

To:

Head of Paediatric Medicines
European Medicines Agency

Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Isavuconazonium (sulfate)

Invented name: Cresemba

Latest Decision number(s): 1) P/0134/2013

Corresponding PIP number(s): 1) EMEA-001301-PIP01-12

Date of initial marketing authorisation granted: No marketing authorisation was granted for the indication primary treatment of invasive candidiasis/candidaemia.

Date of authorisation of new indication, pharmaceutical form or route of administration: Not applicable.

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

Treatment of candida infections / primary treatment of invasive candidiasis/candidaemia

- ☒ 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 Phase 3, double-blind, randomised non-inferiority study designed to evaluate the safety and efficacy of isavuconazole versus caspofungin, followed by oral voriconazole in the treatment of candidaemia and other invasive candida infections was conducted in adult patients. The primary endpoint was assessed as the overall response at the end of the IV treatment phase (EOIV) [assessments of clinical

and mycological responses made by an independent data review committee (DRC)] as well as use of alternative systemic antifungal therapy. Results showed that isavuconazole failed to meet the study's primary endpoint i.e. did not demonstrate non-inferiority relative to caspofungin as the lower boundary of the 95% CI was less than the prespecified NIM of -15%. In addition, isavuconazole's safety profile did not show any advantage over the caspofungin / voriconazole arm of the study.

Please note that if the PIP has been submitted as part of a marketing authorisation application in order to comply with the requirements of Article 7 of the Paediatric Regulation (as a condition of the validation of the respective application) and a marketing authorisation was granted based on this application, then there is a legal obligation to complete that PIP. The same applies if there has been a successful post-authorisation application, where the PIP was included in order to comply with the requirements of Article 8 of the Paediatric Regulation.

Please confirm if any of the above applies to the PIP in question:

Yes ☐ No ☒

If yes, it means that based on the Marketing Authorisation obtained at the end of that initial procedure or the successful post-authorisation application, as applicable, you are obliged to complete that PIP. That obligation cannot be cancelled by a unilateral decision, including by withdrawing the MA. Such PIP must be completed, unless it is modified in agreement with the PDCO by removing all outstanding PIP measures or granting a full product-specific waiver instead (upon relevant circumstances in accordance with the Paediatric Regulation). Non-completion of a binding PIP establishes noncompliance with the requirements of the Paediatric Regulation, which the European Medicines Agency has an obligation to report to the European Commission.

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

Date: 22 March 2022

Contact for inquiries from interested parties: Basilea Pharmaceutica International Ltd.

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