ONO PHARMA

Press Release

Launch of XCOPRI® Tablets for the Treatment of Patients with Partial-onset Seizures, With or Without Secondary Generalized Seizures in Japan

- Ono launched XCOPRI in Japan for the treatment of patients with partial-onset seizures, with or without secondary generalized seizures.
- XCOPRI is approved as a treatment for partial-onset seizures in about 50 countries or regions worldwide, including the U.S. and Europe .

Osaka, Japan, November 13, 2026 -- Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President and COO: Toichi Takino; "Ono") today announced that it has launched XCOPRI® (generic name: cenobamate) Tablets 12.5 mg, 50 mg, 100 mg, 200 mg ("XCOPRI") for the treatment of patients with partial-onset seizures, with or without secondary generalized seizures in Japan.

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 are estimated to have epilepsy, which generally requires long-term drug therapy.[1] Approximately thirty percent of epilepsy patients do not achieve adequate seizure control with existing anti-seizure medications (ASMs).[2,3] Epilepsy is a disease with high unmet medical needs for which new ASMs are still anticipated.

About XCOPRI

XCOPRI is thought to have two mechanisms of action: inhibition of voltage-dependent sodium currents and positive modulation of γ-aminobutyric acid type A ($GABA_A$) ion channels. In a multinational Phase 3 clinical study involving Asian patients with uncontrolled partial-onset (focal) seizures despite treatment with existing ASMs, XCOPRI has demonstrated efficacy and is expected to become a new treatment option that has been associated with seizure freedom in a proportion of patients in clinical studies, which is consistent with the goal of epilepsy treatment.[4] As of November 2026, XCOPRI is approved as a treatment for partial-onset seizures in about 50 countries or regions worldwide, including the U.S. and Europe (where it is marketed as ONTOZRY®).

In Japan, Ono is conducting two Phase 3 clinical studies of XCOPRI: one in adolescents and adults with primary generalized tonic-clonic (PGTC) seizures, and one in pediatric patients with partial-onset seizures.

Overview of XCOPRI® Tablets

Product name	XCOPRI® Tablets 12.5 mg/50 mg/100 mg/200 mg
Generic name (JAN)	Cenobamate
Indication	Patients with partial-onset seizures, with or without secondary generalized seizures
Dosage and administration	The usual adult starting dose is 12.5 mg of cenobamate administered orally once daily. Thereafter, the dose should be increased by 1 step at intervals of at least 2 weeks to 100 to 200 mg once daily as the maintenance dose. The dose may be adjusted according to the patient's condition. The dose should be increased to >200 mg by 50 mg at intervals of at least 2 weeks, and the maximum dose should be 400 mg once daily. (Dose Titration Schedule up to 200 mg)
Approval date	September 16, 2026
NHI price listing date	November 13, 2026
NHI drug price	XCOPRI® Tablets 12.5 mg ：JPY 129.60 XCOPRI® Tablets 50 mg ：JPY 345.20 XCOPRI® Tablets 100 mg ：JPY 563.50 XCOPRI® Tablets 200 mg ：JPY 919.80
Manufacturer/distributor	Ono Pharmaceutical Co., Ltd.

Regimen	Dose
1	12.5 mg
2	25 mg
3	50 mg
4	100 mg
5	150 mg
6	200 mg

Product Photograph



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), which originally discovered and developed the anti-seizure medication XCOPRI. Through this agreement, Ono has obtained the exclusive rights to develop and commercialize XCOPRI in Japan. SK Biopharmaceuticals and its U.S. subsidiary, SK Life Science, Inc., are global biopharmaceutical companies that focus on developing and commercializing innovative treatments. Together, they are advancing innovative treatments for central nervous system (CNS) disorders and expanding into oncology through next-generation modalities including radiopharmaceutical therapy (RPT) and targeted protein degradation (TPD), while leveraging AI-driven innovation to accelerate drug development and enhance patient care. Further information can be found on the SK Biopharmaceuticals website (www.skbp.com/eng) and the SK Life Science, Inc. website (www.SKLifeScienceInc.com).

References:

1. Japan Epilepsy Association (JEA)（accessed on August 26, 2025）
   Available at https://www.jea-net.jp/epilepsy
2. Yushi Inoue. The Guideline Development Committee of the Japan Epilepsy Society. Report of the Guideline Development Committee of the Japan Epilepsy Society: Guidelines for the Pharmacological Treatment of Epilepsy in Adults. Epilepsy Research. 2005;23:249-53.
3. Brodie MJ, Barry SJ, Bamagous GA, Norrie JD, Kwan P. Patterns of treatment response in newly diagnosed epilepsy. Neurology. 2012;78:1548-54.
4. Press release of Ono Pharmaceutical Co., Ltd. as of September 16, 2026.
   Available at https://www.ono-pharma.com/en/news/20260916.html

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