



## KalVista Pharmaceuticals Announces FDA Will Not Meet PDUFA Goal Date for Sebetralstat NDA for Hereditary Angioedema Due to FDA Resource Constraints

Jun 13, 2025

*FDA states heavy workload and limited resources prevent meeting PDUFA goal date of June 17*

*Agency indicates anticipated decision within four weeks*

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jun. 13, 2025-- [KalVista Pharmaceuticals](#), Inc. (Nasdaq: KALV) today announced that the U.S. Food and Drug Administration (FDA) has notified the Company that it will not meet the PDUFA goal date for the New Drug Application (NDA) for sebetralstat, the Company's investigational oral on-demand treatment for hereditary angioedema (HAE). The FDA notified the Company on June 13, 2025, that the previously disclosed June 17, 2025 PDUFA goal date will not be met due to heavy workload and limited resources. The FDA indicated that it expects to deliver a decision within approximately four weeks.

The FDA has not requested additional data or studies and has not raised any concerns regarding the safety, efficacy or approvability of sebetralstat. KalVista has addressed all prior information requests in a timely manner, and the Company believes the only remaining item under FDA review is the finalization of the labelling.

"We are disappointed by this delay, most importantly because we know how much people living with HAE are looking forward to an oral on-demand option to treat their HAE attacks," said Ben Palleiko, CEO of KalVista. "At the same time, we remain confident in the near-term approval of sebetralstat. We are continuing to work closely with the FDA to support the completion of their review. Our commitment to bringing this important therapy to people living with HAE remains unwavering."

### **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 and are investigating 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. 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](http://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 XIIIa 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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