KalVista Pharmaceuticals Awarded UK Promising Innovative Medicine (PIM) Designation for Sebetralstat

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– Full EAMS designation would allow treatment of patients with sebetralstat prior to receiving a Marketing Authorization from UK –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Mar. 12, 2024-- 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 the UK Medicines and Healthcare products Regulatory Agency (MHRA) has awarded the Promising Innovative Medicine (PIM) designation for sebetralstat, an investigational novel, oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE). The PIM is the first step in the Early Access to Medicines Scheme (EAMS) which would allow KalVista to treat patients with sebetralstat prior to receiving a Marketing Authorisation.

“We are proud to have sebetralstat designated as a Promising Innovative Medicine by the MHRA, which is similar to Expanded Access in the US,” said Ben Palleiko, Chief Executive Officer of KalVista. “Receiving the PIM designation shows that the MHRA believes that we have a promising candidate for the EAMS to treat people living with HAE.”

The PIM designation also gives companies the opportunity to have early in-depth discussions with both the National Health Service (NHS) and the UK’s Health Technology Agencies.

KalVista recently provided phase 3 data for sebetralstat at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting, which displayed clinically and statistically significant results across all endpoints, and an excellent safety and tolerability profile.

About the Promising Innovative Medicine Designation

A Promising Innovative Medicine Designation is an early indication that a medicinal product is a promising candidate for the Early Access to Medicines Scheme (EAMS), intended for the treatment, diagnosis or prevention of a life-threatening or seriously debilitating condition with the potential to address an unmet medical need. The designation is issued after an MHRA scientific designation meeting on the basis of non-clinical and clinical data available on the product, in a defined disease area. Following designation, the applicant is expected to complete a clinical development program within a reasonable time period, in order to continue with an application under the EAMS (step II). A designation is a prerequisite to enter the EAMS scientific opinion assessment step.

About Sebetralstat

Discovered by KalVista, sebetralstat is an investigational novel, oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE). Sebetralstat has 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 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 disclosed positive phase 3 data for the KONFIDENT trial for its oral, on-demand therapy sebetralstat in February 2024. The Company anticipates submitting a new drug application to the U.S. FDA for sebetralstat in the first half of 2024 and expects to file for approval in Europe and Japan later in 2024. 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.

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 their results, our ability 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, 2023, 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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