FOR IMMEDIATE RELEASE

ONTOZRY® (Cenobamate) Receives European Commission Approval for the Treatment of Drug-Resistant Focal-Onset Seizures in Adults

SK Biopharmaceuticals and Angelini Pharma will collaborate to launch the treatment in countries in the European Economic Area

Pangyo, Gyeonggi Province, Korea, March 30, 2021 – SK Biopharmaceuticals, Co., Ltd., a global innovative pharmaceutical company, announced today that cenobamate received marketing authorization from the European Commission (EC) under the brand name ONTOZRY® 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.

The marketing authorization, granted to Arvelle Therapeutics, recently acquired by Angelini Pharma, will be valid in all European Union Member States as well as Iceland, Norway and Liechtenstein. Angelini Pharma plans to launch ONTOZRY® in the European Union and other countries in the European Economic Area (Switzerland and the United Kingdom). SK Biopharmaceuticals, which discovered and developed cenobamate, will collaborate with Angelini Pharma to launch ONTOZRY® in Europe. Cenobamate was approved by the U.S. Food and Drug Administration (FDA) for the treatment of partial-onset (focal-onset) seizures in adults in 2019 and is commercially available in the U.S. under the brand name XCOPRI® (cenobamate tablets) CV.

“The approval by the European Commission is another major milestone in our efforts to increase access to cenobamate and to support patients with a much-needed new treatment option,” said Jeong Woo Cho, PhD, President and CEO of SK Biopharmaceuticals and SK life science. “As a fully-integrated global pharmaceutical company, we are committed to discovering, developing and delivering new treatment options for epilepsy and other central nervous system disorders to people around the world.”

Epilepsy is one of the most common neurological diseases in the world, and an estimated six million people in Europe live with seizures.[1] Among adult patients with focal-onset seizures, approximately 40% continue to experience seizures after treatment with two anti-seizure medications (ASMs).[2]

The approval was based on results from a global clinical trial program conducted by SK life science, the U.S. subsidiary of SK Biopharmaceuticals. The clinical trial program includes two randomized, double-blind, placebo-controlled studies and a large, multi-center, open-label safety study. These three studies enrolled more than 1,900 adults with uncontrolled focal-onset seizures.

“ONTOZRY will be a welcome new treatment option in Europe for adults who have not yet been able to control their focal-onset seizures with available treatments. Treatment-resistant epilepsy has a devastating effect on these patients and their families, and we are proud to help address this urgent health challenge,” said Pierluigi Antonelli, CEO of Angelini Pharma. “Angelini Pharma looks forward to bringing ONTOZRY to these patients across Europe and will continue to help address the needs of

patients with central nervous system disorders through our innovative product portfolio and pipeline."

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.

Cenobamate was approved in the EU under the brand name ONTOZRY® for the adjunctive treatment of focal-onset (partial-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 two anti-epileptic medicinal products. SK Biopharmaceuticals entered an exclusive licensing agreement with Arvelle Therapeutics to develop and commercialize cenobamate in Europe in early 2019. Angelini Pharma, which recently announced a definitive merger agreement to acquire Arvelle Therapeutics, plans to launch cenobamate in the European Union and other countries in the European Economic Area (Switzerland and the United Kingdom).

SK Biopharmaceuticals also has an exclusive licensing agreement with Ono Pharmaceutical to develop and commercialize cenobamate in Japan.

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.

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.[3] There are an estimated six million people in Europe with epilepsy.[1] 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.[4] People with epilepsy are at risk for accidents and other health complications, including falling, drowning, depression and sudden unexplained death in epilepsy (SUDEP).[4,5] 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.[2]

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

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 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 Angelini Pharma

Angelini Pharma is an international pharmaceutical company, part of the Italian privately-owned Angelini Group. Angelini Pharma is committed to helping patients in the therapeutics areas of Mental Health (including Pain), Rare Diseases and Consumer Healthcare. 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. Angelini Pharma operates directly in 25 countries employing almost 3.000 people and commercializes its products in more than 50 countries through strategic alliances with leading international pharmaceutical groups. For additional info visit www.angelinipharma.com.

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