KalVista Pharmaceuticals Presents New Sebetralstat Data at the Western Society of Allergy, Asthma & Immunology 2025 Annual Meeting

Feb 10, 2025

– Claims data show 40% of patients on long-term prophylaxis have gaps in prescription refills, leading to greater on-demand use and higher rate of LTP discontinuation-

-Data from KONFIDENT-S show patients on LTP average 1.7 HAE attacks per month and symptom relief for treated attacks in median 1.3 hours -

–Results confirm sebetralstat effective for on-demand treatment of attacks regardless of type of LTP therapy used, including an all-oral regimen–

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Feb. 10, 2025-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today announced the presentation of novel data related to long-term prophylaxis and sebetralstat at the Western Society of Allergy, Asthma & Immunology (WSAAI) 2025 Annual Meeting taking place in Waimea, HI from February 9-13, 2025.

Raffi Tachdjian, MD, MPH, Associate Clinical Professor of Medicine and Pediatrics in the Division of Allergy and Clinical Immunology at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA), presented data on the **Impact of Long-Term Prophylaxis (LTP) Adherence in Hereditary Angioedema Patients: Results of a Claims Database Analysis.**

- According to a US commercial claims analysis, nearly 40% of HAE patients who initiated LTP had substantial refill gaps in claims over 12 months, with more than half of those discontinuing LTP.
- For patients with substantial refill gaps, which increase the likelihood of non-adherence, on-demand claims remained unchanged before and after one year of starting LTP.

“Despite guidelines emphasizing regular assessment of patients using LTP to confirm efficacy and safety of their therapy, these data suggest many patients experience substantial lapses in refilling their LTP, which may reflect non-adherence,” said Dr. Tachdjian. “We saw no decrease in on-demand claims for patients with LTP refill gaps. These findings are important as most HAE patients in the US now receive LTP, and a greater focus on monitoring appears warranted, as LTP effectiveness is not a given. These data may also help to explain why on-demand treatment volumes in HAE have remained steady despite the advent of several effective subcutaneous and oral LTP options since 2017.”

Marc A. Riedl, MD, Professor of Medicine and Clinical Director, US Hereditary Angioedema Association Center at the University of California, San Diego, presented data on the **Safety and Effectiveness of Sebetralstat in Patients with Hereditary Angioedema Receiving Long-Term Prophylaxis: Interim Analysis from the KONFIDENT-S Open-Label Study.**

- Participants receiving LTP treated 382 attacks with sebetralstat (mean 1.7 attacks per month), of which more than half involved the abdomen and/or larynx.
- Sebetralstat enabled early treatment (median 6 minutes) and early symptom relief (median 1.3 hours), and was well-tolerated, regardless of LTP mechanism of action or route of administration.

“Treatment guidelines recommend that patients with HAE should consider treating all attacks regardless of LTP use and should treat attacks as early as possible,” noted Dr. Riedl. “These interim results suggest that, if approved, sebetralstat could be a safe and effective oral on-demand treatment for breakthrough attacks, regardless of severity, location, or type of LTP used.”

Michael E. Manning, MD, allergist-immunologist at Allergy, Asthma and Immunology Associates, Ltd., Scottsdale, Arizona and Past President of WSAAI, presented **Sebetralstat for the Treatment of HAE Attacks in Patients Receiving Berotralstat: Interim Analysis from the KONFIDENT-S Open-Label Study.**

- Participants receiving berotralstat treated 178 attacks with sebetralstat (mean 1.8 attacks per month).
- Sebetralstat enabled early treatment (median 20 minutes), early symptom relief (median 1.3 hours), and was well-tolerated with no increase in gastrointestinal side effects.

“In general, patients prefer oral treatments over injectables, underscoring the strong interest in oral options for HAE,” said Dr. Manning. “These results demonstrate that sebetralstat, when used as an oral on-demand treatment for attacks occurring among patients receiving berotralstat for LTP, enabled rapid treatment and symptom improvement. If approved, sebetralstat could transform the treatment landscape for physicians and patients who prefer to manage HAE without needles.”

“Injectable on-demand treatments have side effects and logistical obstacles that hinder adequate disease control and drive an over-reliance on LTP,” said Paul Audhya, MD, MBA, Chief Medical Officer of KalVista. “LTP does not, however, always yield the anticipated reductions in attacks, possibly due to adherence issues in a chronic lifelong setting. Sebetralstat has the potential to enable early treatment of attacks, thereby halting progression at an early stage and reducing morbidity, even among patients on LTP. By overcoming the barriers imposed by current injectable on-demand therapies, sebetralstat could shift the treatment paradigm and become the foundation of HAE management.”

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

About the KONFIDENT Phase 3 Trial
The KONFIDENT phase 3 clinical trial was a randomized, double-blind, 3-way crossover trial evaluating the safety and efficacy of sebetralstat 300 mg and 600 mg versus placebo for the on-demand treatment of HAE in adult and pediatric patients aged 12 years and older. The trial randomized 136

HAE patients from 66 clinical sites across 20 countries, making it the largest clinical trial ever conducted in HAE. In the trial, participants treated each eligible attack with up to two doses of study drug and treated up to three attacks over the course of the study. The trial included Type I and Type II HAE patients who had at least two documented HAE attacks 90 days prior to randomization and also included patients receiving long-term prophylaxis.

About the KONFIDENT-S Trial
KONFIDENT-S is an open-label extension trial with numerous real-world elements evaluating the long-term safety and efficacy of sebetralstat for the on-demand treatment of HAE attacks in adults and pediatric patients aged 12 years and older with HAE Type I or Type II. KalVista is transitioning ongoing trial participants to a novel oral disintegrating tablet (ODT) formulation to support a planned 2026 sNDA filing. If approved, the ODT formulation would provide people living with HAE with an alternative, novel option for oral, on-demand treatment.

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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250210755734/en/

Jenn Snyder
Vice President, Corporate Affairs
(617) 448-0281
jsnyder@kalvista.com

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

Source: KalVista Pharmaceuticals, Inc.