



SK Biopharmaceuticals Announces 100,000 Patients Globally Have Been Treated with Cenobamate Through Sales of XCOPRI® and ONTOZRY® in the U.S., Europe, Israel, and Canada

Milestone Coincides with SK Biopharmaceuticals' Global Plan Expanding Cenobamate Access to More Than 100 Markets Worldwide

GYEONGGI, KOREA, and ROME, ITALY 11 Mar., 2024 – SK Biopharmaceuticals Co., Ltd., a global biotech focused on developing treatments for central nervous system (CNS) disorders and oncology, and the first and only Korean company to independently develop and commercialize a new drug in the U.S., today announced more than 100,000 patients have been treated globally with cenobamate, an anti-seizure medication (ASM) developed by SK Biopharmaceuticals and its U.S. subsidiary SK Life Science, Inc.

Cenobamate was first launched in the U.S. by SK Life Science, Inc. in 2020 after the Food and Drug Administration (FDA) approved the treatment for adults with partial-onset seizures. In the U.S., cenobamate is marketed under the brand name XCOPRI® (cenobamate tablets) CV. From 2021, with the approvals granted by the European Commission (EC) first, and subsequently by Swissmedic and MHRA, cenobamate was launched in Europe, Switzerland, and UK, under the brand name ONTOZRY® by SK Biopharmaceuticals' licensing partner Angelini Pharma SpA, part of the privately owned Angelini Industries, for the adjunctive treatment of focal-onset seizures in adult patients with epilepsy who have not been adequately controlled despite treatment with at least two antiseizure medications.

Since 2023, Dexcel Pharma, an international specialty pharmaceutical company, has been marketing cenobamate in Israel, and Paladin Labs Inc., launched cenobamate in Canada. Both Dexcel and Paladin commercialized cenobamate under the XCOPRI brand name. Cenobamate is also being developed in over 30 markets by other licensing partners in Southeast Asia and Australia (Dong-A ST), 17 countries in Latin America (Eurofarma), the Middle East and North Africa (Hikma MENA FZE), the Greater China Area (Ignis Therapeutics), and Japan (Ono Pharmaceutical Co., Ltd.).

“We are proud to see the impact that cenobamate is having on those patients living with epilepsy, a condition that is estimated to affect more than 50 million people globally,” said Donghoon Lee, President and CEO of SK Biopharmaceuticals and SK Life Science. “This cenobamate milestone coincides with the completion earlier this year of SK Biopharmaceuticals' strategic Global Partnering plan. The plan, resulting in cenobamate licensing agreements in Asia, Europe, North America, South America, and the Middle East and North Africa region (MENA), will potentially provide access to patients in more than 100 markets worldwide.”

“We are proud of our ongoing collaboration with SK Biopharmaceuticals and today's news reiterates the positive impact of our partnership in meeting the needs of people living with epilepsy in Europe,” said Jacopo Andreose, CEO of Angelini Pharma. “We are excited to continue transforming the landscape of epilepsy care with innovative treatment options and to advocate for epilepsy as a priority for healthcare systems across Europe.”

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About Epilepsy

Epilepsy is the fourth most common neurological disorder. There are approximately 3.4 million people living with epilepsy in the United States, with 150,000 new cases each year in the country.^{1,2} Epilepsy is characterized by recurrent, unprovoked seizures. The seizures in epilepsy may be related to a brain injury or a family tendency, but often the cause is completely unknown. Having seizures and epilepsy can affect one's safety, relationships, work, driving, and much more.^{3,4} 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, almost 40 percent of people with epilepsy are not able to achieve seizure freedom, meaning they have epilepsy that remains uncontrolled.⁵

About Cenobamate

Cenobamate is an anti-seizure medication (ASM) discovered and developed by SK Biopharmaceuticals and SK Life Science, Inc. 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 Canada where Paladin Labs Inc., an operating company of Endo International plc, launched cenobamate in January of 2024. Dexcel Pharma, an international specialty pharmaceutical company, is launching the treatment in Israel in April 2024. Both Dexcel and Paladin are marketing cenobamate under the brand name XCOPRI.

Cenobamate is also approved in the European Union, in the United Kingdom and in Switzerland 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 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 the Greater China region, Asia, Australia, Latin America, and the Middle East and North Africa via development and commercialization agreements with Ono Pharmaceutical, Ignis Therapeutics, Dong-A ST, Eurofarma, and Hikma MENA FZE.

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 Co., Ltd. and SK Life Science, Inc.

SK Biopharmaceuticals and its U.S. subsidiary SK Life Science, Inc. are pharmaceutical companies focused on the research, development, and commercialization of treatments for disorders of the central nervous system (CNS) and oncology. In 2017, SK Biopharmaceuticals established a research center to begin their expansion into oncology. SK Biopharmaceuticals and SK Life Science, Inc. have a pipeline of eight compounds in development in both CNS disorders and oncology. Additionally, through SK Life Science Labs, its R&D subsidiary in the U.S., SK Biopharmaceuticals is focused on the discovery of new treatments in oncology. For more information, visit SK Biopharmaceuticals' website at www.SKBP.com/eng, SK Life Science's website at www.SKLifeScienceInc.com, and SK Life Science Labs' website at www.SKLSLabs.com.

SK Biopharmaceuticals, SK Life Science, and SK Life Science Labs are part of SK Group, one of the largest conglomerates in Korea. SK Inc., 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 Inc. 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.

About Angelini Pharma and Angelini Industries

Angelini Pharma is an international pharmaceutical company, part of the Italian privately-owned multi-business Angelini Industries. The Company research, develops and commercialized health solutions with a focus on the areas of Brain Health, including Mental Health and Epilepsy, and Consumer Health. Founded in Italy at the beginning of the 20th century, Angelini Pharma operates directly in 20 countries, employing more than 3,000 people. Its products are marketed in over 70 countries through strategic alliances with leading international pharmaceutical groups. For more information about Angelini Pharma please visit <https://www.angelinipharma.com>.

Angelini Industries is a multinational industrial group founded in Ancona in 1919 by Francesco Angelini. Today, Angelini Industries represents a solid and diversified industrial reality that employs approximately 5,800 employees and operates in 21 countries around the world with revenues of over 2 billion euros, generated in the health, industrial technology, and consumer goods sectors. A targeted investment strategy for growth; constant commitment to research and development; deep knowledge of markets and business sectors, make Angelini Industries one of the Italian companies of excellence in the sectors in which it operates. To learn more visit www.angeliniindustries.com.

XCOPRI® and ONTOZRY® are registered trademarks of SK Biopharmaceuticals Co., Ltd.

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