KalVista Pharmaceuticals Announces Approval of EKTERLY® (sebetralstat) in Japan, First and Only Oral On-demand Treatment for Hereditary Angioedema

Dec 22, 2025

FRAMINGHAM, Mass. & SALISBURY, England--(BUSINESS WIRE)--Dec. 22, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced that the Ministry of Health, Labor and Welfare (MHLW) in Japan has granted marketing and manufacturing approval for EKTERLY® (sebetralstat), a novel plasma kallikrein inhibitor, for the treatment of acute attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older. EKTERLY is the first and only oral on-demand treatment for HAE approved in Japan.

EKTERLY will be commercialized in Japan by KalVista's partner, Kaken Pharmaceutical Co., Ltd. Kaken will launch EKTERLY shortly after it is listed on the Japanese National Health Insurance System (NHI).

"The approval of EKTERLY in Japan marks another major milestone in our global pursuit to bring the first and only oral on-demand treatment to people living with HAE," said Ben Palleiko, CEO of KalVista. "We recognize the significant efforts of our Japanese team in achieving this outcome. We also appreciate the diligent commercial preparations by Kaken and look forward to their continued leadership in making this therapy available to patients in Japan. This approval underscores both the urgent need for new, effective therapies and the potential of EKTERLY to meaningfully improve the lives of individuals and families affected by HAE across the world."

In December 2024, KalVista received Orphan Drug designation for EKTERLY in Japan. The approval is based on results from the phase 3 KONFIDENT clinical trial, which was the largest clinical study ever conducted in HAE. Data from KONFIDENT were published in the *New England Journal of Medicine* in May 2024, showing that EKTERLY achieved significantly faster symptom relief, reduction in attack severity, and attack resolution than placebo, and was well-tolerated with a safety profile similar to placebo. The trial randomized 136 HAE patients from 66 clinical sites across 20 countries.

Since July 3, 2025, EKTERLY has received seven regulatory approvals across major global markets, including in the United States, United Kingdom, European Union, Switzerland, Australia, Singapore, and Japan. Each approval authorizes its use for treating HAE attacks in individuals aged 12 and older.

About Hereditary Angioedema

Hereditary angioedema (HAE) is a rare genetic disease resulting in deficiency or dysfunction in the C1 esterase inhibitor (C1INH) protein and subsequent uncontrolled activation of the kallikrein-kinin system. People living with HAE experience painful and debilitating attacks of tissue swelling in various locations of the body that can be life-threatening depending on the area affected. Treatment guidelines recommend treating attacks as early as possible to prevent progression of swelling and shorten the time to attack resolution, and to consider treatment for all attacks, regardless of anatomic location or severity.

About EKTERLY® (sebetralstat)

EKTERLY (sebetralstat) is a novel plasma kallikrein inhibitor approved in the United States, European Union, United Kingdom, Switzerland, Australia, Singapore and Japan for the treatment of acute attacks of hereditary angioedema (HAE) in people 12 years of age and older. EKTERLY is the first and only oral on-demand treatment for HAE, offering efficacious and safe treatment of attacks without the burden of injections. With ongoing studies exploring its use in children aged two to 11 and multiple regulatory applications under review in key global markets, EKTERLY has the potential to become the foundational therapy for HAE management worldwide. For more information, including the full U.S. Prescribing Information, visit EKTERLY.com.

About KalVista Pharmaceuticals, Inc.

KalVista is a global pharmaceutical company dedicated to delivering life-changing oral therapies for individuals affected by rare diseases with significant unmet needs. The KalVista team discovered and developed EKTERLY®—the first and only oral on-demand treatment for hereditary angioedema (HAE)—and continues to work closely with the global HAE community to improve treatment and care for this disease around the world. For more information about KalVista, please visit www.kalvista.com and follow us on LinkedIn, X, Facebook and Instagram.

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," "position," "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, information relating to our business and business plans, the success of our efforts to commercialize EKTERLY® (sebetralstat), our ability to successfully obtain foreign regulatory approvals for sebetralstat, our expectations about the safety and efficacy of sebetralstat, the timing of clinical trials and their results, our ability to commence clinical studies or complete ongoing clinical studies, including our KONFIDENT-S and KONFIDENT-KID trials, and the ability of EKTERLY to treat HAE. 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, 2025, our quarterly reports on Form 10-Q, and our other reports that we may 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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Ryan Baker
Head, Investor Relations
(617) 771-5001
ryan.baker@kalvista.com

Molly Cameron
Director, Corporate Communications
(978) 339-3378
molly.cameron@kalvista.com

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