**FOR IMMEDIATE RELEASE**

# SK Biopharmaceuticals Enters into Licensing Agreement with Endo for Cenobamate in Canada

*SK Biopharmaceuticals expands its footprint in North America via a partnership in Canada by out-licensing cenobamate*

*SK Biopharmaceuticals to receive an upfront payment of USD 20 million with future milestones of CAD 21 million*

**Pangyo, Gyeonggi Province, Korea, Dec. 23, 2021 –** SK Biopharmaceuticals announced today that it has entered into a licensing agreement with Endo International plc (Endo)'s subsidiary Endo Ventures Limited for Endo to commercialize cenobamate in Canada.

Paladin Labs Inc., a Canada-based operating company of Endo, will be responsible for all commercial activities related to cenobamate in the region.

Under the agreement, SK Biopharmaceuticals will receive an upfront payment of USD 20 million and will be eligible to receive CAD 21 million based on the achievement of certain development and commercial milestones.

The Canada deal has enabled SK Biopharmaceuticals to further expand its footprint in North America, following its U.S. launch of cenobamate in 2020.

Jeong Woo Cho, PhD, President and CEO of SK Biopharmaceuticals, said: "We are very pleased to establish a relationship with Endo, and will closely collaborate to bring our innovative treatment and provide care to patients in Canada."

**About Cenobamate**

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 (GABAA) 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.

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

**About SK Biopharmaceuticals**

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 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.

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