



**FOR IMMEDIATE RELEASE**

**Long-Term Efficacy and Safety Data of XCOPRI® (cenobamate tablets) CV  
Published in *Neurology***

*The open-label extension of Study C017 demonstrated high response rates with no new safety signals identified in patients receiving XCOPRI (cenobamate) for up to 4 years*

**Paramus, New Jersey, June 22, 2022** – [SK Life Science, Inc.](#), a subsidiary of SK Biopharmaceuticals Co., Ltd., an innovative global pharmaceutical company focused on developing treatments for central nervous system (CNS) disorders, announced that the results of the long-term, open-label extension (OLE) of a randomized, double-blind, placebo-controlled study (C017) of XCOPRI® (cenobamate) were published online in the journal [Neurology](#).

The OLE phase analyzed data from 355 adult patients with uncontrolled focal seizures despite treatment with 1-3 antiseizure medications (ASMs) who completed the 18-week C017 double-blind phase and entered the OLE. Patients included in the study also had  $\geq 8$  seizures during the 8-week baseline period. Results from the study showed the long-term clinical efficacy and safety of cenobamate for adult patients with partial-onset (focal) seizures. Among the 355 patients who received at least one dose of cenobamate, the median treatment duration was 54 months (200 mg median modal daily dose, range 50 mg to 400 mg). As of the data cut-off in July 2019, 59% (209/355) patients continued on treatment with cenobamate.

Retention rates for patients who were enrolled at 12, 24, 36, and 48 months in the study were 83%, 71%, 65%, and 62%, respectively. Additionally, among the observed patients during any 12-month period, 13% to 16% of patients achieved seizure freedom. Among patients who achieved 100% seizure reduction, the median duration of seizure freedom during each 12-month interval was 48 months, 47.2 months and 45.1 months, respectively. Patients taking cenobamate experienced a median percent seizure frequency reduction over baseline that increased with each 6-month interval, up to 76% (IQR: 45%), during months 43-48 of the OLE.

“We were pleased to see these results in such a difficult to treat patient population,” said Pavel Klein, M.D., epileptologist and neurologist, Mid-Atlantic Epilepsy and Sleep Center, Bethesda, MD. “More than three quarters of patients treated with cenobamate experienced a reduction in seizure frequency of 50% or more during years 3-4 of the study. Physicians may want to consider whether patients with partial-onset (focal) seizures are appropriate candidates for adjunctive treatment with cenobamate.”

The safety profile of cenobamate observed was generally consistent with that of the previous double-blind phase 2 clinical studies and the phase 3 open-label safety study. No new safety issues were identified. Treatment discontinuation occurred in 141 patients, with the most common reasons being lack of efficacy (17%, 59/355), withdrawal by patient, (9%, 31/355), and adverse events (8%, 27/355). The most common treatment emergent adverse events (TEAE) were dizziness (34%, 122/355), somnolence (25%, 87/355), fatigue (16%, 56/355) and headache (16%, 54/355). TEAEs leading to

discontinuation occurred in 9% of patients (31/355), with the primary reason being nervous system disorders (3%, 12/355).

### **About Study C017**

Study C017 was a multi-center, double-blind, randomized, placebo-controlled study to evaluate the safety and efficacy of cenobamate 200 mg/day as an adjunctive therapy in adults (18-70 years old) with uncontrolled focal seizures. In the study, 437 patients were randomized to four different groups, including 108 patients treated with placebo and 108, 110, and 111 patients treated, respectively, with 100 mg, 200 mg, and 400 mg/day of cenobamate. Patients included in the study had  $\geq 8$  seizures during the 8-week long baseline period and were taking 1-3 anti-seizure medications (ASMs). The open-label extension (OLE) of the study enrolled 355 patients, including 265 patients originally randomized to cenobamate and 90 patients originally randomized to placebo during the double-blind period. The objective of the OLE was to evaluate long-term efficacy, safety and tolerability of cenobamate as an adjunctive treatment.

