ONO PHARMA

Press Release

Ono Submits an Application for Approval of Cenobamate (ONO-2017), Antiseizure Medications in Japan

- An application for manufacturing and marketing approval of cenobamate in Japan for the treatment of partial-onset seizures, with or without secondary generalized seizures
- Cenobamate significantly improved the primary endpoint: percent change in seizure frequency
- An adjunctive cenobamate therapy was well tolerated

Osaka, Japan, September 30, 2025 – Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President and COO: Toichi Takino; "Ono") today announced that Ono submitted an application for the manufacturing and marketing approval of cenobamate (ONO-2017) for the treatment of partial-onset seizures, with or without secondary generalized seizures.

This application is based on the results of a multinational, Phase 3 clinical trial (YKP3089C035) conducted in Asian patients with uncontrolled partial-onset (focal) seizures despite treatment with antiseizure medications (ASMs). In this trial, adjunctive therapy with cenobamate showed statistically significant improvement on the primary endpoint of median percent change in seizure frequency compared to existing treatments and was well tolerated.

About YKP3089C035

YKP3089C035 was a randomized, double-blind, placebo-controlled, multinational, Phase 3 clinical trial conducted in South Korea, China, and Japan. In this trial, the efficacy and safety of an adjunctive cenobamate therapy in adult patients aged 18–70 with uncontrolled partial-onset (focal) seizures on 1-3 ASMs were evaluated. Patients were randomly allocated to either an adjunctive placebo or cenobamate of 100, 200, or 400mg groups once daily at 1:1:1:1.

All dosage groups of cenobamate achieved the primary efficacy endpoint, showing a significant reduction on the median percent change in seizure frequency during 6-week maintenance phase compared to that in placebo group. Cenobamate 400 mg group showed a 100% reduction in median seizure frequency. (Placebo: 25.9% vs cenobamate: 42.6% for 100mg, 78.3% for 200mg, and 100% for 400mg)

In the secondary endpoints for efficacy, all dosage groups of cenobamate showed significantly higher seizure-free rate compared to placebo group (Placebo: 2.6% vs cenobamate: 12.4% for 100mg, 30.1% for 200mg, and 52.4% for 400mg) *. The most common adverse events with the incidence of 20% or more in cenobamate groups were dizziness and somnolence.

The results of this trial were presented in a poster session at the 2024 Annual Meeting of the American Epilepsy Society (AES)[1)].

* The maximum rate of seizure-free, which aligns with the goal in epilepsy treatment, in adjunctive therapy with existing ASMs is reported to be around 6.4%[2)].

About Epilepsy

Epilepsy is a chronic brain disorder in which seizures are triggered by abnormal excitability of nerve cells in the brain. In Japan, approximately 1 million people have suffered from epilepsy requiring

long-term drug therapy[3]. Thirty percent of epilepsy patients do not achieve adequate seizure control with existing ASMs[4) 5)]. Epilepsy is a disease with high unmet medical needs for which new ASMs are still anticipated.

About cenobamate

Although the detailed mechanism of cenobamate exerting its therapeutic effects remains unclear, cenobamate reduces repetitive neuronal firing by inhibiting voltage-dependent sodium currents. In addition, cenobamate positively modulates γ-aminobutyric acid type A ($GABA_A$) ion channels. Based on its clinical results, cenobamate has demonstrated high efficacy and is expected to become a new treatment option that enables more patients to achieve seizure freedom, which is consist with the goal of epilepsy treatment. As of September 2025, cenobamate is commercialized as a treatment for partial-onset seizures in 25 countries or regions worldwide, including in the United States and Europe.

In Japan, Ono is conducting Phase 3 clinical trial of cenobamate for the treatment of primary generalized tonic-clonic (PGTC) seizures in adolescents and adults.

About Partnership with SK Biopharmaceuticals Co., Ltd.

In 2020, Ono entered into a licensing agreement with SK Biopharmaceuticals Co., Ltd. (headquartered in Gyeonggi-do, South Korea; “SKBP”) for their ASM, cenobamate. Through this agreement, Ono has obtained the exclusive rights to develop and commercialize cenobamate in Japan. SKBP and its U.S. subsidiary, SK Life Science, are global pharmaceutical companies focused on the research, development, and commercialization of treatments for central nervous system (CNS) disorders. Their pipeline includes 7 development compounds for CNS diseases, including epilepsy. In addition, SKBP is actively engaged in early-stage oncology research. Further information can be found on the SKBP website (www.skbp.com/eng) and the SK Life Science website (www.SKLifeScienceInc.com).

References:

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