SK Biopharmaceuticals' Partner Angelini Pharma Launches Cenobamate in France

Cenobamate (ONTOZRY®), for the treatment of uncontrolled focal-onset seizures in adults, is now available in 5 major European countries – Germany, the UK, Italy, Spain, France – and 10 other key markets

Pangyo, Gyeonggi Province, Korea, Dec. 9, 2022 – SK Biopharmaceuticals, an innovative global pharmaceutical company, announced that its European partner Angelini Pharma, an international pharmaceutical company part of the privately held Italian Angelini Industries, has launched cenobamate in France.

Cenobamate – under the brand name ONTOZRY® – has been commercialized in five major European countries such as Germany, the UK, Italy, Spain, and France, accounting for about 73 percent of the total value of the continent's epilepsy market.[1] It is also available in 10 other key European markets, including Switzerland and Belgium.

Cenobamate was approved by the European Commission (EC) in March 2021 for the adjunctive treatment of focal-onset seizures with or without secondary generalization in adult patients who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products.

Following the EC's marketing authorization for cenobamate, Angelini Pharma launched the anti-seizure medication in Germany, Europe's largest pharmaceutical market, in June 2021, and launched in the UK, Europe's largest epilepsy market, in November 2021, following the Medicines and Healthcare products Regulatory Agency's approval.

Cenobamate was discovered by SK Biopharmaceuticals and its U.S. subsidiary SK Life Science, which have forged a partnership with Angelini Pharma for the European markets.

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 Angelini Pharma

Angelini Pharma is an international pharmaceutical company, part of the Italian privately-owned Angelini Industries with a French affiliate established in 2021. Angelini Pharma is committed to helping patients in the therapeutic areas of Brain Health and Consumer Healthcare. In particular, Angelini Pharma is committed to brain health – working every day to reduce and mitigate neurological disorders, while restoring and protecting mental health and cognitive function.

Over the past 50 years, in the field of mental health, Angelini Pharma has gained international recognition for its substantial efforts to improve the management of patients with mental health disorders thanks to important, internally developed molecules (such as trazodone) and its commitment to fighting mental-health stigma.

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[1] SK Biopharmaceuticals data

Angelini Pharma operates directly in 20 countries employing almost 3,000 people and commercializes its products in more than 70 countries through strategic alliances with leading international pharmaceutical groups.
In January 2021, Angelini Pharma announced that they concluded a definitive merger agreement under which Angelini Pharma acquired Arvelle Therapeutics. As a result, Angelini Pharma has the exclusive license to commercialize cenobamate in the European Union and other countries in the European Economic Area (Switzerland and the UK).

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, 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 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 ONTOZRY IN THE EUROPEAN UNION
ONTOZRY® has been approved in the EU for the adjunctive treatment of focal-onset seizures with or without secondary generalization in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products. The recommended starting dose of cenobamate is 12.5 mg per day, titrated gradually to the recommended target dose of 200 mg per day. Based on clinical response, dose may be increased to a maximum of 400 mg per day.

Cenobamate is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients, and patients with familial Short-QT syndrome.

According to the cenobamate EU Risk Management Plan, the occurrence of drug rash with eosinophilia and systemic symptoms (DRESS) has been recognized as an important identified risk of the drug. Important potential risks are hypersensitivity, suicidality (class effect), QT shortening, and reproductive / embryofoetal toxicity.

In clinical trials, the most commonly reported adverse reactions were somnolence, dizziness, fatigue and headache. The approved Product Information of ONTOZRY® includes the routine risk minimisation measures for reducing safety risks in patients treated with the medicinal product.

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.

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