



FOR IMMEDIATE RELEASE

SK life science Receives Schedule V Designation from DEA for XCOPRI® (cenobamate tablets)

XCOPRI is expected to be available in the U.S. in the second quarter of 2020

Paramus, New Jersey, March 10, 2020 – [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 today that the U.S. Drug Enforcement Administration (DEA) has designated XCOPRI® (cenobamate tablets) as a Schedule V medicine. XCOPRI was approved by the U.S. Food and Drug Administration (FDA) on November 21, 2019, for the treatment of partial-onset seizures in adults.

“With the DEA’s decision to designate XCOPRI as a Schedule V medicine, the final step of the regulatory approval process is complete,” said Jeong Woo Cho, PhD, President and CEO of SK Biopharmaceuticals and SK life science. “We are moving forward to launch XCOPRI as planned in the second quarter of 2020 and remain steadfast in our commitment to addressing unmet needs for patients with epilepsy.”

Epilepsy is one of the most common neurological disorders and has significant physical and psychosocial impacts on people who are living with this disease.¹ Partial-onset seizures, which begin in just one part of the brain, affect approximately 60% of people with epilepsy.¹ Of those with partial-onset seizures, 40% have inadequate control of their seizures even after treatment with two anti-epileptic drugs (AEDs) underscoring a need for new treatment options for these patients.²

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 U.S. in the second quarter of 2020. In early 2019, SK Biopharmaceuticals entered into an exclusive licensing agreement with Arvelle Therapeutics to develop and commercialize cenobamate 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.

Additional clinical trials are investigating XCOPRI in other seizure types.

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.

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.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 anti-epileptic therapies, approximately 40% of adults with partial-onset seizures have inadequate control of their seizures, even after treatment with two anti-epileptic drugs (AEDs).²

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, and additionally, SK Biopharmaceuticals is focused on early research 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 Holdings, 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 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/>.

XCOPRI® is a registered trademark of SK Biopharmaceuticals, Co., Ltd.

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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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1. Epilepsy Foundation. What Is Epilepsy? <https://www.epilepsy.com/learn/about-epilepsy-basics/what-epilepsy>. Accessed January 2020.
 2. 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
 3. National Institute of Neurological Disorders and Stroke. The Epilepsies and Seizures: Hope through Research. https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Epilepsies-and-Seizures-Hope-Through#3109_9. Accessed January 2020.
 4. Epilepsy Foundation. Staying Safe. <https://www.epilepsy.com/learn/seizure-first-aid-and-safety/staying-safe>. Accessed January 2020.