# KalVista Pharmaceuticals Announces Initiation of KONFIDENT-S Open Label Extension Study for Sebetralstat in Hereditary Angioedema

August 23, 2022

*- NDA-supporting study extension provides additional two years of treatment with sebetralstat to assess long-term safety and tolerability in HAE patients -*

*- Subtrial will assess sebetralstat profile in adolescent patients -*

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Aug. 23, 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 the initiation of the KONFIDENT-S open label extension (OLE) study for its ongoing Phase 3 KONFIDENT study of sebetralstat for the on-demand treatment of hereditary angioedema (HAE) attacks.

“Initiating this treatment extension represents another significant step in advancing sebetralstat towards an intended FDA filing following completion of the ongoing KONFIDENT Phase 3 trial in the second half of 2023,” said Andrew Crockett, Chief Executive Officer of KalVista. “We can now provide participating patients with up to two additional years of therapy with what we expect will be the first oral, on-demand treatment for HAE attacks. The data we collect in this trial will help us better understand the long-term safety profile of sebetralstat and may also inform future trials in younger patients.”

The KONFIDENT-S trial is evaluating sebetralstat, an oral plasma kallikrein inhibitor designed for the on-demand treatment of HAE attacks in adults living with HAE, and a subtrial will allow participation by adolescents 12-17 years of age. The trial will also evaluate sebetralstat for use as a short-term prophylaxis treatment prior to medical procedures.

Data from the KONFIDENT-S trial will be available in the second half of 2023 to support the Company’s planned NDA filing for sebetralstat in 2024. Initiation of this OLE study follows submission to the FDA of pivotal toxicology studies intended to support the eventual NDA filing.

For more information on the open-label extension study, please refer to NCT# NCT05505916.

**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. KVD824 is in development for prophylactic treatment of HAE, with the Phase 2 KOMPLETE clinical trial underway. 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. 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 study, please visit www.konfidentstudy.com.

For more information on the KVD824 HAE prophylaxis Phase 2 KOMPLETE study, please visit www.kompletestudy.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 and Phase 2 KOMPLETE clinical trials, and to obtain regulatory approvals for sebetralstat, KVD824 and other candidates in development, the ability of sebetralstat, KVD824 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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