### **About XCOPRI® (cenobamate tablets) CV**

Cenobamate is an anti-seizure medication (ASM) discovered and developed by SK Biopharmaceuticals and SK life science. While the precise mechanism by which cenobamate exerts its therapeutic effect is unknown, it is believed to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents. It is also a positive allosteric modulator of the  $\gamma$ -aminobutyric acid (GABA<sub>A</sub>) ion channel.

Cenobamate is approved in the United States for the treatment of partial-onset seizures in adults and is available under the brand name XCOPRI® (cenobamate tablets) CV. Cenobamate can be combined with other ASMs or used alone. The recommended initial dosage of cenobamate is 12.5 mg once-daily, with titration every two weeks; it is available in six tablet strengths for once-daily dosing: 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg.

Cenobamate is also approved in the European Union and the United Kingdom for the adjunctive treatment of focal-onset (partial-onset) seizures with or without secondary generalization in adult patients with seizures that have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products and is marketed by Angelini Pharma under the brand name ONTOZRY®.

Additionally, cenobamate is in clinical development in Asia. Ono Pharmaceutical and Ignis Therapeutics have the rights to develop and commercialize cenobamate in Japan and in the Greater China region, respectively. SK Biopharmaceuticals has recently entered into an exclusive licensing agreement with Endo for cenobamate in Canada.

### **IMPORTANT SAFETY INFORMATION AND INDICATION FOR XCOPRI® (cenobamate tablets) CV**

#### **DO NOT TAKE XCOPRI IF YOU:**

- Are allergic to cenobamate or any of the other ingredients in XCOPRI.
- Have a genetic problem (called Familial Short QT syndrome) that affects the electrical system of the heart.

#### **XCOPRI CAN CAUSE SERIOUS SIDE EFFECTS, INCLUDING:**

**Allergic reactions: XCOPRI can cause serious skin rash or other serious allergic reactions which may affect organs and other parts of your body like the liver or blood cells.** You may or may not have a rash with these types of reactions. Call your healthcare provider right away and go to the nearest emergency room if you have any of the following: swelling of your face, eyes, lips, or tongue, trouble swallowing or breathing, a skin rash, hives, fever, swollen glands, or sore throat that does not go away or comes and goes, painful sores in the mouth or around your eyes, yellowing of your skin or eyes, unusual bruising or bleeding, severe fatigue or weakness, severe muscle pain, frequent infections, or infections that do not go away. **Take XCOPRI exactly as your healthcare provider tells you to take it. It is very important to increase your dose of XCOPRI slowly, as instructed by your healthcare provider.**

**QT shortening: XCOPRI may cause problems with the electrical system of the heart (QT shortening).** Call your healthcare provider if you have symptoms of QT shortening including fast heartbeat (heart palpitations) that last a long time or fainting.

**Suicidal behavior and ideation:** Antiepileptic drugs, including XCOPRI, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your health care provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you: thoughts about suicide or dying; attempting to commit suicide; new or worse depression, anxiety, or irritability; feeling agitated or restless; panic attacks; trouble sleeping (insomnia); acting aggressive; being angry or violent; acting on dangerous impulses; an extreme increase in activity and talking (mania); or other unusual changes in behavior or mood.

**Nervous system problems:** XCOPRI may cause problems that affect your nervous system. Symptoms of nervous system problems include: dizziness, trouble walking or with coordination, feeling sleepy and tired, trouble concentrating, remembering, and thinking clearly, and vision problems. **Do not drive, operate heavy machinery, or do other dangerous activities until you know how XCOPRI affects you.**

**Do not drink alcohol or take other medicines that can make you sleepy or dizzy while taking XCOPRI without first talking to your healthcare provider.**

#### **DISCONTINUATION:**

**Do not stop taking XCOPRI without first talking to your healthcare provider.** Stopping XCOPRI suddenly can cause serious problems. Stopping seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

