KalVista Pharmaceuticals Presents Phase 2 Clinical Data of Oral KVD900 for Treatment of HAE at C1-Inhibitor Deficiency & Angioedema Workshop

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– KVD900 Efficacious Within First Hours of Attack and Significantly Shortens Time to Improvement of Attack Symptoms –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jun. 5, 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 the oral presentation of clinical data supporting KVD900 as an oral on-demand treatment for hereditary angioedema (HAE) at the 12th C1-Inhibitor Deficiency & Angioedema Workshop.

"Our goal is to provide the best outcome for HAE patients experiencing an attack, and that means offering them the ability to treat early in the attack progression to shorten attack duration," said Andrew Crockett, Chief Executive Officer of KalVista. "The data today reinforce that attacks treated with oral KVD900 experience a rapid improvement in symptoms which is maintained for 24 hours, while also being generally safe and well tolerated. We look forward to providing updates on KVD900's upcoming Phase 3 program."

Following is a brief summary of the presentation *Fast improvement of hereditary angioedema (HAE) attacks with the oral on-demand plasma kallikrein inhibitor KVD900: an analysis of the pharmacokinetic and pharmacodynamic profile of KVD900 and attack symptom severity during a double-blind, randomized phase 2 cross-over trial in patients with HAE type I and II* given by Andrea Zanichelli, MD:

- KVD900 achieves rapid plasma exposures, with near complete plasma kallikrein inhibition within 30 minutes.
- Attacks treated with KVD900 experienced a rapid improvement in the most severe baseline symptoms both in absolute terms and relative, when expressed as change from baseline. This improvement was maintained for 24 hours.
- KVD900 significantly accelerated improvement in attack severity as assessed using a composite Visual Analog Scale (VAS). A 50% reduction in the composite VAS was reached for 50% of the attacks treated with KVD900 within six hours versus greater than 12 hours for attacks treated with placebo. By 24 hours, 74% of KVD900-treated attacks showed a 50% reduction in score compared to 38% for placebo-treated attacks.
- Adverse events were of mild or moderate intensity with no severe or serious adverse events reported. Overall, the single administration of KVD900 appeared safe and well tolerated.

About KVD900

KVD900-201 was a double blind, placebo-controlled, crossover trial investigating the safety and efficacy of a single dose of 600 mg KVD900 as an on-demand treatment for HAE attacks in patients with Type 1 or Type 2 HAE. Following an open label phase, in which pharmacokinetic samples were collected over four hours, all patients progressed into the randomized phase of the trial. In this "at home" part of the trial, patients treated two attacks, one with 600 mg KVD900 and one with placebo in a randomized sequence. Patients administered treatment for each attack within one hour of attack onset, following confirmation with their physician, and then recorded symptoms and, if needed, the time to use of rescue (the patient's conventional attack treatment). The time to rescue treatment within 12 hours was the primary outcome of the trial. Secondary outcomes included assessment of attack severity using categorical (PGI-S) and visual analogue scale (VAS) measures and the patient's global impression of change (PGI-C).

The trial planned to complete at least 50 patients and enrolled 68 patients of which 53 completed the trial by treating two attacks. One patient withdrew consent and 14 patients were discontinued due to completion of the trial. No patients withdrew due to adverse events. The trial included 126 administrations of KVD900 and 55 of placebo. During the uncontrolled, open label phase, 5 of 68 patients dosed reported 8 adverse events suspected to be related to treatment. During the randomized, placebo-controlled phase, 5 patients reported adverse events suspected to be treatment-related (3 of 58 dosed with KVD900 and 2 of 55 dosed with placebo).

KVD900 has received Fast Track designation from the U.S. Food and Drug Administration. A Pediatric Investigational Plan ("PIP") has also been approved by the European Medicines Agency ("EMA") for KVD900.

The presentation will available on the Company's website at www.kalvista.com.

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. 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 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 annual report on Form 10-K filed on July 1, 2020, our quarterly reports on Form 10-Q, and other filings 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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