# KalVista Pharmaceuticals Presents New Data Highlighting the Potential of EKTERLY® (sebetralstat) to Transform On-Demand Hereditary Angioedema Treatment in Europe

Oct 06, 2025

*Findings from KONFIDENT and KONFIDENT-S show rapid, effective treatment of HAE attacks among European participants; patient survey highlights barriers linked to injectable therapies*

FRAMINGHAM, Mass. & SALISBURY, England--(BUSINESS WIRE)--Oct. 6, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced new data from its KONFIDENT and KONFIDENT-S studies of EKTERLY® (sebetralstat), the first and only oral on-demand treatment for hereditary angioedema (HAE), presented at the 20th German Allergy Congress in Düsseldorf, Germany from October 2–4, 2025. Across multiple ePoster presentations, EKTERLY demonstrated the ability to rapidly halt the progression of HAE attacks, deliver fast symptom relief and address key barriers associated with injectable therapies. Additional survey findings from German patients further highlight the urgent need for access to innovative on-demand HAE treatments across Europe.

"The data presented at DGAKI underscore the transformative potential of EKTERLY for people living with HAE and highlight the urgent need for innovation across Europe," said Paul Audhya, MD, MBA, Chief Medical Officer of KalVista. "As we've seen in the US, patients in Germany delay or avoid on-demand treatment due the challenges associated with injectable on-demand treatments, including injection-site reactions and the inability to readily access medication. An oral on-demand treatment has the ability to empower patients to better manage their condition, enabling earlier treatment of more attacks. With EKTERLY now approved in the European Union, we look forward to bringing this innovation to more people living with HAE—beginning with a launch in Germany this quarter followed by additional European launches in 2026 and beyond."

**Barriers to Timely Treatment of Hereditary Angioedema Attacks in German Patients** was presented by Thomas Buttgereit, MD, Specialist in Dermatology and Venereology, Additional qualification in Allergology, Head of the Clinical Trial Center, Institute of Allergology, Charité-Universitätsmedizin Berlin, corporate member of Freie Universitätsmedizin Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Immunology and Allergology, Berlin, Germany.

- The survey included 49 German respondents who treated one or more HAE attack with an approved on-demand therapy within the prior three months
- Mean time to treatment: 3.9 hours; only 18% of patients treated within one hour of attack onset; delays in treatment were associated with longer attack durations
- Injection site reactions were experienced by 53% of respondents, including 33% of those receiving intravenous treatment and 94% receiving subcutaneous treatment

"These survey findings reinforce what we also see in clinical practice: too many patients delay treatment because of the challenges associated with injectable on-demand therapies," said Dr. Buttgereit. "These delays not only prolong suffering but can increase the risk of severe outcomes. An oral on-demand treatment like sebetralstat could address key barriers and empower patients to treat earlier to ultimately improve outcomes."

**Time to End of Progression of Hereditary Angioedema Attacks Treated with Sebetralstat** was presented by Markus Magerl, MD, Professor of Dermatology and Allergy, Institute of Allergology, Charité-Universitätsmedizin Berlin, corporate member of Freie Universitätsmedizin Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Immunology and Allergology, Berlin, Germany.

- Sebetralstat halted attack progression in a median of 20 minutes across both KONFIDENT-S and KONFIDENT trials
- Early stopping of HAE attack progression reduced the morbidity associated with HAE attacks

"These data are very compelling. In both the pivotal KONFIDENT trial and the KONFIDENT-S extension, sebetralstat consistently stopped attack progression in under 20 minutes," said Dr. Magerl. "For people living with hereditary angioedema, halting an attack early is critical to minimize severity and reduce morbidity. The ability to achieve such rapid control across a broad range of attacks represents a meaningful step forward in the acute treatment of HAE."

**Sebetralstat for On-demand Treatment of Hereditary Angioedema Attacks in European Participants: Interim Analysis from KONFIDENT-S** was presented by Petra Staubach, MD, Senior Physician, Managing Director Clinical Research Center, Department of Dermatology and Allergy, University Medical Center Mainz, Mainz, Germany.

- The KONFIDENT-S interim analysis included 69 participants from 15 European countries who collectively treated 999 attacks with sebetralstat
- Sebetralstat enabled rapid treatment of HAE attacks and was well-tolerated among European patients:
  - Median time to treatment: 16 minutes; 10 minutes in adolescents (12-17 years)
  - 35% of attacks were still mild at the time of treatment
  - Median time to beginning of symptom relief: 1.6 hours

Links to all presentations can be found on the KalVista website under Publications.

**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 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.

**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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20251006039455/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.