KalVista Pharmaceuticals Provides Progress Updates on Sebetralstat Development

February 14, 2023

- Phase 3 KONFIDENT clinical trial passes 50% enrollment milestone -

- Topline data still expected in H2 2023 -

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Feb. 14, 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 multiple clinical trial and regulatory updates for its lead compound sebetralstat, as a potential oral on-demand therapy for HAE attacks.

Clinical Trial and Regulatory Updates:

- KalVista has enrolled more than 50% of the 114 targeted number of patients in the pivotal phase 3 KONFIDENT clinical trial. The trial will conclude once 84 of the patients enrolled complete the three-attack treatment sequence. As per previous guidance, topline data for the trial remains expected in the second half of 2023.
- KONFIDENT is currently enrolling patients at more than 50 active sites in 17 countries, and the KONFIDENT-S open label extension study also continues to enroll in accordance with plan.
- The Company recently received additional FDA regulatory guidance for the oral disintegrating tablet (ODT) formulation of sebetralstat that confirmed the requirements to support a supplemental NDA (sNDA) filing. The guidance from FDA included that no efficacy trials with the ODT formulation will be required prior to filing the supplemental NDA (sNDA) filing. KalVista anticipates that the ODT formulation will follow the expected initial launch formulation in the US and EU, although it may become the initial launch formulation in other geographies.
- KalVista also recently received guidance from the Japanese regulatory authority (PMDA) on the clinical development pathway to a regulatory submission in that country. KalVista will now be enrolling Japanese patients in both KONFIDENT and KONFIDENT-S to support the filing, and clinical sites for Japanese enrollment have been selected and start up activities are underway.

“We are very pleased with the recent progress of the sebetralstat development program,” said Andrew Crockett, Chief Executive Officer of KalVista. “We have already exceeded our recruitment target goals for KONFIDENT in the US, and recruitment outside the US continues to accelerate as new sites come online. We continue to believe that sebetralstat can fill an important unmet need for efficacious and safe oral, on-demand therapy, and we expect to be the first to provide this important therapeutic advance to people living with HAE.”

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 attacks and is enrolling 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 our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our Phase 3 KONFIDENT 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, 2022, 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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