

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):

(R)-7-Chloro-benzo[b]thiophene-2-carboxylic acid (1-aza-bicyclo[2.2.2]oct-3-yl)-amide hydrochloride hydrate (EVP-6124)

Invented name: None

Latest Decision number(s): 1) P/0288/2014 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001519-PIP01-13 2) EMEA- 3) EMEA- 4) EMEA-

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

Treatment of schizophrenia

☒ 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 approved PIP included a deferral for the initiation of clinical studies in paediatric patients until after a positive risk/benefit ratio has been established in the adult population. The Phase 3 program in adult patients with schizophrenia was recently completed and the co-primary efficacy endpoints were not met for either Study EVP-6124-015 or EVP-6124-016. Therefore, the development of EVP-6124 for the treatment of CIS has been discontinued, and Forum will not initiate any clinical studies in a paediatric population as proposed in the PIP.

Name and signature of the PIP contact point: Helen Scrivener

Date: 13 May 2016

Contact for inquiries from interested parties: info@forumpharma.com

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