KalVista Pharmaceuticals Reports Phase 2 Clinical Trial Results in Patients with Diabetic Macular Edema

Dec 09, 2019

– KVD001 Does Not Meet Primary Endpoint –

– Pre-Planned Analyses Show Clinical Benefit on Vision –

– KVD001 Generally Safe and Well Tolerated –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Dec. 9, 2019-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors, today announced results of the Phase 2 clinical trial evaluating the use of KVD001 in patients with diabetic macular edema (DME).

The KVD001 Phase 2 clinical trial study was designed to evaluate patients who were poor responders to previous treatment with anti-VEGF therapy. The primary efficacy endpoint in the trial was change in best corrected visual acuity (BCVA) at 16 weeks compared to sham. The 6µg dose showed a difference of +2.6 letters versus sham, which was not statistically significant (p=0.223), and the 3µg dose showed a difference of +1.5 letters (p=0.465). No significant differences were observed in the secondary endpoints of central subfield thickness (CST) or the diabetic retinopathy severity scale (DRSS). KVD001 was generally safe and well tolerated with no drug-related serious adverse events.

“This was the first study to evaluate the efficacy of a plasma kallikrein inhibitor in DME,” said Andrew Crockett, Chief Executive Officer of KalVista. “There is a significant population of DME patients who do not respond sufficiently to anti-VEGF therapies, and we want to express our gratitude to these patients as well as the healthcare providers and others who participated. Although the study did not meet the primary endpoint, KVD001 demonstrated what we believe is an important dose responsive clinical benefit on vision in the overall population. In addition, we identified a substantial proportion of patients who experienced a more robust response to treatment, that we believe warrants further study. These data and the safety profile also support continued evaluation of oral plasma kallikrein inhibitors as a treatment for DME.”

In the overall study population, KVD001 demonstrated a protection against vision loss. In the sham treated group 54.5% of patients experienced a reduction in vision compared to 32.5% in the 6µg dose (p=0.042). The study also included a pre-specified subgroup analysis investigating the impact of baseline visual acuity on response. After excluding those patients with the most severe vision loss (visual acuity of <55 letters at baseline), the remaining 70% of the total patient population showed a difference in BCVA compared to sham of 4.9 letters (p=0.056) at the 6µg dose.

“This trial studied a challenging DME patient population with significant persistent vision loss despite prior therapies,” said Lloyd Paul Aiello, MD, PhD, Professor of Ophthalmology, Harvard Medical School. “These study data support the possibility that plasma kallikrein inhibition prevents worsening vision in patients with DME and that KVD001 warrants additional study in this regard as a method to treat this disease.”

KVD001 is a small molecule plasma kallikrein inhibitor administered by intravitreal injection. The Phase 2 trial consisted of 129 patients who had previously been treated with anti-VEGF therapy, and still had significant edema and reduced visual acuity. The sham-controlled, double-masked clinical trial evaluated two dose levels of KVD001, 3µg and 6µg. Four intravitreal injections or sham were administered over three months with a three month follow up period. The study was conducted at 38 sites in the United States.

KVD001 is subject to an option agreement with Merck, signed in 2017. Under the terms of the agreement, KalVista will provide to Merck a package of clinical and other data, after which Merck will have a specified period of time to determine whether to exercise the option. Exercise of the option by Merck will result in a payment due to KalVista, as well as future potential milestone and royalty payments. KalVista will provide further public updates once Merck has notified KalVista of its decision or the option exercise period has expired.

A summary presentation of the KVD001 data findings has been posted to the investors section of the KalVista website, and will be available for the next 30 days.

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 for HAE as well as DME. The Company has selected KVD900 as its program to be advanced as an on-demand therapy for acute HAE attacks and commenced a Phase 2 proof-of-concept study in HAE patients in late 2018. In DME, an intravitreally administered plasma kallikrein inhibitor known as KVD001, completed a Phase 2 clinical trial in 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, available funding, our cash runway, potential 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 15, 2019 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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