FOR IMMEDIATE RELEASE

Epilepsia Publishes Two Post-hoc Analyses from Long-Term Study of XCOPRI® (cenobamate tablets) CV

100% seizure reduction for ≥12 consecutive months occurred at some time during the study in 36% of the 240 patients[1]

Seizure reduction began as early as the first four weeks with XCOPRI treatment[1]

Concomitant ASM reductions contributed to higher retention of XCOPRI and lowered overall drug burden[2]

Paramus, New Jersey, October 12, 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, announced that the results from two post-hoc analyses of the long-term, open-label, multicenter, Phase 3 safety study, C021, have been published online by the journal *Epilepsia* (here and here). The two post-hoc analyses, which retrospectively collected data from a subset of 240 patients with focal seizures across 10 sites in the U.S., showed long-term efficacy and safety of XCOPRI, as well as the impact of adjustments to other baseline anti-seizure medications (ASMs).

"The results of these two new post-hoc analyses provide evidence of the durable efficacy of XCOPRI, as many patients sustained 90% and 100% reductions of their seizures over the course of the entire maintenance period, lasting up to 40.2 months," said William E. Rosenfeld, MD, epileptologist/neurologist who performed the studies and was the principal investigator at the Comprehensive Epilepsy Care Center for Children and Adults in St. Louis, Missouri. “I am encouraged to see the high retention rates associated with XCOPRI. Many patients continued on XCOPRI and remained seizure free, while also reducing or discontinuing one or more concomitant ASMs. These analyses may provide clinicians with real-world insight on managing their patients’ seizures, minimizing drug burden, while potentially reducing the side effects of concomitant ASMs associated with epilepsy treatment.”

Treatment with XCOPRI resulted in long-term seizure reduction with treatment response as early as four weeks[1]

Among the 240 patients who entered the titration period, responder rates of ≥50% were observed in 48% of patients during weeks one through four. Following the titration period, 214 patients entered the maintenance phase. Of these patients treated with XCOPRI, 13% (n=28/214) had no seizures and 40% (n=86/214) had a 90% or greater seizure frequency reduction during the entire maintenance phase lasting up to 40.2 months (median 29.5 months). Additionally, 74% (n=177/240) of patients remained on the drug throughout the entire analysis period (median 2.7 years) and 36% (n=87/240) of patients had 100% seizure reduction for ≥12 consecutive months at some time during the study.

Concomitant ASM reductions contributed to higher retention of XCOPRI (cenobamate tablets) CV[2]
In an analysis studying the effect of adjusting concomitant ASMs with adjunctive XCOPRI, long-term responder rates were generally similar regardless of concomitant ASM usage, with approximately 75% of patients being ≥50% responders during the maintenance phase. Of patients who continued on XCOPRI, 25% were able to discontinue at least one concomitant ASM completely. Among those who were able to reduce concomitant ASM doses, overall drug burden was reduced, allowing for increased tolerability and retention. There were greater reductions in ASM dosages among those who remained on XCOPRI, compared to those who discontinued.

In these post-hoc analyses, no new safety signals were identified, and the most common adverse events in ongoing XCOPRI patients were fatigue, dizziness, and somnolence.

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 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 γ-aminobutyric acid ($GABA_A$) 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. Cenobamate can be combined with other ASMs or used alone.

Cenobamate is approved in the European Union (EU) under the brand name ONTOZRY® for the adjunctive treatment of focal-onset (partial-onset) seizures with or without secondary generalization in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products. SK Biopharmaceuticals entered an exclusive licensing agreement with Arvelle Therapeutics to develop and commercialize cenobamate in Europe in early 2019. Angelini Pharma, which announced a definitive acquisition agreement to acquire Arvelle Therapeutics, is commercializing cenobamate in the EU and other countries in the European Economic Area (Switzerland and the United Kingdom).

SK Biopharmaceuticals also has 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.

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 news cases each year in the country.[3,4] 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.[5,6] People with epilepsy are at risk for accidents and other health complications, including falling, drowning, depression and sudden unexplained death in epilepsy (SUDEP).[5,6] 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.[7]

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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