September 15, 2020

Nick Kozauer, MD, Acting Director
Division of Neurology (DN II)
Center for Drug Evaluation and Research (CDER)
Office of Neuroscience
Food and Drug Administration
10903 New Hampshire Avenue,
Silver Spring, MD 20993
Building 22, Suite 4346

RESPONSE TO PREA NONCOMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

Re: ONZETRA® XSAIL® (sumatriptan nasal powder)
NDA 206099 / SN0089

Dear Dr. Kozauer:

Reference is made to Currax Pharmaceuticals LLC's New Drug Application (NDA) 206099 for ONZETRA® XSAIL® (sumatriptan nasal powder) indicated for the acute treatment of migraine with or without aura in adults. Reference is also made to the Noncompliance letter received on August 12, 2020, regarding the deferred pediatric assessment PMR 3025-1 assigned to NDA 206099 under the Pediatric Research Equity Act (PREA). This submission includes our formal response to the Non-Compliance Letter mentioned above and a Request for Deferral Extension.

In the approval letter for Onzetra, the PMR 3025-1 was listed under Required Pediatric Assessment:

3025-1 Conduct a pediatric study under the Pediatric Research Equity Act (PREA) to evaluate the efficacy and safety, including sparse pharmacokinetic (PK) sampling, of Onzetra Xsail (sumatriptan) for the acute treatment of migraine in pediatric patients of ages 12 to 17 years.

Protocol Submission: September 2016

Study Completion: November 2019

Final Report Submission: June 2020

As part of the fulfillment for PMR 3025-1, on September 30, 2016, Avanir (the previous NDA owner) submitted a draft protocol for Study 17-AVP-825-301, titled "A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of ONZETRA Xsail (Sumatriptan Nasal Powder) for the Acute Treatment of Migraine with or

Without Aura in Adolescents" in IND 110090 Sequence 0033. Avanir subsequently received an INFORMATION REQUEST/ADVICE - PREA PMR dated February 3, 2017, containing several comments on the Study 17-AVP-825-301 protocol. On August 22, 2017, the revised study protocol was submitted IND 110090 Sequence 0035 to address the Divisions comments. The Study17-AVP-825-301 started on November 2, 2017, and the status of this study was provided in IND Annual Reports. The latest update can be found in IND 110090 Sequence 0054.

The FDA was notified by Avanir on April 5, 2019 (NDA 206099 SN 0067) of their intention to suspend enrollment of new subjects into Study17-AVP-825-301 as they entered a formal license agreement wind-down period with the product's originator, Optinose. In September 2019 prior to Optinose reacquiring the product, Currax Pharmaceutical LLC (Currax) acquired ONZETRA® XSAIL® (sumatriptan nasal powder) from Avanir. The ownership of IND 110090 and NDA 206099 was transferred to Currax on September 25, 2019.

Several challenges have caused a delay in completing this study on time. (1) The study has already been delayed before the acquisition. Less than half of the required number of subjects were enrolled prior to enrolment being suspended in April 2019. Thus, the study could not be completed by November 2019. (2) Unlike Avanir who was using internal resources for the study management, Currax needed to select a clinical research organization (CRO) to perform these tasks; (3) COVID-19 pandemic has caused the further delay in our ability to resume the study.

Currax recognizes the importance of the PREA program. As of today, our team has completed the CRO selection process, and clinical restart activities have been ongoing since August 2020.

Currax remains committed to fulfilling the postmarketing requirements under PREA. We hereby requests a Deferral Extension for PMR 3025-1 with the proposed dates set forth below. This timeline is based on the previous pediatric population recruitment rates (estimated to be 0.16 patients per site per month).

Study Completion: October 2023

Final Report Submission: January 2024

As requested by the FDA a cross-reference letter to this submission will also be submitted to IND 110090.

If you have any questions about this submission, please feel free to contact me at (862) 579-2848 or via email at jfan@curraxpharma.com.

Sincerely,

Joyce Fan
Digitally signed by Joyce Fan
Date: 2020.09.15 13:38:16 -04'00'

Joyce Fan
Director, Regulatory Affairs
Currax Pharmaceuticals LLC
10 North Park Place, Suite 201
Morristown, NJ 07960
Phone: 862-579-2848
E-mail: jfan@curraxpharma.com