FOR IMMEDIATE RELEASE

Media Contact:
media@sklsi.com

SK life science announces FDA acceptance of NDA submission for cenobamate, an investigational antiepileptic drug

PDUFA date set for November 21, 2019

Fair Lawn, New Jersey, February 4, 2019 – SK Life Science, Inc., a subsidiary of SK Biopharmaceuticals Co., Ltd., an innovative biopharmaceutical company focused on developing and bringing to market treatments for central nervous system (CNS) disorders, announced today that the U.S. Food and Drug Administration (FDA) has accepted the filing of its New Drug Application (NDA) for cenobamate. Cenobamate, an investigational antiepileptic drug for the potential treatment of partial-onset seizures in adult patients, is the first molecule discovered and developed from inception through to the submission of an NDA without partnering or out-licensing from a Korean pharmaceutical company. SK life science plans to commercialize cenobamate independently.

The NDA submission is based on data from pivotal trials that evaluated the efficacy and safety of cenobamate. Results from the clinical trial program, which enrolled more than 1,900 patients, have been presented at medical conferences including the American Academy of Neurology (AAN) and the American Epilepsy Society (AES) Annual Meetings.

"The FDA's acceptance of our NDA filing is a critical step toward our goal of introducing a new treatment option for people with uncontrolled epilepsy," said Marc Kamin, M.D., chief medical officer at SK life science. "We look forward to working with the FDA during their review of our data on cenobamate."

Despite the availability and introduction of many new AEDs, overall treatment outcomes for people with epilepsy have not improved in 20 years[1] and the CDC states that nearly 60 percent of people with epilepsy are still experiencing seizures, showcasing a great unmet need for patients and their families.[2] Additionally, while some patients may experience a reduction in seizure frequency with current treatments, they continue to live with seizures.[2] The impact of continued seizures can be debilitating and life-altering and the complications of epilepsy can include depression and anxiety, cognitive impairment and SUDEP (sudden unexpected death in epilepsy).[3]

About Epilepsy

Epilepsy is a common neurological disorder characterized by seizures.[4] There are approximately 3.4 million people in the U.S. living with epilepsy, and approximately 65 million worldwide.[5] The majority of people with epilepsy (60%) have partial-onset seizures, which are located in just one part of the brain.[6] People with epilepsy are also at risk for accidents and other health complications including falling, drowning, car accidents, depression and anxiety and SUDEP.[3]

About Cenobamate
Cenobamate (YKP3089) was discovered by SK Biopharmaceuticals and SK life science and is being investigated for the potential treatment of partial-onset seizures in adult patients.

Cenobamate's mechanism of action is not fully understood, but it is believed to work through two separate mechanisms: enhancing inhibitory currents through positive modulation of GABA-A receptors and decreasing excitatory currents by inhibiting the persistent sodium current.

Global trials for adults with partial-onset seizures are ongoing to evaluate cenobamate safety. Additional clinical trials are investigating cenobamate safety and efficacy in other seizure types.

The U.S. Food and Drug Administration (FDA) accepted the filing of the New Drug Application for cenobamate for the potential treatment of partial-onset seizures in adults in February 2019.

Cenobamate is not approved by the FDA or any other regulatory authorities. Safety and efficacy have not been established.

About SK life science
SK Life Science, Inc., a subsidiary of SK Biopharmaceuticals, Co., Ltd., is focused on developing and commercializing treatments for disorders of the central nervous system (CNS). Both are a part of the global conglomerate SK Group, the second largest company in Korea. SK life science is located in Fair Lawn, New Jersey.

We have a pipeline of eight compounds in development for the treatment of CNS disorders including epilepsy, sleep disorder and attention deficit hyperactivity disorder, among others. The first product the company is planning to commercialize independently is cenobamate (YKP3089), an investigational compound for the potential treatment of partial-onset seizures in adult patients, currently in a Phase 3 global clinical trial.

For more information, visit SK life science's website at www.SKLifeScienceInc.com.

For more information, visit SK Biopharmaceuticals' website at www.skbp.com/eng.

---

1. Chen Z, Brodie MJ, Liew D, Kwan P. Treatment outcomes in patients with newly diagnosed epilepsy treated with established and new antiepileptic drugs: a 30-year longitudinal cohort study. https://www.ncbi.nlm.nih.gov/pubmed/29279892 Published online December 26, 2017.

2. Center for Disease Control and Prevention. Active Epilepsy and Seizure Control in Adults — United States, 2013 and 2015. https://www.cdc.gov/mmwr/volumes/67/wr/mm6715a1.htm?s_cid=mm6715a1 Accessed December 27, 2018.

3. Epilepsy Foundation. Staying Safe. https://www.epilepsy.com/learn/seizure-first-aid-and-safety/staying-safe Accessed November 20, 2018.

4. Epilepsy Foundation. What Is Epilepsy? https://www.epilepsy.com/learn/about-epilepsy-basics/what-epilepsy Accessed November 20, 2018.

5. Epilepsy Foundation. Facts about Seizures and Epilepsy. https://www.epilepsy.com/learn/about-epilepsy-basics/facts-about-seizures-and-epilepsy Accessed November 20, 2018.

6. National Institute of Neurological Disorders and Stroke. The Epilepsies and Seizures: Hope through Research. https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Epilepsies-and-Seizures-Hope-Through#3109_9 Accessed November 20, 2018.