

To:

Head of Paediatric Medicines
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Basmisanol

Invented name: N/A

Latest Decision number(s): 1) P/0052/2016 2) P/0075/2015 3) P/ 4)
P/

Corresponding PIP number(s): 1) EMEA-001506-PIP02-14-M01 2) EMEA-001506-PIP02-14
3) EMEA- 4) EMEA-

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

Treatment of Down syndrome

- ☒ 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 CLEMATIS trial was a Phase II study investigating the efficacy and safety of basmisanol in adults and adolescents with Down syndrome. It was a 26 week, multi-centre, randomized, double-blind, three arm, parallel-group, placebo-controlled study. This study was designed to assess the efficacy, safety and tolerability of basmisanol with a composite endpoint derived from clinically meaningful responses in working memory and on the level of independent functioning/adaptive behaviour or global improvement.

The CLEMATIS trial did not meet either the primary or secondary endpoints in either adults or adolescents, and so the additional ongoing paediatric study WP28760 has also been stopped.

As a result, the development of basmisanol for the treatment of Down syndrome will be stopped.

Name and signature of the PIP contact point: Louise Hayes

Date:

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