KalVista Pharmaceuticals Provides Update on Oral Hereditary Angioedema Franchise

October 15, 2020

– KVD900 Phase 2 Trial Recruitment Complete; Data Expected Before End of 2020 –

– KVD824 Achieves Targeted Exposure Levels for Prophylaxis; IND Submission Expected Q1 2021 –

– Oral Factor XIIa Inhibitor Program Announced –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Oct. 15, 2020-- 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 its franchise of oral therapies for treatment of hereditary angioedema (HAE).

"We have completed enrollment of our Phase 2 trial for our oral on-demand HAE treatment, KVD900, and remain on track to deliver data before the end of this year. We are also pleased to announce data from KVD824, our oral program for HAE prophylaxis, and to introduce our oral Factor XIIa program, which we believe represents the next generation of HAE therapeutics," said Andrew Crockett, Chief Executive Officer of KalVista. "Our ongoing work to optimize the exposure profile of KVD824 has yielded a formulation that maintains the concentrations we believe are required to compete with approved injectable therapies, while showing an encouraging safety and tolerability profile in up to 14 days of dosing. We intend to submit an Investigational New Drug application for a Phase 2 study to evaluate KVD824 in prevention of HAE attacks in the first quarter of 2021. Looking to the future, we are also excited to share early data on our oral Factor XIIa inhibitor program as an additional HAE therapy, with IND-enabling studies anticipated in 2021."

About KVD824
KVD824 is our twice-daily oral plasma kallikrein inhibitor for prevention of HAE attacks. We initially evaluated KVD824 in a three-part first-in-human study in which 84 subjects received at least one dose of KVD824. The study evaluated single doses up to 1280 mg, multiple doses up to 640 mg, and the effect of food on KVD824 pharmacokinetics.

We are currently conducting a study in the UK assessing both single and multiple dose formulations of KVD824. Six formulations of 600 to 900 mg have been assessed in 16 healthy subjects in a cross-over single dose phase. Selected formulations are being evaluated for 14 days, dosing two times daily, up to 900 mg per dose in a multiple dose phase. 600 mg of KVD824 twice daily maintained concentrations that we believe are above that required for efficacy. In an ongoing 900 mg, twice daily cohort exposures are increased at all time points.

To date, 98 subjects have been exposed to treatment with KVD824 as single doses up to 1280 mg and up to 14 days of twice-daily dosing of 600 mg and 900 mg and there have been no concerning safety or tolerability signals. In the first-in-human study adverse event rates were similar in placebo and active arms. No subjects withdrew from the study and no serious adverse events were reported. In the ongoing formulation study, all reported adverse events to date have been mild and no subjects have withdrawn from the study. We will release the full safety data set upon completion of the study.

We intend to file an Investigational New Drug (IND) submission for a Phase 2 clinical trial of KVD824 in the first quarter of 2021. This trial is intended to evaluate the efficacy and safety of KVD824 as a twice-daily prophylactic treatment for prevention of HAE attacks. The study size will be guided by previous pivotal studies, considering the already established pathway to approval for prophylactic treatment of HAE, and will be conducted in multiple territories including the United States and Europe.

About Factor XIIa
Factor XIIa is an enzyme that plays a key role in HAE as the most upstream mechanism in the biochemical pathway that initiates HAE attacks. For this reason, we believe that inhibition of Factor XIIa will block the underlying causes of HAE attacks, including the uncontrolled generation of both plasma kallikrein and bradykinin, which cause swelling and pain. Clinical studies of Factor XIIa antibodies have demonstrated efficacy in preventing HAE attacks, and there are no known safety implications of long-term inhibition of this enzyme.

While injectable Factor XIIa antibody therapies are currently in clinical studies for HAE prophylaxis and other indications, developing oral Factor XIIa inhibitors has been a significant scientific challenge, and KalVista's newly announced program represents a major breakthrough in this area. Our internal research team has discovered multiple series of low nanomolar potency Factor XIIa inhibitors with high degrees of selectivity and oral bioavailability. We are pursuing comprehensive IP protection for this advanced medicinal chemistry program that is currently in lead optimization. We anticipate starting IND-enabling studies in 2021.

We have posted an updated corporate presentation on the KalVista web site, www.kalvista.com, that contains further details on both KVD824 and the oral Factor XIIa program.

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 on-demand therapy for acute HAE attacks and is conducting a Phase 2 proof-of-concept study in HAE patients with data expected in the fourth quarter of 2020. KVD824 is in development for prophylactic treatment of HAE with an expected IND filing in the first quarter of 2021. KalVista's recently announced 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 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, 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 future clinical trial timing and results, our ability to commence or complete clinical studies and to obtain regulatory approvals for KVD900 and KVD824 to treat HAE, the future progress and 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, when filed, 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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