

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): Givinostat
Invented name: Givinostat

Latest Decision number(s): 1) P/9/2010 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000551 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/Indication(s)]:
Juvenile idiopathic arthritis

- 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:

A multicenter, open label, dose finding study to evaluate efficacy and safety of givinostat administered in two different doses in patients with polyarticular course Juvenile Idiopathic Arthritis (poly JIA) not adequately responding to the standard treatment was recently closed (EudraCT No. 2010-019094-15). The study was conducted by nine Investigators in five countries across Europe. Treatment with givinostat was generally well-tolerated for 24 weeks in paediatric patients with polyarticular course JIA as no unexpected or serious toxicities were reported during the study. Although positive activity signs were seen in some patients, none of the treatment cohorts achieved the expected efficacy results as defined by the primary endpoint of the study. The results of this trial led to the decision of discontinuing the clinical development of givinostat in patients with JIA.

Name and signature of the PIP contact point: Paolo Bettica, MD PhD

Date: April 24th 2013

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