



**FOR IMMEDIATE RELEASE**

## **SK Biopharmaceuticals and Arvelle Therapeutics Announce Agreement to Develop and Commercialize Cenobamate in Europe**

*Arvelle Therapeutics to receive rights to develop and commercialize cenobamate, an investigational antiepileptic drug developed by SK Biopharmaceuticals, in Europe*

*SK Biopharmaceuticals to receive upfront payment of \$100 million and will be eligible for milestone payments of up to \$430 million*

*Arvelle Therapeutics is funded by a global investment syndicate consisting of NovaQuest Capital Management, Life Science Partners, BRV Capital Management, Andera Partners and H.I.G. BioHealth Partners*

**Gyeonggi, KR February 14, 2019** – SK Biopharmaceuticals and Arvelle Therapeutics GmbH today announced that they have entered into an exclusive licensing agreement for Arvelle to develop and commercialize cenobamate in Europe. Cenobamate is a novel, small molecule investigational antiepileptic drug for the potential treatment of partial-onset seizures in adult patients. Under the agreement, SK Biopharmaceuticals will receive an upfront payment of \$100 million and is eligible to receive up to \$430 million upon achievement of certain regulatory and commercial milestones in addition to royalties on net sales generated in Europe. SK Biopharmaceuticals will have an option to obtain a significant equity stake in Arvelle and will also retain commercial rights for all non-European territories. Cenobamate was discovered and developed by SK Biopharmaceuticals from inception through to the acceptance of a New Drug Application (NDA) by the U.S. Food and Drug Administration (FDA).

“We are very pleased to enter into this licensing agreement with Arvelle, as it provides important validation of the global potential for cenobamate as a new treatment option for adults with partial-onset seizures,” said Dr. Jeong Woo Cho, President and CEO of SK Biopharmaceuticals. “Arvelle’s experienced leadership team and focus on CNS disorders make them the ideal partner to advance the development and commercialization of our compound in Europe.”

Arvelle Therapeutics is a newly created company that received one of the largest initial financing commitments for a European-focused biopharmaceutical company from a global syndicate of investors that include NovaQuest, LSP, BRV Capital Management, Andera Partners and H.I.G. BioHealth Partners. Mark Altmeyer has been named President and CEO of Arvelle. Altmeyer brings more than 30 years of global biopharmaceutical experience to Arvelle. As President and CEO of Otsuka America Pharmaceutical, Inc., Altmeyer oversaw the growth of Abilify® into a multi-billion-dollar product. Most recently, he served as President and Chief Commercial Officer of Axovant Sciences and previously led the neuroscience business unit at Bristol-Myers Squibb Company. Altmeyer is joined by a talented team of colleagues from Axovant with deep experience in CNS drug development and global commercialization. Arvelle intends to file a Marketing Authorization Application (MAA) for cenobamate

for partial-onset seizures in adult patients based on the data generated from SK Biopharmaceuticals' global clinical trial program.

"We launched Arvelle to bring truly innovative CNS products to patients suffering from serious neurological conditions and cenobamate is the perfect first pipeline product," said Altmeyer. "Given the data generated in clinical trials and the FDA acceptance of the NDA, we believe cenobamate has the potential to be an important antiepileptic drug treatment option for adult patients suffering from partial-onset seizures. We appreciate the support and validation of our investors and are very enthusiastic about our potential in the European market."

"We are very excited to invest in the talented team at Arvelle on this new venture," said Martijn Kleijwegt, Managing Partner of LSP. "SK Biopharmaceuticals has done an excellent job on the discovery and development of cenobamate and we believe that Arvelle is the right company to gain EU approval for cenobamate and ultimately bring it to patients in Europe."

### **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 (also known as "focal 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. An additional clinical trial is investigating cenobamate safety and efficacy for another form of epilepsy in adult patients.

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, European Medicines Agency (EMA) or any other regulatory authorities. Safety and efficacy have not been established.

### **About SK Biopharmaceuticals**

SK Biopharmaceuticals is focused on research and development of treatments for disorders of central nervous system (CNS) and cancer. SK Biopharmaceuticals is an affiliate of SK Holdings.

SK Holdings continues to enhance its portfolio value by executing long-term investments with a number of 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/>.

Currently, SK Biopharmaceuticals is conducting basic research for the development of innovative new drugs at its research center in Pangyo, Gyeonggi Province, Korea. Further, the company is pursuing global clinical development and direct marketing through its U.S. subsidiary SK Life Science, Inc., in Fair Lawn, New Jersey, USA.

SK Biopharmaceuticals has 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, cenobamate (YKP3089), is an investigational compound for the potential treatment of partial-onset seizures in adult patients. The NDA for cenobamate for the potential treatment of partial-onset seizures in adult patients is currently under review by the FDA. For more information, visit SK Biopharmaceuticals' website at [www.skbp.com/eng](http://www.skbp.com/eng).

#### **About Arvelle Therapeutics**

Arvelle Therapeutics is a biopharmaceutical company with the mission of bringing innovative solutions to patients suffering from CNS disorders. Arvelle is responsible for the development and commercialization of cenobamate, an investigational antiepileptic drug, in the European market. Arvelle is headquartered in Switzerland and received one of the largest initial financing commitments for a European-focused biopharmaceutical company with investments from a global syndicate including NovaQuest Capital Management, LSP, BRV Capital Management, Andera Partners and H.I.G. BioHealth Partners. More information is available at [www.Arvelletx.com](http://www.Arvelletx.com).

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