To:

Head of Paediatric Medicines
European Medicines Agency
30 Churchill Place
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United Kingdom
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): eculizumab

Invented name: Soliris

Latest Decision number(s): 1) P/0306/2012 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000876-PIP02-11-M01 2) EMEA- 3) EMEA- 4) EMEA-

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

Treatment of Shiga-Toxin Producing Escherichia Coli Hemolytic Uremic Syndrome (STEC-HUS)

☒ 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: internal decision on development portfolio)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:

Following an internal decision on the Alexion development portfolio, the development of eculizumab for the treatment of STEC-HUS has been discontinued.

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

Date: 14 July 2015

Contact for inquiries from interested parties: Alexion Paediatric Inquiries

Telephone: 0033 1 47 10 06 06

Email: pip.enquiries.eu@alxn.com