#### **DRUG INTERACTIONS:**

XCOPRI may affect the way other medicines work, and other medicines may affect how XCOPRI works. **Do not start or stop other medicines without talking to your healthcare provider.** Tell healthcare providers about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

#### **PREGNANCY AND LACTATION:**

XCOPRI may cause your birth control medicine to be less effective. **Talk to your health care provider about the best birth control method to use.**

**Talk to your health care provider if you are pregnant or plan to become pregnant.** It is not known if XCOPRI will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking XCOPRI. You and your healthcare provider will decide if you should take XCOPRI while you are pregnant. If you become pregnant while taking XCOPRI, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334 or go to [www.aedpregnancyregistry.org](http://www.aedpregnancyregistry.org).

**Talk to your health care provider if you are breastfeeding or plan to breastfeed.** It is not known if XCOPRI passes into breastmilk. Talk to your healthcare provider about the best way to feed your baby while taking XCOPRI.

#### **COMMON SIDE EFFECTS:**

The most common side effects in patients taking XCOPRI include dizziness, sleepiness, headache, double vision, and feeling tired.

These are not all the possible side effects of XCOPRI. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. For more information, ask your healthcare provider or pharmacist. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088** or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

#### **DRUG ABUSE:**

**XCOPRI is a federally controlled substance (CV) because it can be abused or lead to dependence.** Keep XCOPRI in a safe place to prevent misuse and abuse. Selling or giving away XCOPRI may harm others and is against the law.

#### **INDICATION:**

XCOPRI is a prescription medicine used to treat partial-onset seizures in adults 18 years of age and older. It is not known if XCOPRI is safe and effective in children under 18 years of age.

Please see additional patient information in the [Medication Guide](#). This information does not take the place of talking with your healthcare provider about your condition or your treatment.

Please see full [Prescribing Information](#).

#### **About Epilepsy**

Epilepsy is the fourth most common neurological disorder. There are approximately 3.4 million people living with epilepsy in the United States, with 150,000 new cases each year in the country.<sup>1,2</sup> Epilepsy is characterized by recurrent, unprovoked seizures. The seizures in epilepsy may be related to a brain injury or a family tendency, but often the cause is completely unknown. Having seizures and epilepsy can affect one's safety, relationships, work, driving, and much more.<sup>3,4</sup> People with epilepsy are at risk for accidents and other health complications, including falling, drowning, depression and sudden unexplained death in epilepsy (SUDEP).<sup>3,4</sup> Despite the availability of many antiepileptic therapies, almost 40 percent of people with epilepsy are not able to achieve seizure freedom, meaning they have epilepsy that remains uncontrolled.<sup>5</sup>

### **About SK Biopharmaceuticals Co., Ltd. and SK Life Science, Inc.**

SK Biopharmaceuticals and its U.S. subsidiary SK life science are pharmaceutical companies focused on the research, development and commercialization of treatments for disorders of the central nervous system (CNS) and oncology. In 2017, SK Biopharmaceuticals established a research center to begin their expansion into oncology through research and development efforts. The companies have a pipeline of eight compounds in development in both CNS disorders and oncology. Additionally, SK Biopharmaceuticals is focused on the discovery of new treatments in oncology. For more information, visit SK Biopharmaceuticals' website at [www.skbp.com/eng](http://www.skbp.com/eng) and SK life science's website at [www.SKLifeScienceInc.com](http://www.SKLifeScienceInc.com).

Both SK Biopharmaceuticals and SK life science are part of SK Group, one of the largest conglomerates in Korea. SK Inc., the parent company of SK Biopharmaceuticals, continues to enhance its portfolio value by executing long-term investments with a number of competitive subsidiaries in various business areas, including pharmaceuticals and life science, energy and chemicals, information and telecommunication, and semiconductors. In addition, SK Inc. is focused on reinforcing its growth foundations through profitable and practical management based on financial stability, while raising its enterprise value by investing in new future growth businesses. For more information, please visit <http://hc.sk.co.kr/en/>.

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