KalVista Pharmaceuticals Announces Publication of Sebetralstat Phase 2 Data in The Lancet

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CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Feb. 10, 2023-- 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 that results from the phase 2 trial evaluating the efficacy and safety of oral sebetralstat for the on-demand treatment of hereditary angioedema (HAE) attacks has been published in the international weekly medical journal, *The Lancet.*

The phase 2 study was a two-part, randomized, double-blind, placebo-controlled clinical trial. The trial included a total of 68 patients with HAE and showed that oral sebetralstat was well tolerated and led to rapid suppression of plasma kallikrein activity, resulting in significantly increased time to use of conventional treatment, reduced attack severity, and faster time to symptom relief and resolution compared to placebo.

“All currently available on-demand treatments in HAE require injections and are associated with substantial treatment burden and delays due to the time required for medication preparation and administration, and associated pain and discomfort,” said Dr. Emel Aygören-Pürsün, Head of the HAE Center at the University Hospital Frankfurt, co-lead author of the manuscript, and Principal Investigator for the phase 2 clinical trial. “In this study, patients were able to orally administer treatment early after attack onset, minimizing time to improvement. This suggests that sebetralstat has the potential to enable patients to improve clinical outcomes.”

“Sebetralstat was rapidly absorbed after oral administration, halting attack progression and expediting symptom relief and attack resolution,” added Dr. Andrea Zanichelli, Unità di Medicina, IRCCS Policlinico San Donato, Università degli Studi di Milano, and co-lead author. “Importantly, sebetralstat was well-tolerated in this trial with very few adverse events. The preliminary safety profile contrasts favorably with the labelled adverse reactions for currently approved on-demand therapies.”

“The publication of these phase 2 results in *The Lancet* underscores their significance and represents further validation of the promise of sebetralstat as potentially the first oral on-demand treatment for people living with HAE,” said Andrew Crockett, Chief Executive Officer of KalVista. “We anticipate clinical results from our ongoing phase 3 KONFIDENT trial for sebetralstat for on-demand treatment in HAE in the second half of this year as we work to bring this innovative therapy to the HAE community.”

The publication abstract can be found at the below link:

An investigational oral plasma kallikrein inhibitor for on-demand treatment of hereditary angioedema: a two-part, randomised, double-blind, placebo-controlled, crossover phase 2 trial - The Lancet

Topline Phase 2 Sebetralstat Results

- Time to use of conventional treatment within 12 h of study drug administration was significantly longer with sebetralstat versus placebo; (p=0·0010)
- Sebetralstat significantly reduced time to onset of symptom relief (p=<0.0001) on the Patient Global Impression of Change scale (PGI-C), with a median time of 1.6 hours versus 9 hours for attacks treated with placebo
- Time to conventional attack treatment use or worsening in severity by 1 level or more on the PGI-S, whichever came first, within 12 h of study administration was significantly longer after treatment with sebetralstat than after treatment with placebo (p<0.001)
- The median time to attack resolution, defined as a PGI-S rating of “none” within 24 h after study drug administration, was significantly shorter with sebetralstat than with placebo (p=0·0021)
- Sebetralstat was well-tolerated and no serious adverse events were reported. The proportion of drug-related treatment-emergent adverse events was similar in attacks treated with sebetralstat and placebo

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 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 the treatment for people living with HAE and other diseases.

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

For more information on the sebetralstat HAE on-demand Phase 3 KONFIDENT study, 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 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 success of any efforts to commercialize sebetralstat, the ability of sebetralstat and other candidates in development to treat HAE or other diseases, 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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