

Newly Published Epilepsia Supplement Highlights Potential of Third Generation Antiseizure Medications to Help More Patients Achieve Seizure Freedom

Paramus, NJ, March 20, 2025 – <u>SK Life Science, Inc.</u>, a U.S. pharmaceutical company developing treatments for central nervous system (CNS) disorders and a subsidiary of SK Biopharmaceuticals Co., Ltd., today announced the publication of a sponsored supplement to *Epilepsia*, the leading journal in the field, focused on improving outcomes for people with epilepsy. The articles, authored by several world-renowned epilepsy experts, provide an in-depth overview of the latest in epilepsy treatment, including XCOPRI® (cenobamate tablets) CV and data for these treatments on sustained seizure control, mortality and sudden unexpected death in epilepsy (SUDEP) risk, and the impact XCOPRI has had with patients worldwide.

"Today, with the approval of newer medicines that have demonstrated impressive efficacy and safety, long-term seizure freedom is more possible than ever for people with drug-resistant epilepsy. Yet, these medicines are underutilized or not introduced when they could have the greatest impact," said Patrick Kwan, PhD, FRACP, Professor of Neurology at Monash University in Melbourne, Australia, who co-edited the *Epilepsia* supplement. "With some newer agents not yet included in professional treatment guidelines, this collection of articles provides clinicians with a comprehensive review of relevant data and practical strategies to proactively incorporate and manage innovative antiseizure medications earlier in treatment."

Key data and insights for XCOPRI include:

Sustained efficacy and tolerability in a range of vulnerable patients: Long-term open label
extension data of adjunctive XCOPRI for ≥4 years in adults show up to 16.4% of patients achieved
seizure freedom. Additionally, a post-hoc analysis of people with drug-resistant epilepsy treated
with more than two antiseizure medications (ASMs) at baseline showed approximately 1 in 5
patients experienced seizure freedom during the maintenance phase in the 400 mg/day dose
group.

Further, a post-hoc efficacy analysis of older adults with focal epilepsy from a Phase 3 safety trial showed 78.6% achieving seizure freedom with XCOPRI at months 21-24, and while rates of dizziness and falls occurred more commonly in older patients compared to the overall population, they were lower than observed in subgroup analyses of other ASMs.

 To reduce the risk of SUDEP in people with focal epilepsy, aggressive treatment strategies are needed to prevent high risk focal to bilateral tonic-clonic seizures (FBTCS): In a post-hoc analysis from a Phase 3 XCOPRI safety study, a 100% reduction in FBTC seizures was achieved by 35% of those patients who entered maintenance dosing with FBTC seizures. Moreover, a recent analysis of more than 2,100 patients in nine completed or ongoing Phase 2 or 3 trials showed that the standardized mortality ratio (SMR) for XCOPRI patients was statistically indistinguishable from the SMR for the general population and from seizure-free patients.

- Flexible dosing, understanding potential drug-drug interactions and concomitant medication
 management can enhance tolerability: One-year retention rates with adjunctive XCOPRI in
 open-label clinical studies range from 73%-83%, with few discontinuing treatment due to
 tolerability. The benefit of titration allows for specific, individualized dosing and modifications to
 concomitant medications.
- Addressing common treatment barriers to adopting cenobamate and other new antiseizure
 medications: Prematurely discontinuing new ASMs like XCOPRI may lead to an inadequate
 assessment of efficacy. Employing strategies like reducing the number and doses of concomitant
 ASMs first should be considered to properly assess new treatment effectiveness and avoid
 improper labeling of drug-resistance.

"XCOPRI provides an alternative approach to the challenging and often complex treatment of partialonset seizures, offering some patients the possibility of sustained seizure control—or even seizure freedom," said Louis Ferrari, BS, RPh, MBA, vice president, Medical Affairs at SK Life Science. "As of September 2024, more than 175,000, patients globally have been treated with XCOPRI, and there is a growing body of evidence supporting the profound impact it can have for others who continue to struggle with ongoing seizures."

