

#### FOR IMMEDIATE RELEASE

# SK Biopharmaceuticals Enters Greater China Out-Licensing 6 Clinical Pipelines to CNS-Focused Biotech Ignis Therapeutics

SK Biopharmaceuticals enters into agreement to out-license a pipeline of 6 compounds, including FDAapproved cenobamate and solriamfetol, to Ignis Therapeutics

SK Biopharmaceuticals raises \$180M in Series A funding, the largest in China's 2021 pharma industry, led by 6 Dimensions Capital to launch the CNS-focused biotech

Partnership to accelerate Ignis Therapeutics to become a leading CNS biotech backed by 6 Dimensions
Capital's strong network and extensive healthcare expertise

**Pangyo, Gyeonggi Province, Korea, Nov. 11, 2021** -- SK Biopharmaceuticals announced the launch of central nervous system (CNS)-focused biotech company, Ignis Therapeutics in China, with a group of investors led by 6 Dimensions Capital, entering the world's second largest pharmaceutical market.

SK Biopharmaceuticals has entered into an agreement to out-license its six clinical compounds, including U.S. FDA-approved cenobamate and solriamfetol, to Ignis Therapeutics, for development and commercialization in China.

In exchange for the out-licensed pipeline, SK Biopharmaceuticals will receive an upfront payment of \$20 million and a milestone payment of \$15 million, as well as royalties on net sales, in accordance with the agreement. The company will also obtain shares worth \$150 million in Ignis Therapeutics, and has an option to co-promote the products in China.

The launch of Ignis Therapeutics comes as SK Biopharmaceuticals raised \$180 million in Series A financing, the largest in China's pharmaceutical industry this year, led by 6 Dimensions Capital, a Shanghai-based global investment firm. Other notable investors that participated in the Series A include Ruentex Group, KB Investment, WTT investment, Mubadala Investment Company, HBM Healthcare Investments, and Goldman Sachs.

Dr. Eileen Long, a former general manager of Sanofi China's CNS business unit, has been named as CEO of Ignis Therapeutics. Dr. Long has a proven track record in China CNS business, contributing to the sales growth of China's No. 1 epilepsy drug.

Cenobamate is an anti-seizure medication that has been approved for marketing in the U.S. under the brand name of XCOPRI® in 2019, and in Europe (ONTOZRY®) in 2021. SK Biopharmaceuticals has also out-licensed cenobamate for development and commercialization in Japan.

Solriamfetol (SUNOSI®) was approved for excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea in adult patients by the U.S. FDA in 2019. SK Biopharmaceuticals, the discoverer

of the compound, out-licensed it to Aerial BioPharma in 2011. Jazz Pharmaceuticals acquired the license from Aerial to develop and commercialize solriamfetol in 2014. SK Biopharmaceuticals maintains the rights in 12 Asian markets, of which jurisdiction in China now belongs to Ignis Therapeutics.

SK Biopharmaceuticals will collaborate with its Chinese partners and investors to accelerate the growth of Ignis to become a full-fledged platform company with a strong CNS treatment portfolio, backed by 6D's strong network and extensive healthcare expertise.

Jeong Woo Cho, PhD, President & CEO of SK Biopharmaceuticals, said, "The launch of Ignis Therapeutics in China reaffirms our commitment to addressing unmet needs in CNS disorders, and bringing care and novel therapies to patients anywhere in the world. We will closely collaborate with Ignis Therapeutics' Dr. Eileen Long and her team, our investors and partners to ensure that Ignis becomes a leading CNS company with innovative pipelines. SK Biopharmaceuticals will continue its journey with them not only to further enter uncharted territory and increase global presence, but also most importantly, generate and maximize social value to create a positive change in the lives of many patients."

Dr. Leon Chen, managing partner and CEO of 6 Dimensions Capital, said, "Central nervous system disorders are a growing concern in our society. There is an urgent need to bring more effective and safer therapeutics to patients suffering from these diseases. Today, we reached a major milestone to form a partnership with SK Biopharmaceuticals, a premier pharmaceutical company in the world, focusing on developing innovative drugs, and completed the largest Series A financing in China's pharmaceutical industry in 2021. I believe that under Dr. Eileen Long's leadership, Ignis will become an innovative and integrated leader in the CNS field, with full-fledged capabilities in both R&D and commercialization."

Dr. Eileen Long, M.D., CEO of Ignis Therapeutics, said, "I am thrilled to enter this long-term strategic collaboration with SK Biopharmaceuticals with strong support from investors, which will help expand our portfolio, fuel the growth of the company, and ignite hope for patients. Under this agreement, Ignis will collaborate with SK Biopharmaceuticals on the ongoing Phase 3 clinical study with cenobamate for partial-onset seizures in adults, and will be the sole sponsor of all the others for clinical development, taking full responsibility for the regulatory, manufacturing, and commercialization of the six products in Greater China. By committing to developing therapeutic options with novel mechanisms of action, Ignis is transforming the approach to treating CNS conditions, and striving to become a leading global CNS company."

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# Pipeline

Compound	Indication
Cenobamate	Epilepsy (Partial-onset seizures)
Solriamfetol	Excessive Daytime Sleepiness in Narcolepsy or Obstructive
	Sleep Apnea
Carisbamate	Lennox-Gastaut Syndrome
SKL20540	Schizophrenia
SKL24741	Epilepsy
SKL13865	Attention Deficit/Hyperactivity Disorder

### 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 <a href="https://www.aedpregnancyregistry.org">www.aedpregnancyregistry.org</a>.

**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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.

# **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 <u>Medication Guide</u>. 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 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 the discovery of new treatments in oncology. For more information, visit SK Biopharmaceuticals' website at <a href="https://www.skbp.com/eng">www.skbp.com/eng</a> and SK life science's website at <a href="https://www.skLifeScienceInc.com">www.skLifeScienceInc.com</a>.

Both SK Biopharmaceuticals and SK life science 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. For more information, please visit <a href="http://hc.sk.co.kr/en/">http://hc.sk.co.kr/en/</a>.

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