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

Actives substances(s): Ombrabulin
Invented name: NA

Latest Decision number(s): 1) P/120/2011 2) NA 3) NA 4) NA

Corresponding PIP number(s): 1) EMEA-000800-PIP01-09-M01 2) NA 3) NA 4) NA

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
-In soft tissue sarcoma
-In Non Small Cell Lung Cancer
-And in ovarian cancer

☒ 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:
Following unfavourable clinical results in the three main indications in adults (Sarcoma, Ovarian and lung cancers), Sanofi has decided in January 2013 to discontinue the development of Ombrabulin project. Therefore, the company would like to withdraw the above PIP application with immediate effect.

Name and signature of the PIP contact point: Schontz Isabelle

Date: 24 June 2014

Contact for inquiries from interested parties: Schontz Isabelle

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