KalVista Pharmaceuticals Receives Positive CHMP Opinion for Sebetralstat for the Treatment of Hereditary Angioedema Attacks

Jul 25, 2025

If approved, sebetralstat will be the first and only oral on-demand treatment for HAE in the European Union (EU)

European Commission decision expected by early October 2025

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 25, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization for sebetralstat, a novel oral plasma kallikrein inhibitor, for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older. The European Commission (EC) final decision is expected by early October.

"This positive CHMP opinion is an important step forward for people living with HAE in Europe, where there remains a high need for effective, easy-to-administer on-demand treatments," said Ben Palleiko, CEO of KalVista. "Coming just weeks after regulatory approvals in the US and UK, this milestone highlights the potential of sebetralstat to transform how HAE is managed globally. Sebetralstat is expected to become the first and only oral on-demand treatment for HAE available in Europe, bringing forward a new treatment approach that enables adherence to guidelines and empowers people to treat attacks quickly, wherever they occur."

The CHMP based its opinion on results from the phase 3 KONFIDENT clinical trial, which was the largest clinical trial ever conducted in HAE. Data from KONFIDENT was published in the *New England Journal of Medicine* in May 2024, showing that sebetralstat 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.

"Access to on-demand treatments that offer easy self-administration and rapid symptom relief is critical for patients living with HAE," said Emel Aygören-Pürsün, M.D., Assistant Professor, Internal Medicine and Hemostaseology, Department for Children and Adolescents, University Hospital Frankfurt. "Until now, on-demand therapies for HAE attacks required parenteral administration via injections. The positive CHMP opinion for sebetralstat is an essential move toward a novel, long-awaited oral on-demand option that could help patients treat attacks early and independently, as advocated by guidelines, with the goal of improving outcomes and normalizing lives."

Sebetralstat is approved in the United States and United Kingdom under the brand name EKTERLY® for the treatment of HAE attacks in people 12 years of age and older. It is currently under review with regulatory authorities in Japan as well as multiple other territories.

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 Sebetralstat
Sebetralstat is a novel plasma kallikrein inhibitor approved in the United States and United Kingdom for the treatment of acute attacks of hereditary angioedema (HAE) in people 12 years of age and older. It is the first and only oral on-demand treatment for HAE. With ongoing studies exploring its use in children aged two to 11 and multiple regulatory applications under review in key global markets, sebetralstat has the potential to become the foundational therapy for HAE management worldwide.

U.S. 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, including approval by the EC, our expectations about the timing of the EC's final decision, 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, 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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[1]Riedl MA, et al. *Oral sebetralstat for on-demand treatment of hereditary angioedema attacks. N Engl J Med.* 2024;391(1):32–43.

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