

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): Enzastaurin (hydrochloride)
Invented name:

Latest Decision number(s): 1) P/0045/2013 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001033-PIP02-11 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Treatment of diffuse large B-cell lymphoma

- ☒ 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:

Enzastaurin did not meet the primary endpoint of the adult Phase III study in the prevention of relapse in diffuse large B-cell lymphoma (DLBCL). As a result, Lilly is stopping development of enzastaurin.

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

Date: 13 May 2013

Contact for inquiries from interested parties:

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