KalVista Pharmaceuticals Announces Positive Phase 1 Data for Orally Disintegrating Tablet Formulation of Sebetralstat for Use in Hereditary Angioedema

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CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Oct. 31, 2022--

KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors, today announced positive phase 1 data for an orally disintegrating tablet (ODT) formulation for its lead compound sebetralstat. Sebetralstat is currently being developed in the phase 3 KONFIDENT clinical trial as a potential on-demand treatment for hereditary angioedema (HAE) attacks.

“This new ODT formulation reflects a next step in our constant efforts to provide people with HAE more options to help them manage this disease,” said Andrew Crockett, Chief Executive Officer of KalVista. “Orally disintegrating tablets are a standard in other disease areas such as migraine and would be of benefit to many people with HAE, particularly younger patients. We expect this formulation to become available in the US and rest of the world following the initial launch of sebetralstat tablets.”

KalVista recently completed a clinical trial to investigate the pharmacokinetics of the ODT. The phase 1, open-label, randomized, single-dose, 3-way crossover trial enrolled 36 healthy adult volunteers to compare the pharmacokinetics (PK) of sebetralstat following administration of ODT and the current film-coated tablets in healthy adult volunteers. Data from the study showed that the ODT tablet formulation has a similar PK profile to the film-coated version currently in development. Based upon these results, KalVista intends to continue to develop the formulation with the intention to make it available as soon as possible after the sebetralstat anticipated launch in the US. KalVista currently expects that data from the KONFIDENT study using the film-coated tablets will be available in the second half of 2023, to support a planned NDA filing in the first half of 2024.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of oral, 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 sebetralstat as an oral on-demand therapy for HAE attacks and is enrolling the Phase 3 KONFIDENT clinical trial. In addition, KalVista’s oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve treatment for people living with HAE. In DME, an intravitreally administered plasma kallikrein inhibitor, called KVD001, has completed a Phase 2 clinical trial.

For more information about KalVista, please visit www.kalvista.com.

For more information on the sebetralstat HAE on-demand Phase 3 KONFIDENT trial, please visit www.konfidentstudy.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, timing or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our Phase 3 KONFIDENT trial, and to obtain regulatory approvals for sebetralstat and other candidates in development, the ability of sebetralstat and other candidates in development to treat HAE or DME, and the future progress and potential success of our oral Factor XIIa program. Further information on potential risk factors that could affect our business and financial results are detailed in our filings with the Securities and Exchange Commission, including in our annual report on Form 10-K for the year ended April 30, 2022, our quarterly reports on Form 10-Q, and our other reports that 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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