Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision[i]

Actives substances(s): Soticlestat

Latest Decision number(s): 1) P/0115/2020

Corresponding PIP number(s): 1) EMEA-002575-PIP01-19

If the PIP has been submitted as part of a marketing authorisation application in order to comply with the requirements of Article 7 of the Paediatric Regulation (as a condition of the validation of the respective application) and a marketing authorisation was granted based on this application, then there is a legal obligation to complete that PIP. The same applies if there has been a successful post-authorisation application, where the PIP was included in order to comply with the requirements of Article 8 of the Paediatric Regulation.

Please confirm if any of the above applies:

Yes ☐ No ☒

If yes, it means that based on the Marketing Authorisation obtained at the end of that initial procedure or the successful post-authorisation application, as applicable, you are obliged to complete that PIP. That obligation cannot be cancelled by a unilateral decision, including by withdrawing the MA. Such PIP must be completed, unless it is modified in agreement with the PDCO by removing all outstanding PIP measures or granting a full product-specific waiver instead (upon relevant circumstances in accordance with the Paediatric Regulation). Non-completion of a binding PIP establishes noncompliance with the requirements of the Paediatric Regulation, which the European Medicines Agency has an obligation to report to the European Commission.

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

Treatment of Chromosome 15q Duplication Syndrome

Treatment of Cyclin-Dependent Kinase-Like 5 deficiency disorder

☒ has been discontinued

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:)

☒ other reason (please specify: Discontinuation of development)

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

In 2024, pivotal phase 3 studies in adult and paediatric patients with Dravet syndrome (DS) and with Lennox-Gastaut syndrome (LGS) (study TAK-935-3001 and TAK-935-3002, included in PIP EMEA-002572-PIP02-19-M05 as study 6 and study 5, respectively) did not meet their primary endpoints. Following engagement with regulatory agencies and internal evaluations, the Applicant decided to discontinue the development of soticlestat in all indications, both in adult and paediatric populations.

All clinical trials ongoing at the time of the decision will be terminated and the access to soticlestat will be offered to eligible patients according to local provisions.

Date: 17 October 2025

Contact for inquiries from interested parties:

Telephone: +44 3333 000181

Email: medinfoEMEA@takeda.com

[i] This form will be published to the corresponding decision available on the website of the European Medicines Agency.