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SK life science Presents Long-Term Data of XCOPRI® (cenobamate tablets) CV in Adults with Partial-Onset Seizures at the American Epilepsy Society 2021 Annual Meeting

Post-hoc analyses of a subset of patients with uncontrolled partial-onset seizures in Study C021 demonstrate long-term efficacy in patients regardless of focal seizure subtype and prior treatment history^{1,2}

Paramus, New Jersey, December 3, 2021 – [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 new post-hoc, retrospective analyses of the long-term safety and efficacy of its anti-seizure medication (ASM) XCOPRI® (cenobamate tablets) CV at the American Epilepsy Society (AES) Annual Meeting, held December 3-7, 2021 in Chicago, Illinois and virtually through AES 2021 Digital Select. The analyses examined data collected from a subset of 240 patients with partial-onset seizures who participated in the long-term, open-label multicenter phase 3 safety study (C021). As of the last clinic visit analyzed on or after September 1, 2019, 74% (n=177) of patients remained on XCOPRI with results showing early onset responder rates and high rates of sustained seizure reductions across a variety of seizure types for as long as 43 months (median 30.2 months).^{1,2}

In an analysis of patients by focal seizure subtype including focal aware motor (FAM), focal impaired awareness (FIA), and focal to bilateral tonic-clonic (FBTC), seizure reductions of at least 50% occurred in 56% (15/27) of FAM patients, 51% (114/223) of FIA patients, and 70% of FBTC patients during the initial 12-week titration phase.¹ Seizure reductions of 100% were observed during titration in 22% (6/27), 22% (48/223), and 50% (28/56) of the FAM, FIA, and FBTC seizure subtype groups, respectively. During months 24-27, complete seizure reduction occurred in 48% (11/23) of patients with FAM seizures, 54% (88/162) of patients with FIA seizures, and 91% (38/42) of patients with FBTC seizures.¹ Additionally, in an analysis of patients (n=85) who had previously received epilepsy-related surgery and continued to experience frequent seizures (average 26 seizures per month), 31% (26/85) maintained seizure freedom for at least 12 consecutive months during exposure to cenobamate (median exposure ~2.5 years).²

“I am encouraged to see that patients across a variety of focal seizure subtypes are having a response to treatment with XCOPRI for an extended period of time,” said William E. Rosenfeld, MD, epileptologist/neurologist principal investigator at the Comprehensive Epilepsy Care Center for Children and Adults in St. Louis, Missouri. “Based on these findings, XCOPRI may be an option for patients both early in their treatment regimen as well as later on, if prior treatments – including surgery – have been unsuccessful.”

Safety data in this patient subset is consistent with the safety data in the larger cohort from the C021 study⁴, with the most commonly observed treatment-emergent adverse events being fatigue, dizziness, and somnolence.^{1,2}

SK life science is presenting six posters at AES, which are available [here](#). To see the SK life science virtual booth at AES, please visit StepIntoXcopri.com.

About Study C021

Study C021 was a large, multi-center, open-label Phase 3 study assessing the safety of cenobamate as adjunctive therapy in 1,340 adults (18-70 years old) with uncontrolled focal seizures taking 1-3 anti-seizure medications (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; no cases of DRESS occurred in the study. 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 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 γ -aminobutyric acid (GABA_A) 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.

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 [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.^{4,5} 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.^{6,7} People with epilepsy are at risk for accidents and other health complications, including falling, drowning, depression and sudden unexplained death in epilepsy (SUDEP).^{6,7} 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.⁸

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 the discovery of new treatments in oncology. For more information, visit SK Biopharmaceuticals' website at www.skbp.com/eng and SK life science's website at 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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References

1. Poster 1.296: Efficacy of Cenobamate by Focal Seizure Subtypes: Post-Hoc Analyses of a Phase 3 Multicenter, Open-Label Study – Rosenfeld et al.
2. Poster 2.206: Efficacy of Cenobamate for Uncontrolled Focal Seizures in Patients With Previous Epilepsy-Related Surgery: Post-hoc Analysis of a Phase 3, Multicenter, Open-Label Study – Abou-Khalil et al.
3. Sperling MR, et al. *Epilepsia*. 2020;61(6):1099-108.
<https://onlinelibrary.wiley.com/doi/full/10.1111/epi.16525>
4. Epilepsy Foundation. Who Gets Epilepsy? <https://www.epilepsy.com/learn/about-epilepsy-basics/who-gets-epilepsy>. Accessed November 2021.
5. Epilepsy Foundation. Epilepsy Statistics. <https://www.epilepsy.com/learn/about-epilepsy-basics/epilepsy-statistics>. Accessed November 2021.
6. Epilepsy Foundation. Staying Safe. <https://www.epilepsy.com/learn/seizure-first-aid-and-safety/staying-safe>. Accessed November 2021.

7. Epilepsy Foundation. Challenges with Epilepsy. <https://www.epilepsy.com/learn/challenges-epilepsy>. Accessed November 2021.
8. 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.