KalVista Pharmaceuticals Announces Termination of KVD824 Phase 2 KOMPLETE Trial for Prophylactic Treatment of Hereditary Angioedema

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- Safety signals observed will not yield targeted product profile –

- No impact on Sebetralstat expected safety profile or Phase 3 KONFIDENT trial –

- Oral Factor XIIa program to become primary focus for HAE prophylaxis -

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Oct. 4, 2022-- 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 has terminated the KOMPLETE phase 2 clinical trial for KVD824 for the prevention of attacks in people with hereditary angioedema (HAE). This decision was based on the observation of liver enzyme (ALT/AST) elevations in multiple patients in all treatment groups of the trial. No patients had concomitant elevation of bilirubin levels and all were asymptomatic.

“The health and safety of participants in our clinical trials is of utmost importance to us,” said Andrew Crockett, Chief Executive Officer of KalVista. “We made the difficult decision to terminate KOMPLETE because we concluded that the emerging safety profile of the current formulation will not meet our requirements for a best-in-class oral prophylactic therapy. This termination conserves our financial resources and allows us to focus on continuing to advance sebetralstat through the ongoing phase 3 program and towards a planned 2024 NDA filing, as well as on our emerging oral Factor XIIa inhibitor program as a potential once daily prophylactic therapy for people with HAE.”

The KOMPLETE trial is a phase 2 clinical trial evaluating KVD824, an investigational oral plasma kallikrein inhibitor designed for the prevention of attacks in adults living with HAE. Patients in the trial were randomized to one of three treatment groups, each placebo controlled: 300 mg, 600 mg, 900 mg KVD824 (or placebo), all dosed twice daily. A total of 33 patients were enrolled in the trial, of which 7 patients experienced either Grade 3 or Grade 4 elevations of liver enzymes at timeframes ranging from two to twelve weeks. The elevations were noted in all treatment groups. One additional Grade 4 elevation was recorded in a patient at the baseline visit, prior to receiving study drug. KalVista will proceed to finalize the database of the trial and assess the unblinded data for efficacy and safety to determine the potential for any further development.

KalVista continues to recruit the phase 3 KONFIDENT trial assessing sebetralstat (formerly KVD900) as a potential oral, on-demand therapy for HAE attacks, with data anticipated in the second half of 2023. Sebetralstat is a distinct compound from KVD824, and no treatment related liver enzyme elevations in patients have been observed in any sebetralstat clinical studies, including in the ongoing Phase 3 KONFIDENT trial.

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 has developed a proprietary portfolio of novel, small molecule plasma kallikrein inhibitors initially targeting hereditary angioedema (HAE) and diabetic macular edema (DME). 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 treatment for people living with HAE. In DME, an intravitreally administered plasma kallikrein inhibitor, called KVD001, has completed a Phase 2 clinical trial.

For more information about KalVista, please visit www.kalvista.com.

For more information on the sebetralstat HAE on-demand Phase 3 KONFIDENT trial, 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, including the potential impact of COVID-19, 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 ability of sebetralstat and other candidates in development to treat HAE or DME, 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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