# KalVista Pharmaceuticals Announces the Lifting of FDA Clinical Hold for Phase 2 Trial of KVD824

Sep 14, 2021

*– US Site Initiations Ongoing –*

*– Regulatory Submissions Complete for All Countries Participating in Trial –*

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Sep. 14, 2021-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors, today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Company's Phase 2 clinical trial of KVD824 for oral prophylactic treatment of hereditary angioedema (HAE).

"The execution of KOMPLETE, our Phase 2 clinical trial for KVD824 as a potential oral prophylactic therapy for HAE, is expected to accelerate now that we can also proceed at our U.S. trial sites," said Andrew Crockett, Chief Executive Officer of KalVista. "Progress continues worldwide, with regulatory submissions complete in all of the countries where the trial will be conducted."

The previously announced clinical hold was removed after FDA review of KalVista's responses to the FDA request for further information and analysis related to certain preclinical studies of KVD824. Refinements were also made to the KVD824 Phase 2 KOMPLETE protocol. The Company is working closely with study investigators and clinical trial sites to proceed with all study activities as soon as possible.

KalVista has previously reported data from first-in-human and formulation studies of KVD824 that were conducted in the UK. To date, a total of 121 subjects have received KVD824 as single doses up to 1280 mg and up to 14 days of twice-daily dosing of 600 mg and 900 mg. Data from the Phase 1 studies indicate that KVD824 maintains the plasma concentrations that we believe are required to deliver efficacy consistent with approved injectable therapies. In both studies adverse event rates were similar in placebo and active arms, no subjects withdrew, and no serious adverse events were reported.

**About KVD824 KOMPLETE Clinical Trial**

KOMPLETE is the Phase 2 clinical trial of KVD824, and is a randomized, double-blind, parallel group design evaluating twice-daily dosing of 300 mg, 600 mg, and 900 mg KVD824 against placebo for 12 weeks. The trial is intended to enroll 48 HAE patients randomized into four equal arms after they report experiencing a minimum of three attacks in an eight-week run-in period. The primary endpoint of the trial is the rate of investigator confirmed HAE attacks during the treatment period. Secondary endpoints include the proportion of participants without investigator confirmed HAE attacks and the rate of investigator confirmed HAE attacks that require conventional treatment. KOMPLETE will be conducted at more than 30 sites in 13 countries.

**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, which completed a Phase 2 efficacy trial in February 2021, demonstrating statistical and clinical significance across all endpoints. 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, please visit www.kalvista.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 2 KOMPLETE clinical trial, 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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