

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Tuesday, January 15, 2019 3:37 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request (Clinical) RE: BLA 125671

Importance: High

Dear Barbara,

Reference is made to original BLA 125671/0, dated February 27, 2018. Please see the information request outlined below in **bold text** by the Clinical review team. I would appreciate a response to the requested information through e-mail communication only by close of business Thursday, January 17, 2019.

FDA Information Request (Clinical):

1. In your response to our information request, dated January 9, 2019; you have proposed the following dosing regimen:

- a. **On-demand treatment/Control of bleeding episodes:** (b) (4) body weight for minor bleeds and (b) (4) body weight for moderate bleeds, and (b) (4) -50 IU/kg body weight for major bleeds.
- b. **Perioperative management: Pre-operative dose of** (b) (4) body weight for minor surgery, and (b) (4) -50 IU/kg body weight for major surgery.

Please update this dosing regimen to reflect what the majority of subjects actually received during the clinical trials for the treatment of bleeds and periop management.

- 2. Please update Table 1 and Table 2 of the label “Dosing of ESPEROCT to Control Bleeding Episodes” and “Dosing for Perioperative Management” with the updated information regarding the Dose (IU/Kg). Please provide a range in dosing based on the median that was observed during the trials.**
- 3. Please note that if the median dosing for the pediatric age group is different than the median for adults, a separate table for the pediatric population should be provided.**
- 4. Please provide updated text in the part of “On-demand Treatment and Control of Bleeding Episodes” in the label Section 14 by including only Trial 3859 main + ext1 and trial 3885 main.**

Please confirm receipt of this communication, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

Jean Dehdashti, MSc, RAC
Regulatory Project Manager

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