

KalVista Pharmaceuticals Commences Two Clinical Trials

January 5, 2018

- Data Expected for Phase 2 Clinical Trial of KVD001 in Diabetic Macular Edema Patients in the Second Half of 2019 -
- Second Oral Hereditary Angioedema Candidate Begins Phase 1 Clinical Trial -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 5, 2018-- 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 initiation of two clinical trials: a Phase 2 proof-of-concept clinical trial evaluating the safety, tolerability, and efficacy of KVD001 as a treatment for diabetic macular edema (DME), as well as a Phase 1 trial for KVD 900, the second candidate in the oral hereditary angioedema (HAE) portfolio. Both trials commenced in December 2017, in line with KalVista's previously stated 2017 objectives.

"After working diligently with Merck since the announcement of our collaboration in October, we are delighted to have begun a Phase 2 clinical trial of KVD001 in diabetic macular edema patients," said Andrew Crockett, Chief Executive Officer of KalVista. "We are particularly hopeful that plasma kallikrein inhibition may offer benefits in patients for whom anti-VEGF therapy doesn't achieve a sufficient response. In addition, 2018 will be an exciting year for our hereditary angioedema portfolio, with our second oral plasma kallikrein inhibitor candidate in a Phase 1 clinical trial and an anticipated regulatory filing for a third candidate before year-end."

KVD001 is a small molecule plasma kallikrein inhibitor administered by intravitreal injection for the potential treatment of DME. The Phase 2 trial will consist of approximately 123 patients in the United States who have discontinued treatment with anti-VEGF therapy, and who still have significant edema and reduced visual acuity. This sham-controlled, double-masked clinical trial will evaluate two dose levels of KVD001. Four intravitreal injections, or sham, will be administered over three months with a three month follow up period. Efficacy endpoints include best corrected visual acuity (BCVA), central subfield thickness (CST), and the diabetic retinopathy severity scale (DRSS). The safety and tolerability of monthly dosing of KVD001 will also be assessed. Top-line results are expected in the second half of 2019.

KVD900 is the second clinical candidate from a portfolio of oral plasma kallikrein inhibitors for potential treatment of HAE. KalVista's strategy is to develop and evaluate multiple oral molecules in pursuit of a best-in-class therapy for HAE patients. This portfolio approach may also lead to development of multiple molecules to address unmet need in both prophylactic and on-demand market segments. The Phase 1 trial of KVD900 is actively screening healthy volunteers to evaluate the safety, tolerability and exposure of the drug candidate, and a plasma-based assay will be used to assess the pharmacodynamic effect of KVD900. KalVista expects to provide an update on the status and progress of the HAE portfolio, including KVD900, in mid-2018, with a goal to advance at least one additional candidate to the clinic before the end of 2018.

About Diabetic Macular Edema (DME)

Diabetic macular edema (DME) is a sight-threatening disease caused by disruption of the blood/retinal barrier leading to the accumulation of fluid in the macula and vision loss. DME affects an estimated 16% of diabetic patients within their lifetime, according to a 2012 study published in Diabetes Care. Approximately 900,000 patients in the United States alone have active DME and are at serious risk of vision loss, according to a 2013 study.

About Hereditary Angioedema (HAE)

Hereditary angioedema (HAE) is a rare and potentially life-threatening genetic condition that occurs in approximately 1 in 50,000 people. HAE patients are susceptible to sudden and prolonged attacks of edema, which often occur in the hands, feet, face, gastrointestinal tract, and airway. Attacks can result in severe swelling and pain, airway blockage, and nausea.

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 from which it plans to select multiple drug candidates to advance into clinical trials for HAE. KalVista's most advanced program, an intravitreally administered plasma kallikrein inhibitor known as KVD001, has successfully completed its first-in-human study in patients with DME and began a Phase 2 clinical trial in 2017.

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, available funding and future 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 27, 2017, our most recent Quarterly Report on Form

10-Q, 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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20180105005163/en/

Source: KalVista Pharmaceuticals, Inc.

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