

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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