



KalVista Pharmaceuticals Shares Latest Sebetralstat Findings at the American Academy of Allergy, Asthma & Immunology 2025 Annual Meeting

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–Sebetralstat enabled prompt treatment of laryngeal HAE attacks with median time of 1 hour and 16 minutes to onset of symptom relief–

–Pooled data analysis showed adolescents treated with sebetralstat in median 4 minutes compared to over 3 hours in surveys –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Mar. 3, 2025-- [KalVista Pharmaceuticals](#), Inc. (Nasdaq: KALV) today announced the presentation of novel sebetralstat data related to laryngeal hereditary angioedema (HAE) attacks and adolescents with HAE at the American Academy of Allergy, Asthma & Immunology (AAAAI) / World Allergy Organization (WAO) 2025 Joint Congress taking place in San Diego, CA from February 28–March 3, 2025.

“The growing body of data from the KONFIDENT-S study consistently demonstrate that sebetralstat enabled early treatment and fast symptom relief from HAE attacks, regardless of age, attack location, or severity,” said Ben Palleiko, CEO of KalVista. “This is especially critical for vulnerable populations, such as those experiencing laryngeal attacks or adolescents whose only approved options are injectable on-demand treatments. Sebetralstat, if approved, would be the first oral on-demand treatment for HAE attacks, with the potential to address some of the most significant unmet needs in HAE and become the foundational therapy for HAE management.”

Effectiveness of Sebetralstat for the On-demand Treatment of Laryngeal Hereditary Angioedema Attacks: Interim Analysis from KONFIDENT-S was presented by Jonathan Bernstein, MD, FAAAAI, Professor of Clinical Medicine in the Department of Internal Medicine, Division of Allergy and Immunology at the University of Cincinnati College of Medicine; Partner at Bernstein Allergy Group and Clinical Research Center.

- 32 laryngeal attacks were treated with sebetralstat (September 14, 2024 cutoff)
- Median time to treatment with sebetralstat: 11.5 minutes after attack onset
- Median time to beginning of symptom relief: 1.27 hours
- 96% of those achieving beginning of symptom relief within 12 hours did so with a single dose
- No reports of difficulty swallowing film-coated tablet

“Laryngeal attacks are often unpredictable and can progress rapidly, potentially leading to asphyxiation,” said Dr. Bernstein. “Any attack involving the larynx must be considered a medical emergency and treated as quickly as possible after onset before symptoms worsen. Despite this, recent U.S. survey data showed the mean time to treatment for laryngeal attacks with injectable on-demand therapies was 2.5 hours. Patients in the KONFIDENT-S study treated their attacks with sebetralstat, with a median time to treatment of just under 12 minutes, followed by symptom relief with a median time of 1 hour and 16 minutes. These results show that in the time it takes many patients to decide whether to treat, prepare and administer an injectable on-demand treatment, most patients in KONFIDENT-S were already experiencing symptom relief. If approved, sebetralstat could represent a therapeutic advance over injectables.”

On-demand Treatment of Hereditary Angioedema Attacks with Sebetralstat In Adolescents: Pooled Analysis From KONFIDENT And KONFIDENT-S was presented by Professor Danny Cohn, Head of the HAE clinic at Amsterdam University Medical Center (UMC), University of Amsterdam, Netherlands.

- 149 attacks were treated with sebetralstat across KONFIDENT/KONFIDENT-S (September 14, 2024 cutoff)
- Median time from attack onset to treatment: 4 minutes
- Safety and efficacy consistent with adults; no serious adverse events or adverse events leading to discontinuation

“Adolescents face considerable challenges in treating their HAE attacks, with substantially longer delays to treatment than adults. This challenge is compounded in the U.S., where the only approved treatments options require either intravenous administration or subcutaneous administration by an HCP,” said Dr. Cohn. “The pooled data from the KONFIDENT and KONFIDENT-S studies show that adolescents administered sebetralstat in a median of 4 minutes after attack onset, which compares favorably to a median of 3 hours and mean of 5.2 hours based on international survey data that was presented at AAAAI by Dr. Paula Busse titled, ‘**Burden of Injectable On-Demand Treatment for Hereditary Angioedema Attacks in Adolescents**’. Importantly, the safety and effectiveness of sebetralstat were consistent with what was observed in adults. The portability and ease of administration of sebetralstat, along with the elimination of injection-site reactions and associated anxiety, has the potential to bring transformative change to this underserved patient population.”

Links to all posters and presentations shared at AAAAI can be found on the KalVista website under [Publications](#).

About Sebetralstat

Sebetralstat 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](#) and [LinkedIn](#).

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.

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