KalVista Pharmaceuticals Announces Early Completion of Enrollment in KONFIDENT-KID Pediatric HAE Trial

Mar 25, 2025

Initial target enrollment surpassed in fewer than seven months; trial expanded due to high demand

First data presentation expected before year-end; sNDA submission by mid-2026

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Mar. 25, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced the completion of enrollment in the open-label KONFIDENT-KID clinical trial of sebetralstat, an investigational, novel, oral plasma kallikrein inhibitor, in pediatric patients between the ages of two and 11 with hereditary angioedema (HAE).

“We're proud to share that we achieved target enrollment in our KONFIDENT-KID trial a full year ahead of schedule and expanded the trial size due to overwhelming interest,” said Ben Palleiko, CEO of KalVista. "The high level of participation from families living with HAE underscores the significant need for an oral treatment option for this population. Even with this larger trial size, we anticipate that initial results will be shared later this year, with an sNDA expected to be filed by mid-2026.”

Originally designed to enroll 24 pediatric patients, the trial was met with high demand and will ultimately include approximately 36 patients between the ages of two and 11 across seven countries in North America, Europe, and Asia. KONFIDENT-KID will collect safety, pharmacokinetic, and efficacy data for up to one year and features a proprietary pediatric oral disintegrating tablet (ODT) formulation of sebetralstat.

Currently, the only on-demand treatment for HAE patients of this age range approved in the U.S. is administered intravenously, highlighting a critical need for new therapeutic options. If approved, sebetralstat would be the first oral on-demand therapy for pediatric patients aged two to 11 years and only the second FDA-approved on-demand therapy of any type in this population.

For more information about KONFIDENT-KID, please visit clinicaltrials.gov.

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

Molly Cameron
Director, Corporate Communications
(857) 356-0164
molly.cameron@kalvista.com

Source: KalVista Pharmaceuticals, Inc.