



KalVista Pharmaceuticals Presents Additional Phase 3 KONFIDENT Data at the 2024 American Academy of Allergy, Asthma & Immunology Annual Meeting

Feb 26, 2024

- 94% of attacks required only one dose to achieve primary endpoint -*
- Further analyses demonstrate efficacy across all levels of attack severity -*
- Additional safety data reinforces flexibility of dosing -*

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Feb. 26, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors, today announced that it presented additional data on its phase 3 KONFIDENT trial for sebetralstat, including a more in-depth analysis of sebetralstat efficacy and safety at the 2024 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting taking place in Washington, DC.

The following late-breaking presentation occurred at AAAAI 2024:

- **Sebetralstat for On-demand Treatment of Hereditary Angioedema Attacks: Results of the Double-blind, Placebo-controlled Phase 3 KONFIDENT Trial:** Marc Riedl, Division of Rheumatology, Allergy and Immunology, University of California San Diego, San Diego, California, United States

Among the additional efficacy analyses from KONFIDENT presented during the poster session were the proportions of attacks reaching the primary (time to beginning of symptom relief) and key secondary endpoints (time to reduction in attack severity and time to complete attack resolution) without the use of a second dose. Proportions of attacks that reached the beginning of symptom relief without a second dose were 93.9% and 95.8% with sebetralstat 300 mg and 600 mg, respectively, while the proportions of attacks reaching a reduction in severity without a second dose were 90.9% and 95.9% with sebetralstat 300 mg and 600 mg, respectively. These proportions were 91.9% and 84.8% for complete attack resolution. Additional safety analyses demonstrated that the safety profiles associated with one dose or two doses of sebetralstat 300 mg or 600 mg were comparable to placebo.

Data presented as a supplement also showed that the median time to all endpoints was shorter for attacks with higher initial severity, at both dose levels. Median times to beginning of symptom relief for moderate attacks were 1.6 hours for 300 mg and 2.1 hours for 600 mg, and for severe attacks the median times were 1.4 and 1.5 hours, respectively. Similarly, time to reduction in attack severity was also shorter for attacks that were rated moderate or severe at baseline, with median times of 5.0 and 3.3 hours, respectively, for moderate attacks and 1.3 and 1.4 hours, respectively, for severe attacks.

"Given the unrestricted use of a second dose of oral sebetralstat in KONFIDENT, it was important to understand the proportion of attacks that achieved the primary and key secondary endpoints without a second dose. What we observed was that the vast majority of attacks that successfully met the three endpoints did so with a single dose of sebetralstat," said Marc A. Riedl, MD, Professor of Medicine and Clinical Director, US Hereditary Angioedema Association Center at the University of California, San Diego.

"If approved, we believe that a single dose of sebetralstat 300 mg would appear to be appropriate for most HAE attacks. However, the ability to dose flexibly depending on the characteristics of a specific attack is supported by the safety and tolerability observed with repeated dosing at both 300 mg and 600 mg," said Andrew Crockett, Chief Executive Officer of KalVista. "We believe that these additional efficacy and safety data only strengthen the case for sebetralstat to become the first, oral on-demand treatment available to the HAE community."

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

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors 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 anticipates submitting a new drug application to the U.S. FDA for sebetralstat in the first half of 2024 and expects to file for approval in Europe and Japan later in 2024. In addition, KalVista's oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve the treatment for people living with HAE and other diseases.

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 the KONFIDENT-S trial, 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, 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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