NDA 208383

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Portola Pharmaceuticals, Inc.
Attention: Susan Fors
Senior Vice President, Regulatory Affairs
270 East Grand Avenue
South San Francisco, CA 94080

Dear Ms. Fors:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for BevyxXa (betrixaban), which was approved on June 23, 2017.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMR 3229-1, which was deferred until June 30, 2020. Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

We acknowledge receipt of your request to withdraw your application. However, until approval of this application is formally withdrawn by FDA, we are required to follow all statutory and regulatory requirements pertaining to any active application, including the issuance of this non-compliance letter. Accordingly, we are issuing this non-compliance letter in accordance with applicable requirements.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDA with a cross-reference letter to the Investigational New Drug Application (IND) to which your protocol has been submitted.

If you have any questions, call Charlene Wheeler, MSHS, (Acting) Chief, Project Management Staff at 301-796-1141.

Sincerely,

{See appended electronic signature page}

Rosanna Setse, MD, PhD
(Acting) Deputy Director for Safety
Division of Non-Malignant Hematology
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ROSANNA W SETSE
08/14/2020 10:58:11 AM