KalVista Pharmaceuticals Announces Initiation of KVD900 Phase 3 KONFIDENT Clinical Trial

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-KONFIDENT to Evaluate KVD900 As First Oral On-Demand Therapy for HAE-

-KONFIDENT Designed to Support Broad Label for Treatment of All HAE Attacks-

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Mar. 7, 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 Phase 3 KONFIDENT clinical trial evaluating the efficacy and safety of KVD900 as the first potential oral, on-demand therapy for hereditary angioedema (HAE) attacks. This worldwide, double-blind, placebo-controlled crossover trial will evaluate the efficacy of two dose levels of KVD900 compared to placebo in adolescents and adults experiencing acute HAE attacks. KVD900 is the most advanced potential oral on-demand therapy for HAE in clinical development, and is intended to provide a substantial improvement over the current on-demand therapies for HAE attacks, which are all delivered by injection.

“Beginning the KONFIDENT trial represents a major milestone for KalVista,” said Andrew Crockett, Chief Executive Officer of KalVista. “We believe that KVD900 has the potential to transform the treatment paradigm for HAE patients experiencing acute attacks, whether they primarily treat with on-demand medications or use long-term prophylaxis. Based upon the results of our Phase 2 study released last year, we expect that KVD900 can provide patients with symptom relief as rapidly as existing therapies, but with an oral tablet that will allow earlier treatment of all patient-recognized HAE attacks. Our goal is to provide patients with the confidence that their attacks will be controlled in the earliest stages and without the associated treatment pain and other challenges of injectable therapies.”

The Phase 3 KONFIDENT trial is a worldwide clinical study being conducted at approximately 60 sites in 20 countries. The trial is intended to enroll a minimum of 84 HAE adolescent and adult patients who will complete treatment of three attacks: one each with 300 mg KVD900, 600 mg KVD900 and placebo in a double-blinded, randomized sequence. The primary endpoint of the trial is time to the beginning of symptom relief, evaluated on a Patient Global Impression of Change (PGI-C) scale, and additional endpoints will evaluate other measures of patient response and attack progression, as well as safety. Patients will dose upon first recognition of an attack, and all attack types including laryngeal attacks will be eligible for treatment. Patients will be permitted to take an additional dose of investigational drug, if symptoms warrant, and will always have access to their conventional injectable therapy. Study participants also will be allowed to maintain their prophylaxis regimen if they were receiving one at study enrollment.

KalVista currently anticipates that data from KONFIDENT will be available in the second half of 2023 and will provide further updates as the trial progresses. Additional information about KONFIDENT can be found at www.konfidentstudy.com and www.clinicaltrials.gov.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of 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 KVD900 as an oral on-demand therapy for acute HAE attacks and has initiated 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 of HAE for patients. 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 KVD900 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 the ongoing COVID-19 pandemic, 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 KVD900, KVD824 and other candidates in development, the ability of KVD900, 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, 2021, 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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