

To:
Head of Paediatric Medicines
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Elacytarabine
Invented name: n/a

Latest Decision number(s): 1) P/0043/2012

Corresponding PIP number(s): 1) EMEA-001121-PIP01-10

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

- ☒ 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: Negative outcome of phase III trial in adults, see description)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:
The pivotal phase III CLAVELA study (EudraCT 2009-014445-80) investigating elacytarabine in patients with relapsed or refractory acute myeloid leukaemia (AML), showed no significant difference in overall survival (OS) between the two arms where patients were randomised to receive either elacytarabine or investigator's choice of treatment. Median survival in the elacytarabine arm was 3.5 months, compared to 3.3 months in the control arm, with a hazard ratio of 0.97. Adverse events were comparable between the two arms, and no meaningful differences were observed in the subgroup analysis. All development work with elacytarabine across all indications has been suspended by Clavis Pharma.

Name and signature of the PIP contact point: Signature on file
Date: 28 June 2013

Contact for inquiries from interested parties:
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