



FOR IMMEDIATE RELEASE

SK Biopharmaceuticals, Ono Pharmaceutical Enter Licensing Agreement for Cenobamate in Japan

SK Biopharmaceuticals and Ono Pharmaceutical collaborate to develop and commercialize cenobamate

SK Biopharmaceuticals to receive an upfront payment of JPY 5 billion from Ono, with future milestones of up to JPY 48.1 billion and royalties on net sales

Pangyo, Gyeonggi Province, Korea, October 13, 2020 – SK Biopharmaceuticals and Ono Pharmaceutical announced that they have entered into an exclusive licensing agreement for Ono to develop and commercialize cenobamate in Japan. Cenobamate is a treatment for partial-onset seizures (POS) that received FDA approval in 2019.

As per terms of the deal, SK Biopharmaceuticals will receive an upfront payment of JPY 5 billion (US \$47 million) from Ono. SK Biopharmaceuticals will also be eligible to receive up to JPY 48.1 billion based on the achievement of certain regulatory and commercial milestones, as well as double digit royalties on net sales generated in Japan.

SK Biopharmaceuticals will conduct a Phase 3 clinical study¹ for partial-onset seizures in adults in Northeast Asia (Japan, China, and Korea). In addition, SK Biopharmaceuticals has an option for co-promotion with Ono in the Japanese market.

“We are very pleased to form a strategic partnership with Ono that will mutually benefit both sides,” said Dr. Jeong Woo Cho, CEO of SK Biopharmaceuticals. “This agreement would give SK Biopharmaceuticals an unprecedented opportunity not only to expand our presence in one of Asia’s largest pharmaceuticals markets but also to further create social value by reaching out to patients with epilepsy in Japan.”

“We are very delighted to enter into this collaboration with SK Biopharmaceuticals on cenobamate discovered and developed by SK Biopharmaceuticals,” said Gyo Sagara, President, Representative Director of Ono. “We believe that cenobamate will be a new treatment option for patients suffering from epilepsy in Japan.”

About SK Biopharmaceuticals Co., Ltd.

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.

Both SK Biopharmaceuticals and SK life science are part of SK Group, one of the largest

¹ SK Biopharmaceuticals announced Sept. 10 that it will initiate a Phase 3 clinical trial in Korea, Japan and China.

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/>.

About Ono Pharmaceutical Co., Ltd.

Ono Pharmaceutical Co., Ltd., headquartered in Osaka, is an R&D-oriented pharmaceutical company committed to creating innovative medicines in specific areas. Ono focuses its research on the oncology, immunology, neurology and specialty research with high medical needs as priority areas for discovery and development of innovative medicines. For further information, please visit the company's website at www.ono.co.jp/eng.

About Cenobamate

Cenobamate was 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 as an anti-seizure medication (ASM) for the treatment of partial-onset seizures in adults, and is available under the brand name XCOPRI® (cenobamate tablets) CV. In early 2019, SK Biopharmaceuticals entered into an exclusive licensing agreement with Arvelle Therapeutics GmbH to develop and commercialize cenobamate in Europe.

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 trademark of SK Biopharmaceuticals Co., Ltd.

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