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): Cilengitide
Invented name:

Latest Decision number(s): 1) P/0042/2013 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000550-PIP02-10-M01 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Treatment of 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:
The Phase III CENTRIC trial of the investigational integrin inhibitor cilengitide did not meet its primary endpoint of significantly increasing overall survival when added to the current standard chemoradiotherapy regimen (temozolomide and radiotherapy) in newly diagnosed glioblastoma. Overall, Merck KGaA does not plan to continue the clinical development program of cilengitide.

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

Date: 20-June-2013

Contact for inquiries from interested parties: Merck Communication Center
Telephone: +49-6151-72-0
Email: service@merckgroup.com