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

Jul 07, 2025

First new on-demand HAE treatment in over a decade, with potential to transform management of the disease

Data demonstrated rapid symptom relief and attack resolution regardless of attack severity, location, age, or use of long-term prophylaxis, and well-established safety profile

Management to host conference call today at 8:30 a.m. ET

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 7, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced that the U.S. Food and Drug Administration (FDA) has approved EKTERLY® (sebetralstat), a novel plasma kallikrein inhibitor, for the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older. EKTERLY is the first and only oral on-demand treatment for HAE.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20250702871458/en/

EKTERLY Logo

"The FDA approval of EKTERLY is a defining moment for people living with HAE," said Ben Palleiko, CEO of KalVista. "EKTERLY enables people to treat attacks the moment symptoms begin, wherever they are. This approval affirms the strength of our science and deep commitment to the HAE community. I am profoundly grateful to the KalVista team for their dedication and perseverance, and to the patients and healthcare providers, as well as the HAEA and HAEi, for making this possible. EKTERLY has the potential to become the foundational treatment for HAE and our focus now is on delivering it to the people who need it."

"As the first orally administered on-demand therapy for HAE attacks, EKTERLY provides patients and physicians with an important and welcome advance in HAE treatment options," said Anthony J. Castaldo, chief executive officer of the U.S. Hereditary Angioedema Association.

Prior to EKTERLY's approval, all on-demand HAE treatment options approved in the U.S. required intravenous or subcutaneous administration, which carries a significant treatment burden.[1] Even with the use of long-term prophylaxis as a preventative therapy, most people living with HAE continue to have unpredictable attacks and require ready access to on-demand medication.[1]

"This is an important moment for patients, giving people living with HAE a treatment option that could provide greater independence and control over managing their condition," said Marc A. Riedl, MD, Professor of Medicine and Clinical Director, U.S. Hereditary Angioedema Association Center at the University of California, San Diego, and an investigator for the KONFIDENT phase 3 trial. "Until now, on-demand treatment relied on injectable subcutaneous or intravenous administration, often resulting in delayed intervention. Having an oral option empowers patients to treat attacks early, which aligns with treatment guidelines and advances our goal as physicians to reduce the overall burden of disease."

The efficacy and safety of EKTERLY was established by the results from KalVista's phase 3 KONFIDENT clinical trial, which was the largest clinical trial program 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.[2] The trial randomized 136 HAE patients from 66 clinical sites across 20 countries. These results were further supported by the more real-world KONFIDENT-S open-label extension trial, which as of September 2024, showed that EKTERLY enabled patients to treat attacks in a median of 10 minutes following onset. The most recent data from KONFIDENT-S shows that beginning of symptom relief occurred in a median of 1.3 hours among attacks involving the larynx, the abdomen, and for breakthrough attacks among patients receiving long-term prophylaxis. The safety profile of EKTERLY 600 mg in KONFIDENT-S, in a much larger number of attacks (>1700), was consistent with that observed in KONFIDENT.

KalVista will launch EKTERLY in the U.S. immediately and physicians can begin writing prescriptions today. As part of the Company's commitment to supporting patients, KalVista has established KalVista Cares™, a comprehensive patient support program that offers personalized services and resources for eligible individuals. This includes assistance with navigating insurance coverage, access support, and ongoing help throughout the treatment journey.

For more information, visit EKTERLY.com.

Conference Call and Webcast
KalVista will host a live conference call and webcast to discuss the FDA approval of EKTERLY today, July 7, 2025, at 8:30 a.m. ET. The webcast will be accessible through the Investors section of the Company's website at ir.kalvista.com. A replay will be available shortly after the conclusion of the live event.

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 therapy approved by the U.S. FDA for the treatment of acute attacks of hereditary angioedema (HAE) in people 12 years of age 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.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is EKTERLY® (sebetralstat)?
EKTERLY is a prescription medicine used to treat sudden (acute) attacks of hereditary angioedema (HAE) in adults and children aged 12 years of age and older. It is not known if EKTERLY is safe and effective in children under 12 years of age.

IMPORTANT SAFETY INFORMATION

Before taking EKTERLY, tell your healthcare provider about all of your medical conditions, including if you:

- **Are pregnant or planning to become pregnant. It is not known if EKTERLY can harm your unborn baby.**
- **Are breastfeeding or plan to breastfeed. It is not known if EKTERLY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking EKTERLY.**
- **Have liver problems.**

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking EKTERLY with certain other medicines can cause side effects or affect how well EKTERLY or the other medicines work. Especially tell your healthcare provider if you take any of the following, as their use with EKTERLY is not recommended: itraconazole, phenytoin, efavirenz.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

What are the possible side effects of EKTERLY?

The most common side effects of EKTERLY include headache. For more information, ask your healthcare provider or pharmacist. Talk to your doctor for medical advice about side effects.

You are encouraged to report side effects related to KalVista products by calling 1-855-258-4782. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit **www.fda.gov/medwatch** or call **1-800-FDA-1088.**

Please click here for full Prescribing Information, including Patient Information.

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, 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. 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 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.

[1]Busse PJ, et al. *J Allergy Clin Immunol Pract*. 2021;9(1):132–150.e3. doi:10.1016/j.jaip.2020.08.046.

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

View source version on businesswire.com: https://www.businesswire.com/news/home/20250702871458/en/

Ryan Baker
Head, Investor Relations
(617) 771-5001
ryan.baker@kalvista.com

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

Source: KalVista Pharmaceuticals, Inc.