



**FOR IMMEDIATE RELEASE**

## **SK life science Announces Results of Large, Open-Label, Long-Term Safety Study of Cenobamate Published in *Epilepsia***

**Paramus, New Jersey, May 20, 2020** – [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 *Epilepsia* has published interim results from an ongoing large, multi-center, open-label Phase 3 study assessing the long-term safety and tolerability of cenobamate, an anti-seizure medication (ASM), in adults with uncontrolled partial-onset (focal) seizures.<sup>1</sup> The study also assessed if a lower starting dose and every other week titration could mitigate the risk of DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms), seen in the early clinical development of cenobamate. The study demonstrated that adjunctive treatment with cenobamate was generally safe and well tolerated with long-term use, with 83% of patients taking cenobamate  $\geq$  6 months. No cases of DRESS were identified using this titration schedule.

In the study, 1,339 patients taking 1-3 other ASMs started cenobamate at 12.5 mg/day. Doses were increased every two weeks to 25, 50, 100, 150 and 200 mg/day, with additional increases up to 400 mg/day (50 mg increases every two weeks) as needed.

The most common treatment-emergent adverse events (TEAEs) reported were somnolence (28%), dizziness (24%), and fatigue (17%). TEAEs resulting in discontinuation occurred in 147 patients (11%). Serious TEAEs occurred in 108 patients (8%), with the most common event being seizure (n=19). No new safety issues were identified.

“These results support a low starting dose and increased titration every two weeks as the recommended way to start treatment with cenobamate, as it may reduce the risk of DRESS in adults with uncontrolled focal seizures,” said Marc Kamin, MD, Chief Medical Officer, SK life science. “The ongoing Phase 3 study as well as the open-label extensions of the randomized studies will provide additional data on the long-term safety profile of adjunctive cenobamate.”

### **About Study 021**

Study 021 is a large, multi-center, open-label Phase 3 study assessing the safety of cenobamate as adjunctive therapy in adults (18-70 years old) with uncontrolled focal seizures, taking 1-3 ASMs. The objectives of the study included the characterization of the long-term safety of cenobamate and to understand how to best add cenobamate to regimens that included phenytoin or phenobarbital. In addition, the study was designed to determine the rate of DRESS in at least 1,000 patients taking cenobamate for at least 6 months, using a low starting dose and every other week titration. Cenobamate was initiated at 12.5 mg/day and increased at 2-week intervals to 25, 50, 100, 150 and 200 mg/day. Further increases to 400 mg/day using bi-weekly 50 mg/day increments were allowed.

### **About Cenobamate**

Cenobamate is an FDA-approved anti-seizure medication (ASM) for the treatment of partial-onset seizures in adults, which is now available in the U.S. under the brand name XCOPRI® (cenobamate

tablets) CV. It was discovered and developed by SK Biopharmaceuticals and SK life science. In early 2019, SK Biopharmaceuticals entered into an exclusive licensing agreement with Arvelle Therapeutics GmbH to develop and commercialize cenobamate in Europe.

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 should be initiated at 12.5 mg once-daily and titrated 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 can be combined with other ASMs or used alone.

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

SK Biopharmaceuticals and its U.S. subsidiary SK life science are global pharmaceutical companies focused on the research, development and commercialization of treatments for disorders of the central nervous system (CNS). The companies have a pipeline of eight compounds in development for the treatment of CNS disorders, including epilepsy. Additionally, SK Biopharmaceuticals is focused on early research 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 Holdings, 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 Holdings 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/>.

*XCOPRI® is a registered trademark of SK Biopharmaceuticals Co., Ltd.*

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1. Sperling M, et al. Cenobamate (YKP3089) as adjunctive treatment for uncontrolled focal seizures in a large, phase 3, multicenter, open-label safety study. *Epilepsia*. 2020; 00:1–10. DOI: 10.1111/epi.16525. Accessed May 2020.