

From: Rana, Pratibha
Sent: Tuesday, February 16, 2016 8:40 PM
To: Vicki Chen
Subject: STN 125574/0 Information Request

Dear Ms. Chen:

We are reviewing your submission to your BLA for Antihemophilic Factor (Recombinant), submitted on December 16, 2014. We are providing the following comments and request for additional information to continue our review.

Please commit to the following clinical Post Marketing Studies; please verify the commitment wording and provide schedules for each study:

Bayer HealthCare LLC commits to collecting additional safety and efficacy information of KOVALTRY in patients with hemophilia A in the following studies:

Leopold Kids Part B clinical study under Protocol 13400 "A multicenter Phase III uncontrolled open-label trial to evaluate safety and efficacy of BAY 81-8973 (KOVALTRY) in children with severe haemophilia A under prophylaxis therapy"

* Study/trial completion date: XX (i.e., completion, not last patient last visit)

* Final Study Report submission date: XX (i.e., submission of the Report to FDA for review)

Leopold Kids extension clinical study under Protocol 13400 "A multicenter Phase III uncontrolled open-label trial to evaluate safety and efficacy of BAY 81-8973 (KOVALTRY) in children with severe haemophilia A under prophylaxis therapy"

* Study/trial completion date: XX (i.e., completion, not last patient last visit)

* Final Study Report submission date: XX (i.e., submission of the Report to FDA for review)

European Haemophilia Safety Surveillance System (EUHASS) Registry epidemiological study 14149

* Study/trial completion date: XX (please note that 3 years of reports collection after the regulatory action is required)

* Final Study Report submission date: XX (i.e., submission of the Report to FDA for review)

The European Paediatric Network for Haemophilia Management and the PedNet Haemophilia Registry epidemiological study 15689

* Study/trial completion date: (please note that 3 years of reports collection after the regulatory action is required)

* Final Study Report submission date: XX (i.e., submission of the Report to FDA for review)

The review of this submission is on-going and issues may be added, expanded upon, or modified

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as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by February 19, 2016 referencing the date of this request.

The action due date for this file is March 16, 2015.

If you have any questions, please contact me at Prati bha.rana@fda.hhs.gov or (240) 402-8433.

Prati bha Rana

Prati bha Rana, M.S.
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