FOR IMMEDIATE RELEASE

European Medicines Agency Accepts Arvelle Therapeutics' Marketing Authorization Application for Cenobamate for the Adjunctive Treatment of Focal-Onset Seizures in Adults

- *The MAA is based on data from a global clinical trial program conducted by SK life science, a subsidiary of SK Biopharmaceuticals*

Pangyo, Gyeonggi Province, Korea, March 26, 2020 – SK Biopharmaceuticals Co., Ltd. announced the European Medicines Agency (EMA) acceptance of Arvelle Therapeutics' Marketing Authorization Application (MAA) for cenobamate, an anti-epileptic drug (AED) for the adjunctive treatment of focal-onset (partial-onset) seizures in adults. In 2019, SK Biopharmaceuticals entered into an exclusive licensing agreement with Arvelle Therapeutics to develop and commercialize cenobamate in Europe. Acceptance of the MAA confirms that the submission is complete and begins the formal review process by the EMA's Committee for Human Medicinal Products (CHMP).

The MAA is 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 global, randomized, double-blind, placebo-controlled studies and a large, global, multi-center, open-label safety study. These three studies enrolled more than 1,900 adults with uncontrolled focal-onset seizures.

"The EMA's acceptance of the filing for cenobamate is an important step toward making a new AED available to patients in Europe," said Jeong Woo Cho, PhD, President and CEO of SK Biopharmaceuticals and SK life science. "We congratulate the Arvelle Therapeutics team for their efforts in preparing the MAA and advancing this important potential treatment option."

There are about 6 million people in Europe with epilepsy,[1] and approximately 40 percent of adults with focal-onset seizures continue to experience seizures, even after treatment with two AEDs, underscoring the need for new treatment options.[2]

About Cenobamate

Cenobamate is an FDA-approved anti-epileptic drug (AED) for the treatment of partial-onset seizures in adults. In the U.S., the drug will be marketed under the brand name XCOPRI® (cenobamate tablets) CV and is expected to be available in the second quarter of 2020. It was discovered and developed by SK Biopharmaceuticals and SK life science. In 2019, SK Biopharmaceuticals entered into an exclusive licensing agreement with Arvelle Therapeutics to develop and commercialize cenobamate in Europe.

While the precise mechanism by which cenobamate exerts its therapeutic effect is unknown, cenobamate is believed to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents and as a positive allosteric modulator of the γ-aminobutyric acid ($GABA_A$) ion channel.

Long-term safety of cenobamate has been evaluated in the ongoing open-label extensions of the randomized studies and the open-label safety study. Additional clinical trials are investigating cenobamate in other seizure types.

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 Arvelle Therapeutics
Arvelle Therapeutics is an emerging biopharmaceutical company focused on bringing innovative solutions to patients suffering from CNS disorders. Arvelle Therapeutics is responsible for the development and commercialization of cenobamate, an investigational anti-epileptic drug, in the European market. Arvelle Therapeutics is headquartered in Switzerland and received start-up financing of $207.5 million, one of the largest initial financing commitments for a European-focused biopharmaceutical company, with investments from a global syndicate including NovaQuest Capital Management, BRV Capital Management, LSP, H.I.G. BioHealth Partners, Andera Partners, F-Prime Capital and KB Investments. More information is available at http://Arvelletx.com.

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