KalVista Pharmaceuticals Provides Clinical Update on KVD900

November 12, 2018

– Enlarged Phase 2 Study to Begin in 2018 for Potential Acute Treatment of Hereditary Angioedema; Data Expected in Late 2019 –

– Food Effect Study Indicates No Dosing Limitations from Food and Confirms Rapid Uptake and High Exposure –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Nov. 12, 2018-- 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 hereditary angioedema (HAE) candidate KVD900.

“Thanks to our recent equity financing and the exciting Phase 1 data from KVD900, we are pleased to announce that we are building on these successes with a more aggressive development plan for KVD900, to potentially accelerate our time to market.” said Andrew Crockett, Chief Executive Officer of KalVista. “Our first step has been to design a larger Phase 2 clinical trial for KVD900 as on-demand treatment for HAE attacks in patients to generate more robust data that we intend to use as the basis for discussions with the FDA about a faster approval pathway. We still plan to initiate this trial before year end, with data anticipated in late 2019. This Phase 2 trial will also benefit from our recently completed food effect study, which showed that dosing following a meal had no significant impact on the pharmacodynamic profile of KVD900. We do not expect food to impose any limitations as to when a patient can take the drug.”

The food effect cohort of our Phase 1 study evaluated the impact of food on the pharmacokinetic profile of KVD900 in healthy volunteers. The Phase 1 study of KVD900 included a total of 68 subjects on active drug, of which 18 received the top dose of 600mg, including the cross-over food effect cohort. Dosing following a standardized high calorie and high fat meal had little impact on the pharmacodynamic profile of KVD900 tablets, which continued to result in 95% inhibition of plasma kallikrein within 30 minutes, a timeframe that KalVista believes potentially compares favorably to approved injected therapies. KalVista believes that KVD900 displays a profile well-suited for use as an on-demand therapy for HAE attacks, with a combination of rapid and high uptake into the plasma resulting in fast and strong inhibition of plasma kallikrein. To date, KVD900 has shown no dose-limiting safety signals.

The enlarged Phase 2 trial evaluating the utility of KVD900 as an on-demand treatment for HAE attacks is expected to initiate before the end of 2018 and is expected to investigate efficacy in approximately 50 type 1 and 2 HAE patients. This two part study will include an in-patient investigation of safety, pharmacokinetic and pharmacodynamic profile of KVD900 and an out-patient cross-over phase to investigate efficacy of KVD900 versus placebo. KVD900 or placebo will be dosed within one hour of the start of an attack, with symptom severity monitored for at least 24 hours following administration. Patients will use their normal, on-demand treatment if the attacks worsen. Data is expected from this trial in late 2019, and KalVista will provide more information on the details of the trial design once the trial has initiated.

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. The initial focus is on inhibitors of plasma kallikrein, which is an important component of the body’s inflammatory response and which, in excess, can lead to increased vascular permeability, edema and inflammation. KalVista has developed a proprietary portfolio of novel, small molecule plasma kallikrein inhibitors initially targeting hereditary angioedema (HAE) and diabetic macular edema (DME). The Company has created a structurally diverse portfolio of oral plasma kallikrein inhibitors and is advancing multiple drug candidates into Phase 1 clinical trials for HAE. The Company has selected KVD900 as its program to be advanced as an on-demand therapy for HAE attacks, and anticipates commencing a Phase 2 proof-of-concept study in HAE patients in late 2018. In DME, KalVista’s most advanced program, an intravitreally administered plasma kallikrein inhibitor known as KVD001, began a Phase 2 clinical trial in 2017 that is anticipated to report data in the second half of 2019.

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 that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, KVD900 clinical trial timing and results. Further information on potential risk factors that could affect our business and its financial results are detailed in the annual report on Form 10-K filed on July 30, 2018 and other reports as filed 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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