KalVista Pharmaceuticals Provides Regulatory Update for Phase 2 Clinical Trial of KVD824

Apr 20, 2021

– KVD824 Phase 2 on Clinical Hold –

– Planning for KVD900 Phase 3 Unaffected –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Apr. 20, 2021-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of small molecule protease inhibitors, announced today that the U.S. Food and Drug Administration (FDA) has notified the Company in a letter that it has placed a clinical hold on the proposed Phase 2 clinical trial of KVD824.

KVD824 is KalVista's oral product candidate being developed for prophylactic treatment of hereditary angioedema (HAE). An Investigational New Drug Application was submitted earlier in 2021 for a Phase 2 clinical trial to evaluate KVD824 as a potential prophylactic treatment for the prevention of HAE attacks. The FDA letter requests further information and analysis related to certain preclinical studies of KVD824 submitted to support the planned Phase 2 trial. Refinements were also proposed to the intended KVD824 Phase 2 study protocol. No new studies were requested nor was it suggested that new data be generated to initiate the Phase 2 trial.

"We intend to fully comply with the requests and recommendations provided by the FDA," said Andrew Crockett, Chief Executive Officer of KalVista. "Although we no longer can confirm that the KVD824 Phase 2 trial will initiate this quarter, we are working to resolve their concerns in a timely fashion. Importantly, this letter relates solely to KVD824, and does not impact our activities or expectations with regard to KVD900, for which we continue to prepare for an End of Phase 2 FDA meeting and commencement of our Phase 3 efficacy trial."

KalVista has previously reported data from first-in-human and formulation studies of KVD824 that were conducted in the UK. To date, a total of 121 subjects have received KVD824 as single doses up to 1280 mg and up to 14 days of twice-daily dosing of 600 mg and 900 mg. In both studies adverse event rates were similar in placebo and active arms, no subjects withdrew and no serious adverse events were reported.

KalVista will continue to work closely with the FDA on the overall development of KVD824 and will provide further updates as appropriate.

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 and 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, 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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