KalVista Pharmaceuticals Provides Progress Update on KVD900 for Oral On-Demand Treatment of Hereditary Angioedema

Nov 10, 2021

– Positive End-of-Phase 2 Meeting Completed –

– Phase 3 Trial Dosing Expected Q1 2022 –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Nov. 10, 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 the clinical trial progress for KVD900 in development for oral on-demand treatment of hereditary angioedema (HAE).

“We had a productive End-of-Phase 2 meeting with the FDA and recently received meeting minutes which confirmed that our Phase 3 trial design, similar to our recent successful Phase 2 trial, is expected to be appropriate to support an NDA submission,” said Andrew Crockett, Chief Executive Officer of KalVista. “Our development team is finalizing the Phase 3 trial protocol and preparing for study initiation, and we anticipate patients will be dosed during the first quarter of 2022. KalVista is well-capitalized, with funding until at least early 2024, which we expect takes us beyond data from both this Phase 3 trial and the ongoing Phase 2 trial of KVD824.”

The Phase 3 clinical trial of KVD900 is a crossover design evaluating dose levels of 300 mg and 600 mg KVD900 against placebo. The primary endpoint of this Phase 3 trial is time to beginning of symptom relief. The trial is expected to be conducted at more than 50 sites worldwide and recruit approximately 100 patients, consistent with late stage trials of approved on-demand treatments for HAE. The trial is intended to evaluate all HAE attacks, including laryngeal attacks and breakthrough attacks for patients using prophylaxis. Similar to the Phase 2 trial for which positive data was announced earlier in 2021, patients will administer treatment as soon as they recognize the onset of an attack. More details will be forthcoming when the trial initiates.

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. 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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KalVista Pharmaceuticals, Inc.
Leah Monteiro
Senior Director, Corporate Communications & Investor Relations
857-999-0808
leah.monteiro@kalvista.com

Source: KalVista Pharmaceuticals, Inc.