KalVista Pharmaceuticals Enters Into Licensing Agreement With Kaken Pharmaceutical to Commercialize Sebetralstat for HAE in Japan

Apr 08, 2025

-Up to $24 million in upfront and milestone payments, plus royalties-

-Sebetralstat has potential to become first, oral on-demand treatment of HAE in Japan, underscoring commercial opportunity-

-Kaken brings regional expertise and proven track record in commercializing innovative therapies-

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Apr. 8, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced that its wholly-owned subsidiary, KalVista Pharmaceuticals, Ltd., has licensed commercialization rights in Japan to Kaken Pharmaceutical, Co., Ltd. (JPX: 4521.T) for sebetralstat, an investigational, oral on-demand treatment for hereditary angioedema (HAE). KalVista will receive an upfront payment of $11 million, with an additional payment of up to $11 million upon achievement of a regulatory milestone anticipated in early 2026. Beyond these payments, the Company is also eligible for commercial milestone payments, plus royalties based on the Japan National Health Insurance (NHI) price, with the royalty rate as a percentage of sales approximately in the mid-twenties.

“We are pleased to partner with Kaken, whose expertise and demonstrated success in the region make them well-suited to work alongside our exceptional team to bring sebetralstat to the HAE community in Japan,” said Ben Palleiko, CEO of KalVista. “This collaboration is an important part of our strategy to expand the global reach of sebetralstat as we prepare for several commercial launches starting this year. Our focus remains on delivering a safe and effective oral on-demand therapy that we believe will make a meaningful difference for people living with HAE worldwide.”

As previously announced, KalVista received Orphan Drug Designation for sebetralstat from Japan’s Ministry of Health, Labour and Welfare (MHLW) and the Company has submitted a New Drug Application (NDA) for sebetralstat in Japan. If approved, sebetralstat would be the first oral on-demand treatment for HAE in the country.

About KalVista Pharmaceuticals, Inc.
KalVista Pharmaceuticals, Inc., is a global biopharmaceutical company dedicated to developing and delivering life-changing oral therapies for individuals affected by rare diseases with significant unmet needs. The Company’s lead investigational product is sebetralstat, a novel, oral, on-demand treatment for hereditary angioedema (HAE). Sebetralstat is under regulatory review by the U.S. FDA, with a PDUFA goal date of June 17, 2025. In addition, KalVista has completed Marketing Authorization Applications for sebetralstat to the European Medicines Agency, the Pharmaceuticals and Medical Devices Agency, and multiple other global regulatory authorities. For more information about KalVista, please visit www.kalvista.com.

About Sebetralstat
Sebetralstat is an investigational, novel oral plasma kallikrein inhibitor for the treatment of hereditary angioedema (HAE). We have filed multiple regulatory applications seeking approval of sebetralstat as the first oral, on-demand treatment for HAE in individuals aged 12 and older, and are investigating its use in children aged 2 to 11. If approved, sebetralstat has the potential to become the foundational therapy for HAE management worldwide.

About Kaken Pharmaceutical, Co., Ltd.
Kaken Pharmaceutical is a specialty pharmaceutical company in Japan with strong experience in developing and commercializing novel pharmaceuticals in the fields of orthopedics and dermatology. Kaken concentrates its R&D resources in areas such as immune system, nervous system, infectious diseases and rare diseases with unmet medical needs. Kaken, in its philosophy, strives to improve the quality of life of patients through the development and distribution of superior pharmaceuticals. For further information, visit www.kaken.co.jp/english.

Forward-Looking Statements
This press release contains “forward-looking” statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: “anticipate,” “intend,” “plan,” “goal,” “seek,” “believe,” “project,” “estimate,” “expect,” “strategy,” “future,” “likely,” “may,” “should,” “will,” and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, timings or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our KONFIDENT-S and KONFIDENT-KID trials, and to obtain regulatory approvals for sebetralstat and other candidates in development, the success of any efforts to commercialize sebetralstat, the ability of sebetralstat and other candidates in development to treat HAE or other diseases, and the future progress and potential success of our oral Factor XIIa program. Further information on potential risk factors that could affect our business and financial results are detailed in our filings with the Securities and Exchange Commission, including in our annual report on form 10-K for the year ended April 30, 2024, our quarterly reports on Form 10-Q, and our other reports that we make from time to time with the Securities and Exchange Commission. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments, or otherwise.

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