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28 January 2022

Nick Kozauer, M.D., Acting Director
Division of Neurology 2
Office of Neuroscience
Center of Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

NDA 212839

Xcopri® (cenobamate tablets) CV

RESPONSE TO A PREA NON-COMPLIANCE LETTER

Cross Reference
IND 76809

eCTD Sequence / Serial No. 0252

Dear Dr. Kozauer,

Reference is made to SK Life Science, Inc.'s (SKLSI) New Drug Application (NDA) 212839 for Xcopri (cenobamate tablets) CV for the treatment of partial-onset seizures in adult patients. Further reference is made to the following agreed upon study timelines for PMR 3712-3 at the time of NDA approval, dated November 21, 2019:

1. Draft Protocol Submission: 06/2020
2. Final Protocol Submission: 09/2020
3. Study Completion: 07/2021
4. Final Report Submission: 11/2021

Reference is also made to the Division's Notification of Non-Compliance with PREA letter, dated December 17, 2021, pertaining to PMR 3712-3. The letter stated that the pediatric assessment was not submitted by November 30, 2021as required under the PMR.

PMR 3712-3 is a study entitled "Relative Bioavailability of a Single 200 mg Dose of Cenobamate (YKP3089) given as an Oral Tablet or as an Oral Suspension and the Effect of Food on a Single 200 mg Dose of Cenobamate given as an Oral Suspension" (Study YKP3089C037). Study was conducted in healthy adult subjects.

The pediatric assessment was delayed for the following reasons:

1. A delay in reaching an agreement with the Division on the final protocol resulted in a delayed study start-up. A draft protocol for Study YKP3089C037 was submitted to the Division on June 29, 2020 in anticipation of receiving feedback to be able to submit the final protocol by September 2020. Although SKLSI made several requests for feedback, a Final Protocol Acknowledgement Letter was not issued until October 13, 2020.

2. The study had an unexpected high discontinuation rate. Although a single dose study, the three-period, three-sequence, balanced cross-over design with long washout periods required a duration of approximately 3 months. Initially, a total of twenty-four subjects were randomized; however, five subjects prematurely discontinued from the study. To ensure an adequate sample size, it was necessary to enroll an additional group of subjects which resulted in approximately a two-month delay.
3. Impact of ongoing Covid-19 pandemic on the recruitment and retention of subjects.

SKLSI submitted the final study report to the Division on January 21, 2021 under sequence number 0247.

Format and Structure of the Submission

This was certified virus free using Symantec Endpoint Protection. Technical questions related to this electronic submission should be directed to Mark Barroqueiro at 201-421-3867 or by email at mbarroqueiro@sklsi.com.

Should you have any questions or comments, please contact the undersigned.

Sincerely,

Jeremy Rybicki
Digitally signed by Jeremy Rybicki
Date: 2022.01.24 17:16:02 -06'00'

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The IT point of contact for this submission is:

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