Trevena, Inc.
955 Chesterbrook Blvd.
Suite 110
Chesterbrook, PA 19087

RESPONSE TO POSTMARKETING REQUIREMENTS NOTIFICATION OF MISSED MILESTONE & DEFERRAL EXTENSION REQUEST

June 10, 2024

CDR Mark A. Liberatore, PharmD, RAC, Deputy Director for Safety
Food and Drug Administration
Division of Anesthesiology, Addiction Medicine, and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research
Attention: Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: NDA No. 210730; Sequence No. 0097
Oliceridine Injection, 1 mg/mL
Response to Postmarketing Requirements Notification of Missed Milestone
Deferral Extension Request

Dear Dr. Liberatore:

Reference is made to Trevena, Inc.'s NDA 210730 for Olinvyk® (oliceridine) injection, approved by the FDA on August 7, 2020 (as well as IND 113537) and to the Postmarketing Requirements Notification of Missed Milestone letter (Reference ID: 5380003) dated May 13, 2024.

The purpose of this submission is to provide Trevena's response to the Postmarketing Requirements Notification of Missed Milestone letter referenced above. Please refer to 1.17.2 Correspondence Regarding Postmarketing Requirements for a detailed response.

This submission also includes a deferral extension request for all PREA postmarketing requirements (PMR) including 3902-1, 3902-2, 3902-3, 3902-4, 3902-5, and 3902-6. Please refer to 1.9.2 Request for Deferral of Pediatric Studies for detailed information regarding this request.

In addition, this submission includes clinical study protocols and reports CP130-1013 and CP130-1016 in 5.3.4.1 and clinical study protocol CP130-4002 in 5.3.4.2.

If you have any questions regarding this submission, please contact me at (804) 243-1679, or via email at rachel.capone@synergbiopharma.com.

Sincerely,

Rachel Capone

Digitally signed by Rachel Capone
Date: 2024.06.05 12:48:40 -04'00'

Rachel L. Capone, MSHS
Regulatory Affairs Manager
Syner-G BioPharma Group
Authorized Regulatory Representative for NDA 210730

This submission is being submitted in eCTD format. This electronic submission is approximately 35 MB in total size. All files were checked and verified to be free of viruses prior to being sent via the Electronic Submissions Gateway using CrowdStrike Version 7.15.18511.0.