KalVista Pharmaceuticals Highlights Strategic Plans for Coming Fiscal Year

May 01, 2024

- Regulatory filings planned for US, EU, UK and Japan to enable multiple 2025 commercial launches –

- Development strategy refined for oral Factor XIIa program –

- Organizational focus to drive results and set path to positive cash flow –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--May 1, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today announced its strategic plans for fiscal year 2025, beginning May 1, including for sebetralstat, the Company's investigational novel, oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE).

"2024 has been an exciting and busy year for KalVista, as we achieved key milestones with our positive phase 3 KONFIDENT data and the completion of a substantial financing," said Ben Palleiko, Chief Executive Officer of KalVista. "For the coming fiscal year, we have set a high bar as we finalize multiple regulatory filings for sebetralstat and plan for rapid commercialization upon approval. Given the scale of that opportunity, we will focus our resources on activities that support the launch, enabling sebetralstat to become the leading on-demand therapy for all people living with HAE and allowing us to work towards positive cash flow within the first few years of commercialization."

Fiscal Year 2025 Strategic Plans:

Regulatory filings and commercial partners for sebetralstat, to support global launch plans

- New Drug Application submission to US FDA planned for June 2024
- Market Authorization Application submissions to both European Medicines Agency and UK MHRA planned for Q3 2024
- JNDA submission to Japanese Pharmaceuticals and Medical Devices Agency planned for Q4 2024
- Regulatory review timelines enable potential launches of sebetralstat in these territories in calendar 2025 and early 2026
- To enable the broadest possible global launch, we intend to engage commercial partners in certain international markets, targeting to select initial partners over the course of 2024

Continued lifecycle extension activities for sebetralstat, to grow the market opportunity

- Commence pediatric trial (KONFIDENT-KID) in Q3 2024, using an orally disintegrating tablet (ODT) formulation developed specifically for pediatric use. If approved, sebetralstat would be the first oral therapy in pediatric patients under age 18. In addition, sebetralstat would be only the second FDA-approved on-demand therapy of any type in this population
- Conversion of adolescent and adult participants in the ongoing KONFIDENT-S study to an ODT formulation in Q4 2024, enabling a potential 2026 sNDA approval. If approved, the ODT formulation would provide people living with HAE with an additional novel option for oral on-demand treatment

Resources focused on sebetralstat for on-demand HAE with goal of positive cash flow

- Following a strategic review of the preclinical oral Factor XIIa program, we have determined that the most promising indications for development lie outside the Company's core capabilities. Therefore, further development of the program will be dependent upon collaboration with a strategic partner with expertise and resources to support advancement of the clinical candidates in these potential indications. We intend to engage with potential partners over the course of 2024 and will provide updates as warranted
- Based on this prioritization we intend to reduce spending on discovery and preclinical activities by more than 75%, to less than $5 million per year
- We believe that these portfolio and investment prioritization decisions, in combination with the anticipated launch of sebetralstat, can support the Company becoming cash flow positive within the first few years of the anticipated sebetralstat commercial launch

Upcoming medical & patient organization meetings at which KalVista will present data

- EAC 2024 (May 30 – June 2, Palm Beach, FL)
- EAACI Congress 2024 (May 31 – June 3, Valencia, Spain)
- Bradykinin Symposium 2024 (September 5-6, Berlin, Germany)
- HAEi Global Leadership Workshop (October 3-6, Copenhagen, Denmark)
- ACAAI Conference 2024 (October 24-28, Boston)

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 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. Food and Drug Administration (FDA) for sebetralstat in June 2024 and expects to file for approval in the UK, Europe and Japan later in 2024.

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 or other international regulatory agencies, our expectations about safety and efficacy of our product candidates, our ability to obtain regulatory approvals for sebetralstat and other candidates in development within our expected timelines or at all, our success in engaging with potential commercial partners, the success of any efforts to commercialize sebetralstat, the ability of sebetralstat and other candidates in development to treat HAE or other diseases, our ability to commence pediatric trials of sebetralstat and develop an OTD formulation, the future progress and potential success of our oral Factor XIIa program, our ability to reduce spending on discovery and preclinical activities, and our expectation to become cash flow positive. 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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