

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): Eleclazine (GS-6615)

Invented name:

Latest Decision number(s): 1) P/0177/2016 2) P/0178/2016 3) P/ 4)
P/

Corresponding PIP number(s): 1) EMEA-001697-PIP01-14 2) EMEA-001697-PIP02-14 3)
EMEA- 4) EMEA-

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

Treatment of congenital long QT syndromes and Treatment of hypertrophic cardiomyopathy

☒ 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: Gilead has determined that the totality of the data do not support continuation of the eleclazine development program. Therefore, all ongoing trials will be stopped and the program terminated.)

☐ 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:

After a thorough analysis of clinical information from study GS-US-356-0101 entitled "A Phase 2, Randomized, Double-Blind, Placebo Controlled, Dose-Ranging, Parallel Group Study Evaluating the Effect of Eleclazine (GS-6615) on Ventricular Arrhythmia in Subjects with Implantable Cardioverter-Defibrillator (ICD) or Cardiac Resynchronization Therapy-Defibrillator (CRT-D)", Gilead has determined that the totality of the data do not support continuation of the eleclazine development program. Therefore, all ongoing trials will be stopped and the program terminated.

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

Date: 9 February 2017

Contact for inquiries from interested parties:

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