KalVista Pharmaceuticals Announces European Commission and Swissmedic Approval of EKTERLY® (sebetralstat), First and Only Oral On-Demand Treatment for Hereditary Angioedema

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First European launch of EKTERLY expected in Germany Q4 2025

EKTERLY now approved in the US, EU, UK and Switzerland with additional regulatory applications under review in key global markets

FRAMINGHAM, Mass. & SALISBURY, England--(BUSINESS WIRE)--Sep. 19, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced that the European Commission (EC) and Swiss Agency for Therapeutic Products, Swissmedic, have approved EKTERLY® (sebetralstat), a novel, oral plasma kallikrein inhibitor, for the symptomatic 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 in the European Union (EU) and Switzerland.

“As the first orally administered on-demand therapy for HAE attacks, EKTERLY provides patients and physicians with an important and welcome new HAE treatment option,” said Henrik Balle Boysen, President of HAE International.

“The approval of EKTERLY in Europe and Switzerland is a significant step forward in our efforts to deliver the first and only oral on-demand treatment for HAE to patients around the world,” said Ben Palleiko, CEO of KalVista. “With our US launch progressing well and approvals now secured in the UK, EU and Switzerland, we look forward to bringing this innovation to more people living with HAE, beginning with our first European launch in Germany. This continued progress underscores the strength of our science and reinforces the potential of EKTERLY to become the foundational treatment for HAE worldwide.”

The EC and Swissmedic marketing authorizations for EKTERLY are 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.[1] The trial randomized 136 HAE patients from 66 clinical sites across 20 countries.

“The KONFIDENT trial showed that EKTERLY delivers rapid and reliable symptom relief with a favorable safety profile,” said Danny Cohn, MD, PhD, Head of the HAE clinic at Amsterdam UMC, University of Amsterdam, Netherlands and principal investigator for the KONFIDENT phase 3 trial. “With today’s approvals, this innovation can now be brought into clinical practice, empowering patients and clinicians across Europe and Switzerland with the first oral on-demand treatment for HAE. By moving beyond injections, EKTERLY introduces a novel approach to managing acute HAE attacks, enabling patients to treat early, discreetly and confidently.”

KalVista is working closely with local regulatory authorities and health technology assessment bodies across the EU and Switzerland to help ensure that patients who may benefit from EKTERLY are able to access the novel treatment as soon as possible. The Company expects to initiate its first European launch in Germany in the fourth quarter of 2025, with availability in Switzerland anticipated in the second half of 2026, pending finalization of reimbursement plans.

The EC approval is applicable to all 27 EU member states as well as Iceland, Liechtenstein and Norway. As recently announced, the European Medicines Agency confirmed maintenance of orphan designation for EKTERLY, underscoring the critical unmet need that EKTERLY addresses in the EU and granting it 10 years of market exclusivity.

[1] Riedl MA, et al. Oral sebetralstat for on-demand treatment of hereditary angioedema attacks. N Engl J Med. 2024;391(1):32–43.

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 and Switzerland 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 complete product information for the European Union, please see the Summary of Product Characteristics (SmPC) that will be available at www.ema.europa.eu.

The prescribing information for Switzerland will be available on the Swissmedic website here.

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.

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), including in the United States, the United Kingdom, the European Union, and Switzerland, our ability to successfully obtain other 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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