



Media Contact:
media@sklsi.com

SK life science Provides Update on Recent Company Milestones and Accomplishments

- Continuing to execute commercial build and launch readiness ahead of anticipated PDUFA target date in November*
- Initiated additional Phase 3 clinical trial of cenobamate to evaluate its efficacy and safety as a potential treatment for adults with primary generalized tonic-clonic seizures*
- Parent company SK Biopharmaceuticals and Arvelle Therapeutics announce agreement to develop and commercialize cenobamate in Europe; upfront payment of \$100 million*

Paramus, New Jersey, May 13, 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, today announced key business and scientific accomplishments from the fourth quarter of 2018 through the first quarter of 2019.

“In the first few months of 2019, we’ve demonstrated significant momentum toward our goal of developing a new treatment option for adults with partial-onset seizures,” said Marc Kamin, MD, chief medical officer, SK life science. “Our lead investigational compound, cenobamate, was accepted for review by the FDA in early February 2019 – a critical milestone, as it was the first time a Korean company discovered and developed a compound from inception to NDA acceptance without another global pharmaceutical partner.”

Sebby Borriello, chief commercial officer, SK life science added, “As we look toward our PDUFA target date, we are focused on strategically expanding our corporate presence and commercial infrastructure. We plan to double our current headcount of over 100 employees, bringing in new talent with deep knowledge of the pharmaceutical industry and a passion for making a difference in peoples’ health and lives.” Borriello added, “As part of SK Group, one of the largest conglomerates in Korea, we have the support of a global network as we advance toward the next phase of our growth and development into a fully-integrated global pharmaceutical company.”

Recent Accomplishments from Fourth Quarter 2018 and First Quarter 2019

- **Regulatory and Clinical Milestones**
 - The FDA accepted the filing of the new drug application (NDA) for cenobamate, an investigational antiepileptic drug for the potential treatment of partial-onset seizures in adult patients. SK life science plans to commercialize cenobamate independently in the U.S.

- SK life science provided updates on the results of a large, Phase 3, multicenter, open-label safety study of cenobamate, designed to mitigate the rate of DRESS syndrome, at the American Epilepsy Society Annual Meeting, November 30-December 4, 2018 in New Orleans, Louisiana. In the study, no cases of DRESS syndrome were identified in 1,339 patients exposed to cenobamate using a lower starting dose and slower titration.
 - SK life science presented data on the effect of cenobamate on the single dose pharmacokinetics of a variety of drugs metabolized by specific cytochrome P450 enzymes in healthy subjects at the American Society for Clinical Pharmacology and Therapeutics Annual Meeting, March 13-16, 2019 in Washington, D.C.
 - SK life science initiated a randomized, double-blind, placebo-controlled Phase 3 clinical trial to study the efficacy and safety of cenobamate as a potential treatment for adults with primary generalized tonic-clonic seizures. The trial, which will enroll approximately 150 adults across the U.S. and Europe, is expected to be completed in November 2021.
 - SK Biopharmaceuticals initiated a Phase 1b clinical trial, a PK study in patients for carisbamate (YKP509), which is being investigated for Lennox-Gastaut syndrome.
- **SK Biopharmaceuticals Global Business Development**
 - In February 2019, SK Biopharmaceuticals, the parent company of SK life science, entered into a licensing agreement with Arvelle Therapeutics to advance the development and commercialization of cenobamate in Europe. Under the terms of the agreement, SK Biopharmaceuticals received 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.
- **Expanded Team**
 - SK life science continued to build its team in the U.S., increasing headcount by 17% in the first quarter of 2019 – bringing its total employee base to more than 100 employees.
 - Targeting employees with rich industry expertise and experience at leading biopharma organizations, SK life science recently hired the following employees:
 - Jiyoung Jung, Chief Financial Officer – With a Master of Business Administration degree from ESADE Business School, Jung brings 20 years of experience in leadership and financial strategy to SK life science’s executive team and previously worked at SK Holdings and SK Networks.
 - Kenneth Olsen, General Counsel and Chief Compliance Officer – Olsen brings over 30 years of legal and compliance experience in the global pharmaceutical landscape to SK Life Science, including almost 20 years at Johnson & Johnson, as well as executive leadership roles at Olympus Corporation and BioMarin.
 - Stephanie Loiseau, Associate Director, CNS Marketing – Brings more than 10 years of experience in product marketing strategy for Fortune 500 companies, including Allergan, Johnson & Johnson, Boehringer Ingelheim and Coca Cola.
 - Shannon Levin, Corporate Account Director – Brings 20 years of account management experience to SK life science and previously worked at EMD

Serono, UCB Pharmaceuticals and Ironshore Pharmaceuticals & Development, Inc.

- Kevin Black, Government Account Director – Black previously worked at UCB Pharmaceuticals and brings nearly 20 years of experience driving contract, sales and marketing strategy.
- Wanho Nam, Head of Corporate Center – Nam has held numerous positions within SK Group, working for SK Biopharmaceuticals, SK Holdings, SK Continental JV and SK Innovations. Most recently and prior to joining SKLSI, Nam was the head of Business Support for SK Biopharmaceuticals.

- **Upcoming Medical Meetings & Data Presentations**

- American Academy of Neurology Annual Meeting, Philadelphia, PA – May 4-10
- International Society for the Study of Xenobiotics Annual Meeting, Portland, Oregon – July 28-31

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. An additional clinical trial is investigating cenobamate safety and efficacy for another form of epilepsy in adult patients.

The FDA accepted the filing of the NDA 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 Paramus, New Jersey.

We have a pipeline of eight compounds in development for the treatment of CNS disorders including epilepsy, Lennox-Gastaut syndrome 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.

For more information, visit SK life science's website at www.SKLifeScienceInc.com and SK Biopharmaceuticals' website at www.skbp.com/eng.