From:	Dehdashti, Seameen (Jean)
To:	"jcastillo@portola.com"
Cc:	Gildner, Jean; Giordano, Erica
Subject:	Additional FDA Information Request (IR): BLA 125586
Date:	Thursday, December 28, 2017 8:45:00 AM
Attachments:	image001.png
Importance:	High

Good morning Janice,

In addition to FDA IR issued on December 27, 2017, the clinical review team is requesting the information in bolded text below. Please provide a response to the requested information as a formal submission to BLA 125586 no later than 12:00 PM EST, Friday, December 29, 2017. In addition, please provide a courtesy replicate copy of your response by e-mail communication to all parties copied on this e-mail communication.

FDA Information Request:

3. **Please clarify where in the BLA submission for the response to CRL have you submitted the PMR studies (ANNEXA 4/Study 14-505) and UCC study/Study 16-510)?**

Please confirm receipt of this e-mail 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

Center for Biologics and Evaluation
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-9146
Seameen.Dehdashti@fda.hhs.gov

From: Dehdashti, Seameen (Jean)
Sent: Wednesday, December 27, 2017 7:41 PM
To: 'jcastillo@portola.com' <jcastillo@portola.com>
Cc: Gildner, Jean <Jean.Gildner@fda.hhs.gov>; Giordano, Erica <Erica.Giordano@fda.hhs.gov>
Subject: FDA Information Request (IR): BLA 125586

Importance: High

Good evening Janice,

FDA clinical review team is requesting the information outlined below. Please provide the requested information as a formal submission to BLA 125586 no later than 12:00 PM EST, Friday, December 29, 2017. In addition, please provide a courtesy replicate copy of your response by e-mail communication to all parties copied on this e-mail communication.

FDA Information Request:

1. **Please update the ADSL table with 185 subjects to include information on the type of bleeding categorized as ICH, GI and other?**

2. **Please provide the total number of subjects screened and enrolled in relation to the disposition of the 185 subjects in the safety evaluable population. Specifically, please clarify the reasons the number of subjects that were screened, enrolled to treat the 185 subjects. You may either reference the table or text in the clinical study report for Study 14-505 which has the information regarding screen failures, subjects who were enrolled but did not receive treatment. If such information is not available, please provide a table with the link to the table in your response.**

Please confirm receipt of this e-mail 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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