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ESG

RESPONSE TO PREA NON-COMPLIANCE LETTER

Jessica J. Lee, MD, Director
Division of Gastroenterology (DG)
Office of Immunology and Inflammation
Food and Drug Administration
Center for Drug Evaluation and Research
Attention: Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 208745: TRLUANCE® (plecanatide) tablets, 3 mg
Sequence 0403: Response to PREA Non-compliance Letter

Dear Dr. Lee:

Reference is made to Salix Pharmaceuticals Inc. and to New Drug Application (NDA) 208745 TRULANCE® (plecanatide) tablets, 3 mg for the treatment of chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C) in adults.

Reference is made to the following Post Marketing Requirement (PMR):

3304-1 Perform a double-blind, dose ranging study in pediatric patients ages 6 years to less than 18 years in order to evaluate the safety and efficacy of once daily oral Trulance (plecanatide) for 4 weeks as treatment of IBS-C. Patients will be stratified by age group (6 years to 11 years and 12 years to less than 18 years of age).

Final Protocol Submission: June 2018

Study Completion: Mar 2020

Final Study Report: August 2020

Reference is also made to the FDA Notification of Non-compliance with PREA dated September 17, 2020 requesting a sponsor response including the reason(s) for the delayed pediatric

assessment under PMR 3304-1, which was deferred until August 31, 2020 and a date by which you expect to submit the assessment. (Reference ID: 4672350).

The Sponsor provides a formal response located in Module 1.17.2.

This submission is provided in electronic Common Technical Document (eCTD) format and is approximately 5 MB in size. The content of the submission has been verified to be free of viruses using the latest version of Carbon Black Defense. The submission is being provided via the FDA's Electronic Submission Gateway (ESG). Please note that a letter of non-repudiation dated January 13, 2015 is on file with the Agency.

The information contained in this submission is confidential and as such should be handled in accordance with the provisions established in 21 CFR 314.430.

Should you have questions or need additional information, please do not hesitate to contact me. Alternatively, you may contact Lee W. Evans, PhD, Vice President, Head of Global Regulatory Affairs at 908-541-2179 or by email at lee.evans@bauschhealth.com.

Sincerely,

BAUSCH Health

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1.17.2 Correspondence Regarding Postmarketing Requirements

Reference is made to the following Post Marketing Requirement (PMR):

3304-1 Perform a double-blind, dose ranging study in pediatric patients ages 6 years to less than 18 years in order to evaluate the safety and efficacy of once daily oral Trulance (plecanatide) for 4 weeks as treatment of IBS-C. Patients will be stratified by age group (6 years to 11 years and 12 years to less than 18 years of age).

Final Protocol Submission: June 2018

Study Completion: Mar 2020

Final Study Report: August 2020

Reference is made to the FDA Notification of Non-compliance with PREA dated September 17, 2020 requesting a sponsor response including the reason(s) for the delayed pediatric assessment under PMR 3304-1, which was deferred until August 31, 2020 and a date by which you expect to submit the assessment. (Reference ID: 4672350).

1.17.2.1 Justification / DEFERRAL EXTENSION REQUESTED

The completion of study PREA PMR 3304-1 (protocol SP304202-14) has been delayed due to the COVID-19 pandemic. The study was placed on hold March 2020 of which the study was 43% enrolled. The study is planned to resume Q12021. Based on lower anticipated enrollment rates due to the pandemic, the study is targeted to complete Q42022. The target enrollment for the study is (b) (4) patients. There are currently (b) (4) patients enrolled with approximately (b) (4) patients to be enrolled for the study. As such, the Sponsor would like to request a deferral extension in order to complete the study and submit the final study report to Agency as required. As part of this extension, the Sponsor will be adding additional Investigational sites to support the enrollment of this study.

1.17.2.2 Timeline

The Sponsor proposed the following revised timeline for consideration:

Study Completion: December 2022

Final Study Report: March 2023