KalVista Pharmaceuticals Presents Sebetralstat Data at Bradykinin Symposium 2024

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–Patient perspectives shed additional light on the challenges of treating hereditary angioedema attacks with injectable on-demand therapies–

–New analyses of sebetralstat clinical trials bolster efficacy and safety profile –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Sep. 6, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today announced that it presented additional analyses of the efficacy and safety of sebetralstat from phase 2 and phase 3 double-blind, placebo-controlled crossover clinical trials as well as interim data from KONFIDENT-S, a phase 3 open-label extension trial, and real-world patient data at the Bradykinin Symposium 2024 taking place in Berlin, Germany, on September 5-6. Sebetralstat is a novel, investigational oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE) attacks in adult and pediatric patients aged 12 years and older.

“Delay or denial in the treatment of HAE attacks is often related to the administration of the currently approved injectable on-demand treatments which commonly result in injection-site reactions or pain. The data presented today highlight that oral sebetralstat may remove these challenges and has a safety profile no different than placebo,” said Emel Aygören-Pürsün, MD, specialist in internal medicine at the Division of Oncology, Hematology and Hemostaseology at the Department for Children and Adolescents of the University Hospital Frankfurt, and a leading investigator for the phase 2, phase 3 KONFIDENT and KONFIDENT-S trials. “Sebetralstat also resulted in rapid symptom relief in the clinical trials. If approved, sebetralstat might become a major advance for people living with HAE by addressing critical gaps in the current standard of care for on-demand treatment of attacks.”

“We are encouraged by the observation of exceptional consistency of both safety and efficacy across the entire clinical program for sebetralstat for the on-demand treatment of HAE,” said Paul Audhya, MD, MBA, Chief Medical Officer of KalVista Pharmaceuticals. “These data reinforce the potential for sebetralstat to transform the management of HAE.”

The presentations at Bradykinin Symposium 2024 included:

- **Delayed On-demand Treatment of Hereditary Angioedema Attacks and Associated Barriers Reported by Italian patients:** Mauro Cancian, Azienda Ospedaliera, Università degli Studi di Padova, Padova, Italy (Oral presentation)
  - Many patients did not meet guideline recommendations for early on-demand treatment following attack recognition, which resulted in more severe attacks.
- **Pooled Sebetralstat Placebo-controlled Efficacy for On-demand Treatment of Hereditary Angioedema:** Emel Aygören-Pürsün, University Hospital Frankfurt, Goethe University Frankfurt, Germany (Poster presentation)
  - Pooled analysis of a larger number of HAE attacks corroborates the efficacy of sebetralstat for on-demand treatment, offering an oral administration route to potentially enable early treatment and rapid symptom relief.
- **Pooled Sebetralstat Placebo-controlled Safety for On-demand Treatment of Hereditary Angioedema:** Emel Aygören-Pürsün, University Hospital Frankfurt, Goethe University Frankfurt, Germany (Oral presentation)
  - In the pooled safety analysis in phase 2 and phase 3 double-blind, placebo-controlled crossover trials, sebetralstat was well-tolerated with a safety profile no different than placebo.
- **KONFIDENT-S Interim Analysis: Sebetralstat for Hereditary Angioedema Attacks Including Laryngeal:** Henriette Farkas, Hungarian Angioedema Center of Reference and Excellence, Semmelweis University, Budapest, Hungary (Oral presentation)
  - Among 640 attacks treated, median time to treatment was 9 minutes for all attacks and 8 minutes for laryngeal attacks; the median time to beginning of symptom relief was 1.8 hours for all attacks and 1.3 hours for laryngeal attacks.
- **Phase 3 KONFIDENT Trial of Sebetralstat for HAE: European Subgroup:** Andrea Zanichelli, Operative Unit of Medicine, Angioedema Center, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy; Department of Biomedical Sciences for Health, University of Milan, Milan, Italy (Poster presentation)
  - In the KONFIDENT phase 3 clinical trial, the positive efficacy and safety of sebetralstat as an on-demand treatment for HAE was consistent between European participants and the overall cohort.
- **A specific, sensitivity assay measuring patient sample plasma kallikrein activity**: Daniel Lee, KalVista Pharmaceuticals (Oral presentation)
  - Measuring specific plasma kallikrein activity could be useful as a biomarker for normal C1INH, which currently has no standardized diagnostic pathway.

Links to all posters and presentations can be found on the KalVista website under Publications.

About Sebetralstat
Discovered and developed entirely by the scientific team at KalVista, sebetralstat is a novel, investigational oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE). Sebetralstat received Fast Track and Orphan Drug Designations from the U.S. FDA, as well as Orphan Drug Designation and an approved Pediatric Investigational Plan from the European Medicines Agency (EMA).

About Hereditary Angioedema
Hereditary angioedema (HAE) is a rare genetic disease resulting in deficiency or dysfunction in the C1 esterase inhibitor (C1INH) protein and subsequent uncontrolled activation of the kallikrein-kinin system. People living with HAE experience painful and debilitating attacks of tissue swelling

in various locations of the body that can be life-threatening depending on the location affected. All currently approved on-demand treatment options require either intravenous or subcutaneous administration.

About KalVista Pharmaceuticals, Inc.
KalVista Pharmaceuticals, Inc. is a global pharmaceutical company focused on the development and delivery of oral medicines for diseases with significant unmet need. KalVista announced positive phase 3 data from the KONFIDENT trial for its oral, on-demand therapy, sebetralstat for HAE in February 2024. The Company's NDA for sebetralstat has been accepted by the FDA with a PDUFA goal date of June 17, 2025. In addition, KalVista received validation of its MAA from the EMA in August 2024. KalVista expects to file for approval in the UK, Japan, and other countries later in 2024.

For more information about KalVista, please visit www.kalvista.com or follow on social media at @KalVista and LinkedIn.

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 KONFIDENT-S and KONFIDENT-KID trials, 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, 2024, 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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