KalVista Pharmaceuticals Announces Phase 3 KONFIDENT Trial Milestone Achieved

November 13, 2023 at 6:30 AM EST

- Study completion activities underway; topline data expected early 2024 –

- Largest-ever HAE clinical trial meets on-treatment attack target –

- NDA submission remains on track for first half 2024 –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Nov. 13, 2023-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors, today provided clinical trial and regulatory updates for its lead program sebetralstat, in development as a potential oral on-demand therapy for hereditary angioedema (HAE).

Clinical Trial and Regulatory Updates:

- KalVista has achieved the targeted number of on-treatment attacks required to complete the phase 3 KONFIDENT trial. The trial is a cross-over study in which patients are intended to treat a total of three attacks: one each with 300 mg sebetralstat, 600 mg sebetralstat and placebo, given in a randomized sequence.
- Topline data readout is expected in early 2024, remaining on track for a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) in the first half of 2024. The Company also expects to file for approval in the European Union and Japan later in 2024.
- KONFIDENT randomized a total of 136 participants from 66 sites across 20 countries, making it the largest clinical trial ever conducted in HAE based on number of subjects. The enrolled patients are representative of the global HAE population and include participants 12 years of age and above, with or without long-term prophylaxis, with all attack locations eligible for treatment, including the larynx.
- In addition, the KONFIDENT-S open label extension study continues to enroll, and the Company expects it will provide a robust safety database to support the planned NDA filing. In total, more than 600 attacks have been treated across KONFIDENT and KONFIDENT-S, and KONFIDENT-S includes numerous patients who have taken multiple doses for treatment as well as short-term prophylaxis.

“We are excited to have reached the number of on-treatment attacks required for completion of KONFIDENT,” said Andrew Crockett, Chief Executive Officer of KalVista. “We have now initiated study closeout activities which enables topline data readout in early 2024, maintaining the timing of our planned NDA submission in the first half of 2024. We are grateful and highly encouraged by the overwhelming interest in this trial from people living with HAE and, if approved, we look forward to introducing a novel therapeutic that offers the potential to transform the treatment of this disease.”

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 is developing sebetralstat as an oral on-demand therapy for HAE and has achieved target enrollment for the phase 3 KONFIDENT clinical trial. 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.

For more information on the sebetralstat HAE on-demand Phase 3 KONFIDENT study, please visit www.konfidentstudy.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 sebetralstat and timing of clinical trials and results, including our Phase 3 KONFIDENT trial, our ability to commence clinical studies or complete ongoing clinical studies, 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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