KalVista Announces Orphan Drug Designation and NDA Submission for Sebetralstat in Japan for Hereditary Angioedema

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–Orphan drug designation paves the way for potential of sebetralstat to be first oral on-demand treatment for HAE in Japan–

– Submission advances Company's strategic plan to address unmet needs in HAE on global scale–

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jan. 21, 2025-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has granted sebetralstat Orphan Drug Designation. The Company has also submitted a New Drug Application (NDA) for sebetralstat to the Agency. If approved, sebetralstat, a novel, investigational oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE) attacks in adults and adolescents aged 12 years and older, would be the first oral on-demand treatment for HAE in Japan.

"The submission of our NDA for sebetralstat in Japan represents another key step toward our efforts to make this important new treatment available to as many people living with HAE as possible," said Ben Palleiko, CEO of KalVista. "The Orphan Drug Designation not only acknowledges the critical need for new, effective treatments for HAE in Japan but underscores the potential of sebetralstat to provide meaningful relief for people who have faced ongoing challenges with existing options. We are proud to be at the forefront of advancing care for the HAE community."

The NDA submission is supported by previously disclosed results, including data from the KONFIDENT phase 3 clinical trial and ongoing KONFIDENT-S open-label extension trial.

About the KONFIDENT Phase 3 Trial

The KONFIDENT phase 3 clinical trial was a randomized, double-blind, 3-way crossover trial evaluating the safety and efficacy of sebetralstat 300 mg and 600 mg versus placebo for the on-demand treatment of HAE in adult and pediatric patients aged 12 years and older. The trial randomized 136 HAE patients from 66 clinical sites across 20 countries, making it the largest clinical trial ever conducted in HAE. In the trial, participants treated each eligible attack with up to two doses of study drug and treated up to three attacks over the course of the study. The trial included type 1 and type 2 HAE patients who had at least two documented HAE attacks 90 days prior to randomization and also included patients receiving long-term prophylaxis.

About the KONFIDENT-S Trial

KONFIDENT-S is an open-label extension trial with numerous real-world elements evaluating the long-term safety and efficacy of sebetralstat for the on-demand treatment of HAE attacks in adults and pediatric patients aged 12 years and older with HAE Type I or Type II. KalVista is currently transitioning ongoing participants in the trial to a novel oral disintegrating tablet (ODT) formulation to support a planned 2026 sNDA filing. If approved, the ODT formulation would provide people living with HAE with an alternative, novel option for oral, on-demand treatment.

About Sebetralstat

Sebetralstat is an investigational, novel oral plasma kallikrein inhibitor for the treatment of hereditary angioedema (HAE). We have filed multiple regulatory applications seeking approval of sebetralstat as the first oral, on-demand treatment for HAE in individuals aged 12 and older, with ongoing studies exploring its use in children aged 2 to 11. If approved, sebetralstat has the potential to become the foundational therapy for HAE management worldwide.

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 area affected. All currently approved on-demand treatment options require either intravenous or subcutaneous administration.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc., is a global biopharmaceutical company dedicated to developing and delivering life-changing oral therapies for individuals affected by rare diseases with significant unmet needs. Our lead investigational product is sebetralstat, a novel, oral, on-demand treatment for hereditary angioedema (HAE). Sebetralstat is under regulatory review by the U.S. FDA, with a PDUFA goal date of June 17, 2025. In addition, we have completed Marketing Authorization Applications for sebetralstat to the European Medicines Agency and multiple other global regulatory authorities.

For more information about KalVista, please visit **www.kalvista.com** or follow us 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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