FOR IMMEDIATE RELEASE

Latest XCOPRI® (cenobamate tablets) CV Post-hoc Analysis Presented at the 75th American Academy of Neurology Annual Meeting

- *SK Life Science will present analysis of 2,131 patients taking cenobamate during Phase 2 and 3 trials showing sudden unexpected death in epilepsy (SUDEP) rate of 0.88 per 1,000 person years is similar to community-based analyses of 0.35 to 2.3 per 1,000 person-years*[1]

- *Data also includes new post-hoc analysis from open-label Phase 3 study showing treatment with cenobamate led to a reduction in the number of concomitant anti-seizure medications (ASMs) while maintaining ≥50% and 100% seizure reduction response rates*[2]

- *SK Life Science will also host a symposium titled "*An Update on Pharmacological Treatments for Refractory Epilepsy and Its Prevention," *on Saturday, April 22 at 6:00 pm ET*

Paramus, New Jersey, April 17, 2023 – 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 ten abstracts at the American Academy of Neurology (AAN) 75th Annual Meeting, to be held in Boston, MA, April 22–27, 2023. The data includes post-hoc analyses on the rate of SUDEP and drug load in adults with partial-onset (focal) seizures taking XCOPRI® (cenobamate tablets) CV.

"We look forward to presenting a variety of additional analyses from our trials which continue to show encouraging data on the use of XCOPRI in adults with partial-onset (focal) seizures," said Louis Ferrari, RPh, MBA, Vice President of Medical Affairs at SK Life Science. "Epilepsy is a priority at SK Life Science, so we look forward to presenting our new post-hoc analyses as well as hosting an informative symposium for those attending this year's AAN meeting."

For people with epilepsy, the all-cause mortality rate is typically higher than the general population, with one factor being SUDEP. A pooled analysis of data from four ASM development programs involving 9,144 adults and children with 13,617 person-years showed the rates of all-cause mortality and SUDEP to be 9.1 and 3.8, respectively, per 1,000 person-years. For those with drug resistant epilepsy, the SUDEP rate increases to as high as 9.3 deaths per 1,000 person years. When analyzing the deaths amongst patients taking XCOPRI (cenobamate tablets) CV (2,131 patients totaling 5,693 person-years) in the Phase 2 and 3 clinical studies, it was found that the all-cause mortality rate was 4 per 1,000 person years and the rate of SUDEP was 0.88 per 1,000 person-years. The rate of SUDEP is similar to reported rates of 0.35 to 2.3 per 1,000 person-years in community-based analyses of patients with epilepsy.

"When treating patients with epilepsy, the number of ASMs they are taking, or their drug load, is an

important factor to be mindful of as increased drug load may lead to increased adverse events," said William E. Rosenfeld, MD, FAAN, FAES, epileptologist/neurologist, principal investigator at the Comprehensive Epilepsy Care Center for Children and Adults in St. Louis, Missouri, and SK Life Science consultant. "At AAN, we will be presenting data from the open-label Phase 3 study which showed that some patients taking XCOPRI (cenobamate tablets) CV were able to reduce their drug load while maintaining similar rates of seizure reduction."

When analyzing data from 240 patients taking cenobamate, as treatment began, patients had an average drug load of 3.57 anti-seizure medications (ASMs). After taking cenobamate, all patient subsets experienced a reduction in their average drug load with a mean change of 29% (mean drug load = 2.52) and 32% (mean drug load = 2.43) after 12 and 24 months of treatment, respectively. In patients who had prior epilepsy-related surgery and had ≥3 seizures at baseline (n=50), patients were able to reduce their drug load by 35% and 37% after 12 and 24 months of treatment with cenobamate, respectively.

When reducing concomitant ASMs, patients taking cenobamate still experienced similar maintenance of ≥50% and 100% seizure reduction. Maintenance of seizure reduction response was measured by determining if the previous visit's 3-month seizure reduction response was the same or better than the current 3-month visit; this was then used to compare patients who had a (low, medium or high) concomitant ASM drug load reduction versus no change in drug load reduction.

An oral presentation titled "Predictors of Achievement of Response With Cenobamate: Post-hoc Subset Analysis From a Phase 3, Open-Label Safety Study" will take place on Thursday, April 27 at 2:00 PM EST. The post-hoc analysis being presented at AAN evaluated whether clinical characteristics could predict a meaningful response to cenobamate in a subset of patients from a phase 3, multicenter, open-label, safety study. Data from 214 patients (mean age 41.9 years; median duration of maintenance treatment 29.5 months) were analyzed. Of these patients, 188 (87.9%) and 145 (67.8%) achieved ≥50% and 100% seizure reduction, respectively, over any 3-month interval. Lower baseline concomitant drug load was associated with a higher likelihood of achieving ≥50% and 100% seizure reduction. Lower baseline seizure frequency (<3 seizures/28 days) was associated with a higher likelihood of achieving 100% seizure reduction.

SK Life Science will be hosting a symposium event, "An Update on Pharmacological Treatments for Refractory Epilepsy and Its Prevention," on Saturday, April 22 at 6:00 pm ET at the Westin Boston Seaport District in Grand Ballroom B.

All abstracts being presented at AAN, including the ten being presented by SK Life Science, can be found here and also at booth #2091.

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. SK Biopharmaceuticals has recently entered into an exclusive licensing agreement with Endo for cenobamate in Canada.

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.[6]

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

SK Biopharmaceuticals and its U.S. subsidiary SK Life Science are pharmaceutical companies focused on the research, development and commercialization of treatments for disorders of the central nervous system (CNS) and oncology. In 2017, SK Biopharmaceuticals established a research center to begin their expansion into oncology through research and development efforts. The companies have a pipeline of eight compounds in development in both CNS disorders and oncology. 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 https://sk-inc.com/en/main/mainpage.aspx.

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