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

Jul 15, 2025

EKTERLY to be added to the Orphan Register and awarded 10 years of market exclusivity

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 15, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) has granted marketing authorization for EKTERLY® (sebetralstat), a novel plasma kallikrein inhibitor, for the treatment of hereditary angioedema (HAE) attacks in adults and adolescents aged 12 years and older. EKTERLY is the first and only oral on-demand treatment for HAE approved in the UK.

"The approval of EKTERLY in the United Kingdom builds on our recent FDA approval and advances our global commitment to bring this innovative treatment option to people living with HAE," said Ben Palleiko, CEO of KalVista. "This approval holds particular significance for KalVista as EKTERLY was discovered in our Salisbury, UK labs—making it even more exciting that now we will be able to offer this therapy to people living with HAE in the UK. More broadly, this is another example of the incredible skills of our entire team in pursuing what we expect to be the fastest global launch of an HAE therapy ever."

The MHRA's marketing authorization for EKTERLY is based on results from the phase 3 KONFIDENT clinical trial, which was the largest clinical study ever conducted in HAE. Data from KONFIDENT was 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.

"The MHRA approval of EKTERLY brings us one step closer to having an oral on-demand treatment available to patients in the UK for the first time," said Dr. Sinisa Savic, Professor of Clinical Immunology, St James's University Hospital Leeds and sebetralstat investigator. "I look forward to seeing the impact this new treatment option will have on the HAE community in the UK."

EKTERLY also met the requirements of the MHRA Orphan Designation criteria and will be added to the Orphan Register held by the MHRA, allowing it to benefit from up to 10 years of market exclusivity.

In March of this year, sebetralstat was granted a positive scientific opinion for an Early Access to Medicines Scheme (EAMS) from the MHRA for the treatment of HAE attacks. This has enabled healthcare professionals to prescribe the treatment prior to marketing authorization, based on clinical factors for patients with a clear unmet need. It will continue to be available through the EAMS until KalVista receives a decision from the National Institute for Health and Care Excellence (NICE) for use of EKTERLY under the UK's National Health Service (NHS), which is anticipated in the first half of 2026.

On July 3, 2025, EKTERLY was approved by the U.S. Food and Drug Administration for the treatment of HAE attacks in people 12 years of age and older. KalVista has submitted marketing authorization applications for sebetralstat in the EU, Japan and other key global markets.

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), a novel plasma kallikrein inhibitor, is the first and only oral on-demand treatment for hereditary angioedema (HAE) attacks in adults and adolescents aged 12 years and older. 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 complete product information, please see the Summary of Product Characteristics that can be found on https://products.mhra.gov.uk/.

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. In the U.S., KalVista markets EKTERLY®, the first and only oral on-demand treatment for hereditary angioedema (HAE). The Company has multiple regulatory applications under review in key global markets. For more information about KalVista, please visit www.kalvista.com and follow us on LinkedIn, X, Facebook and Instagram.

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, 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, including the outcome of the decision from the NICE regarding the use of

EKTERLY under the UK's NHS, our expectations about the safety and efficacy of sebetralstat and our other product candidates, 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 , 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, 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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