KalVista Pharmaceuticals Awarded UK Innovation Passport for Sebetralstat

Feb 20, 2024

– Provides entry to UK Innovative Licensing and Access Pathway (ILAP), which aims to accelerate time to market and facilitate patient access to innovative medicines –

– Late-breaking sebetralstat phase 3 data to be presented at the upcoming 2024 American Academy of Allergy, Asthma & Immunology Annual Meeting –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Feb. 20, 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 Innovation Passport for sebetralstat, an investigational novel, oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE). The Innovation Passport is the first step in the UK's Innovative Licensing and Access Pathway (ILAP), which is designed to accelerate a product's time to market and facilitate patient access to innovative medicines.

"As a company which has its roots in the UK, we are pleased to receive the ILAP designation, which will enable us to further accelerate our regulatory submission for sebetralstat," said Andrew Crockett, Chief Executive Officer of KalVista. "We look forward to collaborating with the MHRA and other health regulatory agencies worldwide as we continue to work towards bringing the first oral, on demand treatment to people living with HAE."

KalVista recently provided topline phase 3 data for sebetralstat, which displayed clinically and statistically significant results across all endpoints, and an excellent safety and tolerability profile. The Company will be presenting late-breaking KONFIDENT trial data on February 25, 2024, at the upcoming American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting.

About the Innovation Passport

Delivered in partnership by the All Wales Therapeutics and Toxicology Centre (AWTTC), the Medicines and Healthcare products Regulatory Agency (MHRA), the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC), the Innovation Passport prioritizes innovative medicines in development for the treatment of diseases for patients with significant unmet need. Benefits of the ILAP include opportunities for enhanced regulatory and other stakeholder access with the aim of accelerating the time it takes for a product to reach the market, thereby boosting patients' access to innovative medicines.

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 its results, our ability to commence clinical studies or complete ongoing clinical studies, including the KONFIDENT-S 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, 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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KalVista Pharmaceuticals, Inc.
Jarrod Aldom
Vice President, Corporate Communications

(201) 705-0254
jarrod.aldom@kalvista.com

Ryan Baker
Head, Investor Relations
(617) 771-5001
ryan.baker@kalvista.com

Source: KalVista Pharmaceuticals, Inc.