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): Bitopertin
Invented name: N/A

Latest Decision number(s): 1) P/0229/2012 2) 3) 4)

Corresponding PIP number(s): 1) EMEA-000439-PIP02-11 2) 3) 4)

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

☒ 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:
Bitopertin is an investigational glycine reuptake inhibitor from Roche that was studied in the SearchLyte programme as an add-on (adjunct) therapy for the treatment of symptoms of schizophrenia not fully addressed by current antipsychotic drugs. After reviewing the totality of the phase III data, we found no consistent evidence across the six studies to support further development or applications for regulatory approval of bitopertin for schizophrenia. All six SearchLyte studies and the bitopertin schizophrenia programme have been discontinued.

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

Date: 28. October, 2014

Contact for inquiries from interested parties: Lindsay Ham, PhD, Global CNS Franchise Head

Telephone: +41 61 688 2870

Email: lindsay_mark.ham@roche.com