



KalVista Pharmaceuticals Medical Congress Presentations Highlight Potential of Sebetrastat to Redefine Hereditary Angioedema Management

Jun 02, 2025

–Attack progression halted in median 19.8 minutes after treatment with sebetrastat in both KONFIDENT and KONFIDENT-S trials–

–Sebetrastat data demonstrated rapid relief and resolution of severe HAE attacks–

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jun. 2, 2025-- [KalVista Pharmaceuticals](#), Inc. (Nasdaq: KALV) today announced new sebetrastat findings related to time to end of progression of hereditary angioedema (HAE) attacks, and the effectiveness of treatment of attacks considered the most debilitating by patients, mucosal attacks, and attacks that have progressed in severity after a treatment delay. These data were presented at two congresses taking place concurrently: the 14th C1-inhibitor Deficiency & Angioedema Workshop in Budapest, Hungary, and the Eastern Allergy Conference (EAC) in Palm Beach, Florida, from May 29–June 1, 2025.

Time to End of Progression of Hereditary Angioedema Attacks Treated with Sebetrastat was presented by William Lumry, M.D., Clinical Professor of Internal Medicine at the University of Texas Southwestern Medical School in Dallas and Director at Allergy and Asthma Research Associates, Dallas, Texas, United States.

- Time to end of attack progression (n=1591 attacks) in KONFIDENT-S: median 19.8 minutes
- Results from the open-label extension (KONFIDENT-S) aligned closely with the pivotal phase 3 trial, KONFIDENT, reinforcing the rapid effect of sebetrastat after absorption

“Stopping the progression of an HAE attack as early as possible is paramount to mitigating its impact on patients,” said Dr. Lumry. “In both the KONFIDENT and KONFIDENT-S studies, sebetrastat halted attack progression in a median time of 19.8 minutes. As prior data have demonstrated near-complete plasma kallikrein inhibition 15 minutes after treatment, this analysis reveals that attacks are halted minutes after absorption. The consistency of findings across the KONFIDENT and KONFIDENT-S trials underscores the potential of sebetrastat as an effective and rapid-acting on-demand treatment for HAE attacks.”

Effectiveness of sebetrastat for the on-demand treatment of mucosal hereditary angioedema attacks: interim analysis from KONFIDENT-S was presented by Henriette Farkas, M.D., PhD, DSc, Professor of Allergology and Clinical Immunology at Semmelweis University and Head of the Hungarian Angioedema Center of Reference and Excellence, Budapest, Hungary.

- Patients were able to self-administer sebetrastat quickly, with a median time to treatment of 20 minutes for abdominal attacks and 11.5 minutes for laryngeal attacks
- The median time to beginning of symptom relief was 1.3 hours for both abdominal and laryngeal attacks
- Of attacks reaching symptom relief within 12 hours, 96% did so before or without the need for an additional sebetrastat administration
- Sebetrastat was well-tolerated, even in laryngeal attacks, with no reported difficulties swallowing the oral tablet

“Mucosal HAE attacks, particularly those affecting the larynx, are a significant concern for patients and clinicians due to the risk of rapid progression and severe consequences, including the possibility of asphyxiation if left untreated,” said Dr. Farkas. “These interim data from KONFIDENT-S demonstrate that sebetrastat provided rapid relief and resolution of both abdominal and laryngeal attacks with a favorable safety profile. Patients were able to self-administer sebetrastat very early in the course of an attack, when most attacks were still mild or moderate in severity.”

Effectiveness of Sebetrastat for Severe or Very Severe Hereditary Angioedema Attacks in KONFIDENT-S was presented by H. Henry Li, M.D., Director of Immunology at the Institute for Asthma and Allergy, Wheaton, Maryland, United States.

- Sebetrastat was used to treat 76 attacks that had progressed to severe or very severe after a median of 2.16 hours from attack onset, demonstrating its utility in more advanced stages of HAE attacks
- The median time to beginning of symptom relief for these attacks was 1.36 hours, with reduction in attack severity and substantial reduction of symptom burden in a median of 1.77 hours and 9.15 hours, respectively

“When attacks are not treated early in accordance with guidelines, they can escalate and become severe,” said Dr. Li. “We conducted this analysis of KONFIDENT-S to assess the utility of sebetrastat in more advanced stages of attacks that were associated with delayed treatment. Sebetrastat delivered symptom relief in a median time of 1.36 hours, reinforcing its potential as an on-demand treatment for challenging attack scenarios.”

“These new data underscore the potential of sebetrastat to fundamentally change HAE attack management,” stated Paul Audhya, M.D., MBA, Chief Medical Officer of KalVista. “Even in real-world, high-stakes scenarios—be it mucosal attacks or severe attacks due to delayed treatment—sebetrastat consistently delivered rapid and reliable relief. The uniformity of these results, paired with an oral tablet formulation, solidifies our belief that sebetrastat can empower patients to act swiftly and recover quickly. We remain committed to bringing this innovative therapy to the HAE community as quickly as possible.”

Links to all presentations can be found on the KalVista website under [Publications](#).

About Sebetrastat

Sebetrastat is an investigational, novel oral plasma kallikrein inhibitor for the treatment of hereditary angioedema (HAE). We have filed multiple

regulatory applications seeking approval of sebetralstat as the first oral, on-demand treatment for HAE in individuals aged 12 and older, with ongoing studies exploring its use in children aged 2 to 11. If approved, sebetralstat has the potential to become the foundational therapy for HAE management worldwide.

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. All currently approved on-demand treatment options require either intravenous or subcutaneous administration.

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. Our lead investigational product is sebetralstat, a novel, oral, on-demand treatment for hereditary angioedema (HAE). Sebetralstat is under regulatory review by the U.S. FDA, with a PDUFA goal date of June 17, 2025. In addition, we have completed Marketing Authorization Applications for sebetralstat to the European Medicines Agency and multiple other global regulatory authorities.

For more information about KalVista, please visit www.kalvista.com or follow us on social media at [@KalVista](https://twitter.com/KalVista) and [LinkedIn](https://www.linkedin.com/company/kalvista).

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, timing or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our KONFIDENT-S and KONFIDENT-KID trials, and to obtain regulatory approvals for sebetralstat and other candidates in development, the success of any efforts to commercialize sebetralstat, the ability of sebetralstat and other candidates in development to treat HAE or other diseases, 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, 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20250602100361/en/): <https://www.businesswire.com/news/home/20250602100361/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.