FOR IMMEDIATE RELEASE

FDA Approves XCOPRI® (cenobamate tablets), an Anti-Epileptic Drug (AED) from SK Biopharmaceuticals, Co., Ltd., and U.S. Subsidiary SK Life Science, Inc.

XCOPRI is approved for the treatment of partial-onset seizures in adult patients

In two adequate and well-controlled studies, XCOPRI significantly reduced partial-onset seizure frequency and up to 20% of patients achieved zero seizures during the maintenance phase

XCOPRI is expected to be available in the U.S. in the second quarter of 2020, following scheduling review by the U.S. Drug Enforcement Administration (DEA)

Pangyo, Gyeonggi Province, Korea and Paramus, New Jersey, USA, November 21, 2019 – SK Biopharmaceuticals, Co., Ltd., an innovative global pharmaceutical company focused on developing and bringing treatments to market for central nervous system (CNS) disorders, and its U.S. subsidiary SK Life Science, Inc. announced today that the U.S. Food and Drug Administration (FDA) approved XCOPRI® (cenobamate tablets) as a treatment for partial-onset seizures in adults.

"The approval of XCOPRI will provide clinicians with an effective medication for our patients who are continuing to have focal (partial-onset) seizures," said Michael Sperling, MD, Professor of Neurology and Director of the Jefferson Comprehensive Epilepsy Center at the Vickie and Jack Farber Institute for Neuroscience – Jefferson Health in Philadelphia, and an investigator in the XCOPRI clinical development program. "It is very encouraging to see that patients receiving XCOPRI saw significant reductions in frequency of seizures, with some even achieving zero seizures."

The approval is based on results from two global, randomized, double-blind, placebo-controlled studies and a large, global, multi-center, open-label safety study that enrolled adults with uncontrolled partial-onset seizures, taking one to three concomitant anti-epileptic drug (AEDs). In the randomized studies (Study 013 and Study 017), XCOPRI demonstrated significant reductions in seizure frequency compared to placebo at all doses studied.

"Approximately 3 million adults live with epilepsy in the U.S. and according to the Centers for Disease Control and Prevention (CDC), nearly 60% reported having seizures, even if they took an AED," said Beth Lewin Dean, Chief Executive Officer of Citizens United for Research in Epilepsy (CURE). "There is an urgent need to advance research and introduce new treatment options. The FDA approval of XCOPRI for the treatment of partial-onset seizures is a welcome option for the epilepsy community."

The approval also marks the first time a Korean company has independently brought a compound from discovery to U.S. FDA approval.

"Today's approval is a major step toward our goal of becoming a fully-integrated global pharmaceutical company that can discover, develop and deliver new treatment options in epilepsy and CNS," said Jeong

Woo Cho, PhD, President and CEO of SK Biopharmaceuticals and SK life science. “We are grateful to the thousands of participants in our trials, clinical investigators, partners in the epilepsy community and our employees for their important contributions in bringing forward this treatment option for adults with partial-onset seizures.”

In Study 013, which included a 6-week titration phase followed by a 6-week maintenance phase, a statistically significant 56% reduction in median seizure frequency was seen with XCOPRI 200 mg/day (n=113) versus a 22% reduction with placebo (n=108). In Study 017, which included a 6-week titration phase followed by a 12-week maintenance phase, patients randomized to XCOPRI 100 mg/day (n=108), 200 mg/day (n=109) or 400 mg/day (n=111) had statistically significant 36%, 55% and 55% reductions in median seizure frequency, respectively, versus a 24% reduction with placebo (n=106). During the maintenance phase of Study 013, a post-hoc analysis showed that 28% of patients receiving XCOPRI had zero seizures, compared with 9% of placebo patients. During the maintenance phase of Study 017, 4% of patients in the XCOPRI 100 mg/day group, 11% of patients in the XCOPRI 200 mg/day group, 21% of patients in the XCOPRI 400 mg/day group and 1% of patients in the placebo group reported zero seizures.

Serious reactions associated with XCOPRI include drug reaction with eosinophilia and systemic symptoms (DRESS), QT shortening, suicidal behavior and ideation, and neurological adverse reactions. The most common (≥10% and greater than with placebo) treatment-emergent adverse events associated with XCOPRI include somnolence (sleepiness), dizziness, fatigue, diplopia (double vision) and headache.

XCOPRI is expected to be available in the U.S. in the second quarter of 2020, following scheduling review by the DEA, which typically occurs within 90 days of FDA approval. SK life science is committed to supporting patients taking XCOPRI and will introduce a new access program to help patients get started and stay on track with their medicine.

About XCOPRI® (cenobamate tablets)
XCOPRI was discovered and developed by SK Biopharmaceuticals and SK life science and is an FDA-approved anti-epileptic drug (AED) for the treatment of partial-onset seizures in adults. XCOPRI is expected to be available in the second quarter of 2020, pending scheduling review by the U.S. Drug Enforcement Administration (DEA). In early 2019, SK Biopharmaceuticals entered into an exclusive licensing agreement with Arvelle Therapeutics GmbH to develop and commercialize XCOPRI in Europe.

While the precise mechanism by which XCOPRI exerts its therapeutic effect is unknown, XCOPRI 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.

XCOPRI should be initiated at 12.5 mg once-daily and titrated every two weeks; it will be available in six tablet strengths for once-daily dosing: 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg. XCOPRI can be combined with other AEDs or used alone.

Long-term safety of XCOPRI has been evaluated in the ongoing open-label extensions of the randomized studies and the open-label safety study. Additional clinical trials are investigating XCOPRI in other seizure types.

IMPORTANT SAFETY INFORMATION AND INDICATION FOR XCOPRI® (cenobamate tablets) CX

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.

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 healthcare 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 healthcare provider about the best birth control method to use.**

Talk to your healthcare 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 http://www.aedpregnancyregistry.org/.

Talk to your healthcare 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 http://www.fda.gov/medwatch**.**

DRUG ABUSE:
Scheduling of XCOPRI is pending review by the U.S. Drug Enforcement Administration (DEA).

About Epilepsy
Epilepsy is a common neurological disorder characterized by seizures.[1] There are approximately 3 million adults in the U.S. living with epilepsy and approximately 60% have partial-onset seizures, which begin in just one part of the brain.[2,3] 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, approximately 40% of adults with partial-onset seizures have inadequate control of their seizures, even after treatment with two anti-epileptic drugs (AEDs).[5]

About SK Biopharmaceuticals, Co., Ltd. and SK Life Science, Inc.
SK Biopharmaceuticals and its U.S. subsidiary SK life science are focused on the research, development and commercialization of treatments for disorders of the central nervous system (CNS). Additionally, SK Biopharmaceuticals is focused on early research and development in oncology. Both are part of SK Group, one of the largest conglomerates in Korea.

SK Holdings 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/.

Currently, SK Biopharmaceuticals is conducting basic research for the development of innovative new therapies at its research center in Pangyo, Gyeonggi Province, Korea. SK life science, based in Paramus, New Jersey, is pursuing clinical development and the U.S. commercialization of XCOPRI.

The companies have a pipeline of eight compounds in development for the treatment of CNS disorders including epilepsy, Lennox-Gastaut syndrome and attention-deficit/hyperactivity disorder, among others. For more information, visit SK Biopharmaceuticals' website at www.skbp.com/eng and SK life science's website at www.SKLifeScienceInc.com.

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Media Contacts:

U.S. Media Inquiries
SK Life Science, Inc.
media@sklsi.com

Korea Media Inquiries
SK Biopharmaceuticals, Co., Ltd.
Gahye Kim
gahyekim@sk.com

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