



FOR IMMEDIATE RELEASE

SK life science Initiates Phase 3 Clinical Trial of Carisbamate for Lennox-Gastaut Syndrome

Paramus, New Jersey, January 6, 2022 – [SK Life Science, Inc.](#), a subsidiary of SK Biopharmaceuticals Co., Ltd., an innovative global pharmaceutical company focused on developing treatments for central nervous system (CNS) disorders, submitted a clinical study protocol to the U.S. Food and Drug Administration (FDA) for a Phase 3 clinical trial to evaluate the efficacy and safety of carisbamate for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS). Carisbamate has received orphan drug designation from the FDA for the potential treatment of LGS.

The Phase 3, global, multicenter, randomized, double-blind, placebo-controlled trial will evaluate the efficacy of two doses of carisbamate in more than 250 patients aged 4-55.

“The initiation of the Phase 3 trial evaluating carisbamate in Lennox-Gastaut syndrome marks a new chapter for SK life science in developing therapies to treat central nervous system disorders in adult and pediatric patients,” said Marc Kamin, MD, chief medical officer at SK life science. “We are committed to applying our expertise in epilepsy to develop new therapy options for LGS, a condition with high unmet medical need.”

“Our aim is to provide effective treatment options for people with central nervous system disorders,” said Jeong Woo Cho, PhD, President and CEO of SK Biopharmaceuticals and SK life science. “Moving carisbamate into Phase 3 development reaffirms our commitment to expanding our CNS pipeline and realizing this important goal.”

Additional information about the trial and enrollment will be available on clinicaltrials.gov.

About Carisbamate

Carisbamate was discovered by SK Biopharmaceuticals and is being developed by SK life science for the potential treatment of Lennox-Gastaut syndrome (LGS). While the precise mechanism by which carisbamate exerts its therapeutic effect is unknown, it is believed to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents. Carisbamate has received orphan drug designation for the potential treatment of LGS from the U.S. Food and Drug Administration (FDA).

About Lennox-Gastaut Syndrome (LGS)

Lennox-Gastaut syndrome (LGS) is a rare form of childhood-onset epilepsy that is marked by multiple types of seizures. People with LGS have developmental and behavioral disorders, which are often worsened by seizures and seizure activity, and are at a higher risk of death than their peers due to poorly controlled seizures, sudden unexpected death in epilepsy (SUDEP), and injuries from falls.¹ LGS is often unresponsive to treatment, and over 85% of children with LGS will continue to have seizures into adulthood.¹ This rare

syndrome accounts for approximately 3-4% of childhood epilepsy cases; approximately 48,000 children and adults in the U.S. and 1 million people worldwide have LGS.²

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

SK Biopharmaceuticals and its U.S. subsidiary SK life science are pharmaceutical companies focused on the global 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 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 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 <http://hc.sk.co.kr/en/>.

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