KalVista Announces Validation of Marketing Authorization Application by the European Medicines Agency for Sebetralstat for Hereditary Angioedema

Aug 15, 2024

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Aug. 15, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today announced that the European Medicines Agency (EMA) has validated the submission of a Marketing Authorization Application (MAA) for sebetralstat, a novel, investigational oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE). This application will now be reviewed by the EMA's Committee for Medicinal Products for Human Use (CHMP) under the centralized licensing procedure for all 27 Member States of the European Union, as well as the EEA countries Norway, Iceland and Liechtenstein.

"The validation of this MAA, which we submitted in July, brings us another step closer to our goal of delivering sebetralstat on a global scale to people living with HAE," said Ben Palleiko, Chief Executive Officer of KalVista. "If approved, sebetralstat would be the first oral, on-demand treatment for HAE in Europe. We believe it has the potential to become the foundational treatment for this disease, addressing many underlying unmet needs in the community."

The MAA submission was supported by previously disclosed results, including data from the KONFIDENT phase 3 clinical trial and ongoing KONFIDENT-S open label extension trial. Sebetralstat met the primary endpoint for its phase 3 trial with both 300 mg and 600 mg formulations achieving the beginning of symptom relief significantly faster than placebo ($p<0.0001$ for 300 mg, $p=0.0013$ for 600 mg) and was well-tolerated, with a safety profile similar to placebo. In KONFIDENT-S, sebetralstat enabled patients to treat attacks earlier with a median time from attack onset to treatment of 9 minutes and a consistent safety and efficacy profile including a median time to beginning of symptom relief for laryngeal attacks of 1.3 hours.

Detailed data from KONFIDENT were recently published in *The New England Journal of Medicine*. Data from KONFIDENT and KONFIDENT-S were also presented at the European Academy of Allergy and Clinical Immunology Congress 2024. In June 2024, KalVista submitted a New Drug Application (NDA) for sebetralstat to the U.S. Food & Drug Administration.

KalVista intends to present EU data from the KONFIDENT trial, as well as additional data from KONFIDENT-S, at the 7th Bradykinin Symposium on September 4-6, 2024 in Berlin, Germany.

KalVista also recently announced initiation of the KONFIDENT-KID clinical trial, to evaluate the safety and efficacy of sebetralstat in a pediatric population aged 2-11 years.

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 a total of 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 1 and type 2 HAE patients who had at least two documented HAE attacks in 90 days prior to randomization, including 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 on-demand treatment of HAE attacks in adult patients and pediatric patients aged 12 years and older with HAE Type I or Type II. KalVista plans to transition ongoing participants in the trial to an oral disintegrating tablet (ODT) formulation in Q4 2024 to support a planned 2026 sNDA filing of this additional formulation. If approved, the ODT formulation would provide people living with HAE an alternative, novel option for oral, on-demand treatment.

About the KONFIDENT-KID Trial

KONFIDENT-KID is an open label trial enrolling 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. If approved, sebetralstat would be the first oral on-demand therapy for this age group, and only the second FDA-approved on-demand therapy of any type for this population.

About Sebetralstat

Discovered and developed entirely by the scientific team at KalVista, sebetralstat is a novel, investigational oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE). Sebetralstat received Fast Track and Orphan Drug Designations from the U.S. FDA, as well as Orphan Drug Designation and an approved Pediatric Investigational Plan from the European Medicines Agency (EMA).

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

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 announced positive phase 3 data from the KONFIDENT trial for its oral, on-demand therapy sebetralstat in February 2024, and submitted an NDA to the FDA in June 2024 and an MAA to the EMA in July 2024. KalVista expects to file for approval in the UK, Japan, and other countries 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, 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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