KalVista Submits New Drug Application to FDA for Sebetralstat as First Oral On-demand Treatment for Hereditary Angioedema

Jun 18, 2024

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jun. 18, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today announced the submission of a New Drug Application (NDA) for U.S. Food and Drug Administration (FDA) review of sebetralstat, a novel investigational oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE) attacks in adults and pediatric patients aged 12 years and older.

“This NDA submission represents a pivotal moment not only for our company, but for the entire HAE community as we seek to bring an important therapeutic advancement through the first-ever, oral on-demand treatment for HAE,” said Ben Palleiko, Chief Executive Officer of KalVista. “This achievement is the culmination of the entire KalVista team’s long-term efforts, with the critical support of people living with HAE, as well as our partnerships with the HAE scientific community, the HAEA and HAEi patient advocacy organizations, regulators and other stakeholders, that demonstrate our commitment to addressing persistent unmet needs for people living with this rare disease. If approved, we believe sebetralstat could become a foundational treatment that will transform the way people living with HAE treat their disease.”

The NDA submission is based on previously disclosed clinical trial results, including data from the KONFIDENT phase 3 clinical trial and the KONFIDENT-S extension trial. Sebetralstat met the primary endpoint in the 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). The median time to beginning of symptom relief was 1.61 hours with sebetralstat 300 mg (CI 1.28, 2.27), 1.79 hours with sebetralstat 600 mg (CI 1.33, 2.27) and 6.72 hours with placebo (CI 2.33, >12).

Consistent with previous studies, sebetralstat was well-tolerated, with a safety profile no different than placebo. There were no treatment-related serious adverse events (SAEs) observed. This favorable safety profile has been consistently observed in all clinical studies for sebetralstat to date.

The FDA has a 60-day filing review period to determine whether the NDA is complete and accepted for review. The Company currently anticipates receiving notification from the FDA on the status of the submission in September. KalVista intends to submit additional marketing authorization applications to other global health authorities throughout 2024.

If approved, sebetralstat would be the first oral, on-demand therapy for people living with HAE. The NDA filing includes patients aged 12-17 years, whom the Company believes have a particularly high level of unmet need because of the challenges of using injectable medications in that age group. KalVista plans to commence a pediatric trial (KONFIDENT-KID) in Q3 2024 that, if successful, would enable a future filing to extend this coverage to patients aged 2-11 years.

KalVista intends to present additional data from the KONFIDENT and KONFIDENT-S trials at the 2024 Annual Scientific Conference of the American College of Allergy, Asthma, and Immunology (ACAAI) Conference on October 24-28, 2024, in Boston, Massachusetts.

About the KONFIDENT Phase 3 Trial

The KONFIDENT phase 3 trial was a randomized, double blind, 3-way crossover clinical trial evaluating the safety and efficacy of sebetralstat 300 mg and 600 mg versus placebo for the on-demand treatment of HAE in adults and pediatrics 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.

About the KONFIDENT-S Trial

The KONFIDENT-S trial is an open label extension study evaluating the long-term safety and efficacy of sebetralstat for on-demand treatment of HAE attacks in adults and pediatrics aged 12 years and older with HAE Type I or Type II. KalVista is planning to transition ongoing participants in the trial to an oral disintegrating tablet (ODT) formulation in Q4 2024 to support a potential 2026 sNDA approval 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 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 disclosed positive phase 3 data for the KONFIDENT trial for its oral, on-demand therapy sebetralstat in February 2024. The Company 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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