



KalVista Initiates KONFIDENT-KID Trial for On-demand Treatment of Hereditary Angioedema Attacks with Sebetralstat in Children Aged 2 to 11

Jun 27, 2024

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jun. 27, 2024-- [KalVista Pharmaceuticals, Inc.](#) (NASDAQ: KALV), today announced the initiation of the open-label KONFIDENT-KID clinical trial of sebetralstat, a novel, oral, plasma kallikrein inhibitor, in pediatric patients with hereditary angioedema (HAE). The trial will enroll approximately 24 children aged 2 to 11 years across seven countries in North America, Europe and Asia. KONFIDENT-KID will collect safety, pharmacokinetic, and efficacy data for each patient for up to one year and will feature a proprietary pediatric oral disintegrating tablet (ODT) formulation of sebetralstat.

"We are pleased to announce that the KONFIDENT-KID trial has started earlier than previously anticipated," said Ben Palleiko, Chief Executive Officer of KalVista. "This timeline reflects the high level of excitement among physicians, caregivers, and our patient advocacy partners regarding the potential of sebetralstat to treat children with HAE. Currently, the only approved on-demand treatment for this population is administered intravenously, making this a critical area of unmet need for people living with HAE."

If approved, sebetralstat would be the first oral on-demand therapy in pediatric patients aged 2 – 11 years, and only the second FDA-approved on-demand therapy of any type in this population.

For more information on KONFIDENT-KID, please visit our listing on [clinicaltrials.gov](#).

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a global pharmaceutical company focused on the development and delivery of oral medicines for diseases with significant unmet need. KalVista disclosed positive phase 3 data for the KONFIDENT trial for its oral, on-demand therapy sebetralstat in February 2024 and submitted an NDA with the FDA in June 2024. KalVista expects to file for approval in the UK, Europe, and Japan later in 2024.

For more information about KalVista, please visit [www.kalvista.com](#).

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 or other international regulatory agencies, our expectations about safety and efficacy of our product candidates, our ability to obtain regulatory approvals for sebetralstat and other candidates in development within our expected timelines or at all, our success in engaging with potential commercial partners, the success of any efforts to commercialize sebetralstat, the ability of sebetralstat and other candidates in development to treat HAE or other diseases, our ability to commence pediatric trials of sebetralstat and develop an ODT formulation, the future progress and potential success of our oral Factor XIIa program, our ability to reduce spending on discovery and preclinical activities, and our expectation to become cash flow positive. 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, 2023, 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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