its primary endpoint based on results to date.

Name and signature of the PIP contact point:

Rosemary E Derbyshire

Date: 14th October 2015

Contact for inquiries from interested parties:

Telephone: +44 (0) 1276 483000

Email: eu_paediatric@lilly.com