The *Epilepsia* supplement is co-edited by Professor Martin Brodie, MD. Lead authors of the articles in the supplement are Pavel Klein, MD; Gregory L. Krauss, MD; William E. Rosenfeld, MD; and Michael R. Sperling, MD. To read the supplement please visit https://onlinelibrary.wiley.com/toc/15281167/2025/66/S1.

Media Contact:

Dina Albanese media@sklsi.com

###

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

SK Life Science, Inc., with headquarters in Paramus, New Jersey, is a U.S. subsidiary of **SK Biopharmaceuticals Co., Ltd.**, a pioneering South Korean company in drug development and commercialization. Together, they are advancing innovative treatments for central nervous system (CNS) disorders and oncology, with eight compounds currently in development. Utilizing target-based drug

discovery, high-throughput organic screening/high content screening, computer-aided drug design, and combinatorial chemistry, the companies drive R&D efforts in biology/discovery, medicinal chemistry, pharmacology, and clinical development. For more information, visit www.SKLifeScienceInc.com.

SK Biopharmaceuticals Co., Ltd. is part of SK Group, South Korea's second-largest conglomerate. SK Group is a collection of global industry-leading companies driving innovations in energy, advanced materials, biopharmaceuticals and digital business. Based in Seoul, SK invests in building sustainable businesses around the world with a shared commitment to reducing global greenhouse gas emissions. SK companies combined have \$151 billion in global annual revenue and employ more than 100,000 people worldwide. SK Group is one of TIME's 100 Most Influential Companies of 2023. 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 about SK Inc., visit https://sk-inc.com/en/main/mainpage.aspx.. For more information about SK Biopharmaceuticals, visit https://sk-inc.com/en/main/mainpage.aspx.. For more information about SK Biopharmaceuticals, visit

About XCOPRI® (cenobamate tablets) CV

Cenobamate is an antiseizure medication (ASM) discovered and developed by SK Biopharmaceuticals and SK Life Science. Cenobamate reduces neuronal excitability through a unique dual mechanism of action, preferentially inhibiting the persistent sodium current and enhancing GABAergic inhibition at the type A γ -aminobutyric acid (GABA_A) ion channel. The precise mechanism by which cenobamate exerts its therapeutic effect is unknown.

Cenobamate is marketed under the brand name XCOPRI® in the U.S. by SK Life Science, Inc. Additionally, XCOPRI is commercialized in Canada and Israel by SK Biopharmaceuticals' partners, Paladin Labs Inc. and Dexcel Ltd. Cenobamate is marketed as ONTOZRY® by Angelini Pharma S.p.A. in Europe, the UK, and Switzerland.

Cenobamate is also being developed for commercialization by SK Biopharmaceuticals' partners in many other countries to meet the needs of patients living with epilepsy, including Dong-A ST Co., Ltd., Eurofarma Laboratórios S.A., Hikma MENA FZE, Ignis Therapeutics, Inc. and ONO Pharmaceutical Co., Ltd.

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.

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.

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 <u>Medication Guide</u>. 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.^{1,2} 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.^{3,4} People with epilepsy are at risk for accidents and other health complications, including falling, drowning, depression and sudden unexplained death in epilepsy (SUDEP).^{3,4} 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.⁵

XCOPRI® and ONTOZRY® are registered trademarks of SK Biopharmaceuticals Co., Ltd.

References

- 1. Epilepsy Foundation. Who Can Get Epilepsy? https://www.epilepsy.com/learn/about-epilepsy-basics/who-gets-epilepsy. Accessed April 2024.
- 2. Epilepsy Foundation. Facts & Statistics About Epilepsy. https://www.epilepsy.com/learn/about-epilepsy-basics/epilepsy-statistics. Accessed April 2024.
- 3. Epilepsy Foundation. Staying Safe. https://www.epilepsy.com/learn/seizure-first-aid-and-safety/staying-safe. Accessed April 2024.
- 4. Epilepsy Foundation. Complications and Risks. https://www.epilepsy.com/learn/challenges-epilepsy. Accessed April 2024.
- 5. 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.