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): Telcagepant
Invented name: N/A

Latest Decision number(s): 1) P/44/2011 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000274-PIP01-08-M01 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]: Migraine with or without aura

☒ 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 decision is based on an assessment of data across the clinical program, including findings from a recently completed six-month Phase III study (Protocol 065) in which a small number of patients taking telcagepant once daily for seven days for the prevention of menstrually related migraine were found to have elevations in liver enzymes ≥ 3 times the upper limit of normal.
Please note that a pediatric investigational plan is approved by PDCO for telcagepant. As a result of this action, pediatric development will be discontinued.

Name and signature of the PIP contact point: Geert Preuveneers

Date: 29/07/2011

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