KalVista Pharmaceuticals Announces Collaboration with Merck

October 10, 2017

- Covers Development of Investigational Plasma Kallikrein Inhibitors for Treatment of Diabetic Macular Edema—

- $37 Million Upfront Fee Plus Potential Milestone Payments and Sales Royalties —

- Merck Acquires 9.9% Stake in KalVista in Private Placement —

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 10, 2017-- KalVista Pharmaceuticals, Inc. (NASDAQ:KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors, today announced that it has entered into a collaboration agreement with Merck, known as MSD outside the United States and Canada, through a subsidiary, for KVD001, the Company’s investigational intravitreal (IVT) injection candidate currently in development for potential treatment of diabetic macular edema (DME), as well as future oral DME compounds based upon plasma kallikrein inhibition.

“We are pleased to collaborate with Merck for the continuing development of KVD001 and future oral programs for patients with DME,” said Andrew Crockett, Chief Executive Officer of KalVista. “Plasma kallikrein inhibition is a novel approach to the treatment of DME that we believe may offer benefit to a significant number of patients, and an oral therapy particularly would represent a groundbreaking advance for treatment of this indication. We have always believed that development and commercialization of our DME therapies would require the resources of a large pharmaceutical company, and we believe Merck has the wherewithal and resources to help us advance development of our DME drug candidates. Importantly for KalVista, this collaboration also meets our strategic objectives of maintaining control of our oral HAE portfolio that we plan to develop independently. We look forward to providing more details about the Phase 2 trial for KVD001 in DME patients as the trial commences.”

Under the terms of the agreement, KalVista has granted to Merck certain rights including an option to acquire KVD001 through a period following completion of the Phase 2 proof-of-concept trial that KalVista intends to commence later this year. KalVista also has granted to Merck a similar option to acquire investigational orally delivered molecules for DME that KalVista will continue to develop as part of its ongoing research and development activities. As consideration for the agreement, Merck will pay to KalVista a $37 million non-refundable upfront fee. KalVista is further eligible to receive payments associated with the exercise of the options by Merck and the achievement of milestones for each program that potentially total up to $715 million. KalVista also will receive tiered royalties on net sales for therapeutic candidates commercialized under this agreement. KalVista will fund and retain control over the planned Phase 2 clinical trial of KVD001 as well as development of the investigational oral DME compounds through Phase 2, unless Merck exercises its options earlier.

In addition to the collaboration, KalVista has entered into a separate $9.1 million private placement transaction with Merck under which Merck has acquired 1,070,589 shares of KalVista, representing a 9.9% ownership stake, at a price of $8.50 per share. This private placement closed concurrent with execution of the Option Agreement.

“The KalVista team has already made important progress in advancing this candidate into the clinic. At Merck, we look forward to the opportunity to apply our expertise and resources upon the achievement of proof of concept for KVD001,” said Ben Thorner, senior vice president and Head of Business Development & Licensing Merck Research Laboratories. “Merck is seeking to collaborate on the development of candidates that we believe have the potential to transform practice in areas where there is a clear need for new and improved therapeutic options.”

The agreement with Merck covers only the investigational IVT and oral plasma kallikrein inhibitor programs for DME. KalVista retains full rights to its oral hereditary angioedema (HAE) portfolio, and will have the opportunity to select and develop future oral HAE compounds. KalVista intends to continue to aggressively pursue its efforts to develop a best-in-class oral therapy for HAE, as well as additional programs focused on other proteases.

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. The first candidate of this planned portfolio, KVD818, is currently in a first-in-human study and additional program candidates are in preclinical development. 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 is being prepared for Phase 2 studies 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.


Source: KalVista Pharmaceuticals, Inc.

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