KalVista Pharmaceuticals Provides Progress Update on Phase 2 Clinical Trial of KVD824 for Oral Prophylactic Treatment of Hereditary Angioedema

August 23, 2021

– KVD824 Clinical Trial Regulatory Approvals in Canada, Australia, and the UK –

– Response Submitted to FDA on IND Requests for KVD824 Phase 2 –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Aug. 23, 2021-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors, today provided an update on clinical trial progress for KVD824 in development for oral prophylactic treatment of hereditary angioedema (HAE).

“Over the past month we have made substantial progress in commencing KOMPLETE, our worldwide Phase 2 clinical trial of KVD824 as a potential oral prophylactic therapy for HAE,” said Andrew Crockett, Chief Executive Officer of KalVista. “The regulatory submissions have been approved in Canada, Australia, and the UK, with patient enrollment expected to begin this quarter. We also submitted our clinical hold response to the FDA related to the US IND filing for KVD824 and will provide further updates once we have additional information.”

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 will 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.

To date, a total of 121 subjects have been exposed to treatment with KVD824 as single doses up to 1280 mg and up to 14 days of twice-daily dosing of 600 mg and 900 mg. The formulation of KVD824 maintains the plasma concentrations that we believe are required to deliver efficacy consistent with approved injectable therapies. Twice-daily dosing of KVD824 up to 14 days has demonstrated an encouraging safety and tolerability profile.

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, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence or complete clinical studies, including our Phase 2 KOMPLETE clinical trial, and to obtain regulatory approvals for KVD900, KVD824 and other candidates in development, our ability to resolve a clinical hold with regards to KVD824, the ability of KVD900, KVD824 and other candidates in development to treat HAE or DME, the future progress and potential success of our oral Factor XIIa program, and the sufficiency of our cash, cash equivalents and investments to fund our operations. 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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Source: KalVista Pharmaceuticals, Inc.