



**FOR IMMEDIATE RELEASE**

**SK life science Presents Latest Cenobamate Data  
at the American Epilepsy Society AES2020 Virtual Event**

*Presentations to feature new post-hoc analyses of safety, efficacy and pharmacokinetic clinical trial data from adult patients taking cenobamate for uncontrolled partial-onset (focal) seizures*

*SK life science continues to support continuing education and special programming for advanced practice providers at AES2020*

**Paramus, New Jersey, December 1, 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, will present the latest data on its anti-seizure medication (ASM) cenobamate at the American Epilepsy Society AES2020 Virtual Event, which will be held December 4-8, 2020.

During the event, the company will present seven virtual posters highlighting new post-hoc efficacy and safety analyses from an ongoing large, multi-center, open-label Phase 3 study of cenobamate. The analyses include time to onset of seizure reduction during titration, long-term efficacy and contributing factors, and impact of dose adjustments of concomitant ASMs on the safety and efficacy of cenobamate in adult patients with partial-onset (focal) seizures. Additionally, the company will present a post-hoc analysis of trough cenobamate plasma concentrations in patients from two randomized placebo-controlled trials with uncontrolled focal seizures who achieved 50% and 100% seizure reduction.

“We remain committed to further characterize the clinical efficacy and safety of cenobamate in adult patients with partial-onset seizures,” said Marc Kamin, MD, chief medical officer at SK life science. “With cenobamate now available in the U.S. to treat partial-onset seizures in adult patients, we are pleased to present physicians and other healthcare providers with more information about cenobamate as they consider treatment options for their patients.”

Cenobamate Presentations at AES2020

*\*Note, all presentations are available to AES2020 registrants [here](#)*

<b>Abstract #340</b>	Sunday, December 6 12:00 – 1:30 pm ET	Efficacy of Cenobamate for Uncontrolled Focal Seizures: Post-hoc Analysis of a Phase 3, Multicenter, Open-Label Study
<b>Abstract #336</b>	Sunday, December 6 12:00 – 1:30 pm ET	Dose Adjustments to Concomitant Antiseizure Medications: Post-hoc Analysis of a Phase 3, Open-Label Study of Cenobamate for the Treatment of Uncontrolled Focal Seizures
<b>Abstract #338</b>	Sunday, December 6 12:00 – 1:30 pm ET	Seizure Reduction With Adjunctive Cenobamate During Titration in the Phase 3 C021 Study
<b>Abstract #335</b>	Sunday, December 6 12:00 – 1:30 pm ET	Efficacy of Cenobamate by Concomitant Antiseizure Medications in Patients With Uncontrolled Focal Seizures: Post-hoc Analysis of a Phase 3, Multicenter, Open-Label Study



<b>Abstract #339</b>	Sunday, December 6 12:00 – 1:30 pm ET	Post-hoc Analysis of the Effects of Dose Reductions of Concomitant Clobazam in a Phase 3, Open-Label Study of Cenobamate for the Treatment of Uncontrolled Focal Seizures
<b>Abstract #333</b>	Sunday, December 6 12:00 – 1:30 pm ET	Adjunctive Cenobamate Dose in Seizure-Free Patients by Baseline Seizures in the Phase 3 C021 Study
<b>Abstract #334</b>	Sunday, December 6 12:00 – 1:30 pm ET	Post-hoc Analysis of a Phase 3, Open-Label Study of Cenobamate for Treatment of Uncontrolled Focal Seizures: Effects of Dose Reductions to Concomitant Lamotrigine and Carbamazepine
<b>Late-Breaker Abstract #634</b>	Sunday, December 6 5:15 – 6:45 pm ET	Cenobamate Trough Plasma Concentrations in Patients with Uncontrolled Focal Seizures Achieving 50% and 100% Seizure Reduction in Two Randomized Clinical Studies

#### Cenobamate Scientific Exhibit at AES2020

<b>Special Scientific Exhibit and Posters</b>	Monday, December 7 2:00 – 5:00 pm ET	Will feature poster presentations on cenobamate, including information on: <ul style="list-style-type: none"> <li>• Mechanism of action</li> <li>• Clinical pharmacology</li> <li>• Clinical efficacy and safety</li> </ul>
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#### *Continued Support of AES Advanced Practice Providers Program*

SK life science is continuing to aid in the professional development and education of advanced practice providers (APP) through its ongoing support of the AES APP Program. At this year’s virtual event, AES will launch its first-ever symposium for APPs, focusing on epilepsy diagnostics and results interpretation. Additionally, the AES APP special interest group, supported by SK life science, will facilitate a session focused on neurology APP residency and fellowship programs, in addition to year-round programming offered to APPs. AES will further foster collaboration at the meeting through a virtual APP reception, informal networking opportunities for APPs, and features of interest to APPs in the AES Live Studio and Short Topics sessions.

“We are excited to expand the educational and networking offerings for APPs during this year’s meeting, made possible in part through SK life science’s commitment to the APP program since 2018,” said Eileen M. Murray, Executive Director of the American Epilepsy Society. “SK life science’s contribution has made a considerable difference in the level of programming AES is able to provide for our APP members. APPs are instrumental to the care of people with epilepsy, and their vital role continues to grow.”

#### **About Cenobamate**

Cenobamate was 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 as an anti-seizure medication (ASM) for the treatment of



partial-onset seizures in adults, and is available under the brand name XCOPRI® (cenobamate tablets) CV. SK Biopharmaceuticals has an exclusive licensing agreement with Arvelle Therapeutics GmbH to develop and commercialize cenobamate in Europe and an exclusive licensing agreement with Ono Pharmaceutical to develop and commercialize cenobamate in Japan.

## **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 and affects people of all ages. 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>i</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>i</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>ii,iii</sup> Despite the availability of many antiepileptic therapies, almost 40% of people with epilepsy are not able to achieve seizure freedom, meaning they have epilepsy that remains uncontrolled.<sup>iv</sup>

### **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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<sup>i</sup> Epilepsy Foundation. What Is Epilepsy? <https://www.epilepsy.com/learn/about-epilepsy-basics/what-epilepsy>. Accessed November 12, 2020.

<sup>ii</sup> Epilepsy Foundation. Staying Safe. <https://www.epilepsy.com/learn/seizure-first-aid-and-safety/staying-safe>. Accessed November 12, 2020.

<sup>iii</sup> Epilepsy Foundation. Challenges with Epilepsy. <https://www.epilepsy.com/learn/challenges-epilepsy>. Accessed November 12, 2020.

<sup>iv</sup> Chen Z, Brodie MJ, Liew D, Kwan P. Treatment outcomes in patients with newly diagnosed epilepsy treated with established and new antiepileptic drugs: a 30-year longitudinal cohort study. <https://www.ncbi.nlm.nih.gov/pubmed/29279892>. Published online December 26, 2017.