ONO PHARMA

Press Release

December 10, 2024

SK Biopharmaceuticals' Cenobamate Demonstrates Clinical Efficacy and Safety in Epilepsy Patients across Korea, China and Japan

This material is intended to notify the press release issued on December 9 (local time in South Korea) by SK Biopharmaceuticals, our alliance partner for cenobamate.

Please refer to the following link below for the original press release issued by SK Biopharmaceuticals:
https://www.skbp.com/kor/news/view.do?boardCode=BDCD0002&boardSeq=720&currentPage=1&search=

License Agreement between Ono Pharmaceutical Co., Ltd. and SK Biopharmaceuticals：
In October, 2020, Ono Pharmaceutical Co., Ltd. entered into an exclusive license agreement with SK Biopharmaceuticals (SKBP) for the development and commercialization of cenobamate, SKBP's antiepileptic drug, in Japan.

(English translation)

SK Biopharmaceuticals' Cenobamate Paves the Way for Expansion in Northeast Asia, Demonstrating Clinical Efficacy and Safety in Epilepsy Patients across Korea, China and Japan

Presented phase 3 clinical trial results (YKP3089C035) involving patients from Korea, China, and Japan at the 2024 AES Annual Meeting.

Demonstrated the efficacy and safety of adjunctive cenobamate in Asian patients with uncontrolled focal seizures despite treatment with ASMs.

Seoul, Korea – December 09, 2024 – SK Biopharmaceuticals a biotech unveiled the Phase 3 clinical trial results of cenobamate (U.S. brand name: XCOPRI®) in Northeast Asian epilepsy patients through a poster presentation at the 2024 American Epilepsy Society (AES) Annual Meeting in Los Angeles, USA. Based on these findings, cenobamate's partners in Asia plan to proceed with New Drug Application (NDA) submission in their respective countries.

Epilepsy, the third most common neurological disorder after apoplexy and dementia, with approximately 5 million new cases diagnosed globally each year[1-2]. Cenobamate has already demonstrated significant seizure-free rates in adult epilepsy patients suffering from unexpected seizures and has been actively prescribed since its U.S. launch in 2020 and European launch in 2021. Since then, it has been actively prescribed, achieving the highest share of new patient prescriptions in the U.S. last year (43%) and reaching a cumulative global prescription of 140,000.

The phase 3 clinical trial, conducted in Korea, China, and Japan, evaluated the efficacy and safety

of cenobamate as an adjunctive treatment in adults aged 18–70 with focal seizures, despite treatment with 1-3 ASMs (Antiseizure medications). The randomized, double-blind, placebo-controlled, multicenter study assigned patients in a 1:1:1:1 to receive either a placebo or adjunctive cenobamate at doses of 100, 200, or 400mg once daily.

According to the study results, cenobamate met the primary efficacy outcome, showing a significant reduction in the median percent change in seizure frequency across all doses during 6-week maintenance phase. A 100% reduction in seizure frequency was achieved at the 400mg dose. (Placebo: 25.9% vs cenobamate: 42.6% for 100mg, 78.3% for 200mg, and 100% for 400mg)

In the secondary efficacy analysis, responder rates during the 6-weeks of maintenance phases also showed a significant seizure-free rate (Placebo: 2.6% vs cenobamate: 12.4% for 100mg, 30.1% for 200mg, and 52.4% for 400mg). The most common TEAEs (≥20%) were dizziness and somnolence in the cenobamate dose groups.

Additionally, significant reduction in focal seizure frequency were observed early during cenobamate titration at week 5-6, with reduction rates of 42.9% compared to 15.4% for placebo. Significant seizure reductions occurred across assessed seizure subtypes, including focal aware motor, focal impaired aware, and focal to bilateral tonic-clonic.

At 2024 AES Annual Meeting, nine research posters on cenobamate were presented. These included studies on cenobamate's dual mechanism of action, publication detailing its unique dual mechanism of action—highlighting features not seen with traditional ASMs, initial dosing associated with seizure freedom—emphasizing the potential for flexible and individualized dosing, and the effect of cenobamate on responsive neurostimulation-related epileptiform events.

"We are pleased to announce the successful completion of cenobamate's phase 3 clinical trial in Northeast Asia." said Dong-Hoon Lee, the CEO "Recognized globally as an innovative treatment, cenobamate offers a promising new paradigm for patients in Northeast Asia on these results."
He added, "The diverse studies presented at this year's AES underscore our commitment to addressing unmet medical needs and enhancing the quality of life for epilepsy patients worldwide. We remain dedicated to advancing global innovation in medicine and fostering a sustainable healthcare ecosystem."

Reference:

[1] WHO, Epilepsy, Available at https://www.who.int/news-room/fact-sheets/detail/epilepsy?utm_source=chatgpt.com (accessed on 25 Nov, 2024)

[2] Available at Korea Disease Control and Prevention Agency (KDCA) National Health Information Portal, Epilepsy https://health.kdca.go.kr/healthinfo/biz/health/gnrlzHealthInfo/gnrlzHealthInfo/gnrlzHealthInfoView.do?cntnts_sn=5961&utm_source=chatgpt.com (accessed on 25 Nov, 2024)