To:
Head of Paediatric Medicines
European Medicines Agency
7 Westferry Circus
London E14 4HB
United Kingdom
paediatrics@ema.europa.eu

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

Actives substances(s): cediranib maleate
Invented name: Not available

Latest Decision number(s): 1) P/86/2010/ 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000477-PIP01-08 2) EMEA- 3) EMEA- 4) EMEA-

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

☒ 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:
While cediranib maleate is an active drug, the failure of a Phase III study in adults with glioblastoma to meet statistical significance in the primary endpoint led AstraZeneca to discontinue development of the investigational product.

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

Date: May 13th 2013

Contact for inquiries from interested parties: AstraZeneca AB

Telephone: +46 855327591

Email: paediatrics@AstraZeneca.com