## For Immediate Release

# SK Biopharmaceuticals, Eurofarma Enter into Licensing Agreement for Cenobamate in Latin America

*SK Biopharmaceuticals will now be present in four continents: North America, Europe, Asia, and Latin America*

**Pangyo, Gyeonggi Province, Korea, July 14, 2022 –** SK Biopharmaceuticals, Co., Ltd., today announced that it has entered into a licensing agreement for Eurofarma, a Brazilian pharmaceutical company with business in over 20 countries, to develop and commercialize cenobamate in Latin America for the treatment of epilepsy. Cenobamate is approved and available in the United States and Europe for the treatment of partial-onset seizures in adults.

Under the terms of the agreement, SK Biopharmaceuticals has granted Eurofarma the exclusive rights to develop and commercialize cenobamate in Latin America. In return, SK Biopharmaceuticals will receive an upfront payment of US$15 million and will be eligible to receive future milestones of up to US$47 million, in addition to royalties on sales generated in Latin America.

The agreement reinforces the company's commitment and capabilities in developing medicines for central nervous system disorders and providing treatment options for the epilepsy communities in this region and around the world. Cenobamate has been previously launched in the United States and Europe, and SK Biopharmaceuticals completed partnerships for cenobamate in Japan, China, Canada, and Israel. With this agreement, SK Biopharmaceuticals will now be present in four continents: North America, Europe, Asia and Latin America.

"We are extremely pleased to partner with Eurofarma, which has a proven track record in the region and a widespread network to drive development and commercialization of cenobamate in Latin America," said Jeong Woo Cho, PhD, President and CEO of SK Biopharmaceuticals. "This partnership reaffirms our commitment to provide innovative treatments to people with epilepsy. We will continue to broaden our footprint around the world to support the patient community with cenobamate."

Epilepsy is one of the most common neurological diseases, affecting over 6 million people in Latin America.[1] According to the Pan American Health Organization (PAHO), the regional office of the World Health Organization (WHO) for the Americas, over half of the people living with epilepsy in Latin America and the Caribbean do not receive appropriate treatment.[2] Collaborating with Eurofarma, a Brazilian pharmaceutical company that covers 100% of Latin America and has, for 2022, a projected investment in innovation of more than BRL500 million, SK Biopharmaceuticals aims to bring its innovative product widely to the region.

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[1] Kevin Pacheco-Barrios, et al. Burden of epilepsy in Latin America and The Caribbean: a trend analysis of the Global Burden of Disease Study 1990 – 2019. The Lancet Regional Health – Americas. available at: https://doi.org/10.1016/j.lana.2021.100140

[2] Pan American Health Organization | Word Health Organization. Available at: https://bit.ly/3nF31qV [Last accessed July 2022]

**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 ($GABA_A$) 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 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.

**About Eurofarma**

The Eurofarma Group has been operating in the healthcare industry since its establishment in 1972, producing and marketing innovative products and services to improve people's quality of life. Focused on generating shared value, it operates in the areas of Prescription, Non-Prescription, OTC and Generic Drugs, Hospital and Oncology. Offers more than 700 products, over 2,000 SKUs, and serves 42 medical specialties. Present in over 20 countries, with a manufacturing park in Brazil and plants in six other Latin American countries, it generated net sales of BRL 7.1 billion in 2021, growth of 23% over the previous year, and employs more than 8,100 people.

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