KalVista Pharmaceuticals Announces Maintenance of Orphan Designation for Sebetralstat in European Union

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Sebetralstat is one of only two hereditary angioedema therapies to maintain orphan designation, underscoring its major contribution to patient care

If approved, sebetralstat will be granted 10 years of market exclusivity in EU

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Aug. 11, 2025-- KalVista Pharmaceuticals, Inc. (Nasdaq: KALV) today announced that the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) confirmed maintenance of orphan designation for sebetralstat, underscoring the critical unmet need that sebetralstat addresses in the European Union (EU). Sebetralstat, a novel, oral plasma kallikrein inhibitor, has received a positive CHMP opinion for the treatment of acute attacks of hereditary angioedema (HAE), and the European Commission (EC) final decision is expected by early October.

“We are pleased with the decision to maintain EU orphan designation for sebetralstat, which is an uncommon achievement that reflects the significant benefits sebetralstat offers,” said Ben Palleiko, CEO of KalVista. “Orphan status provides benefits that will support the commercialization of sebetralstat in the EU, including 10 years of market exclusivity, as we continue our efforts to bring this important new treatment option to people living with HAE around the world.”

The decision to maintain orphan designation was based on a finding of comparable efficacy of sebetralstat to injectable on-demand treatments while offering a major contribution to patient care by reducing the morbidity of HAE attacks. Maintenance of orphan designation provides several important regulatory and financial benefits, including 10 years of market exclusivity in the EU following approval. Notably, sebetralstat is now one of only two HAE medicines to have maintained orphan designation in the EU, highlighting its distinctive position within the HAE treatment landscape.

“Maintaining orphan designation for sebetralstat is a recognition of the meaningful impact this therapy can have on people living with HAE,” said Mauro Cancian, MD, PhD, Head of the Allergy Division at the University of Padua in Padova, Italy. “With currently available injectable therapies, many patients delay or avoid treatment due to the hassle and fear of injection-site reactions, often suffering through attacks longer than they need to. Oral sebetralstat has the potential to change that, giving patients the ability to treat attacks early, with confidence, in a way that fits their lifestyle.”

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. Treatment guidelines recommend treating attacks as early as possible to prevent progression of swelling and shorten the time to attack resolution, and to consider treatment for all attacks, regardless of anatomic location or severity.

About Sebetralstat

Sebetralstat is a novel plasma kallikrein inhibitor approved in the United States and United Kingdom under the brand name EKTERLY® for the treatment of HAE attacks in people 12 years of age and older. With ongoing studies exploring its use in children aged two to 11 and multiple regulatory applications under review in key global markets, sebetralstat has the potential to become the foundational therapy for HAE management worldwide.

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. In the U.S., KalVista markets EKTERLY®, the first and only oral on-demand treatment for hereditary angioedema (HAE). The Company has multiple regulatory applications under review in key global markets. For more information about KalVista, please visit www.kalvista.com and follow us on LinkedIn, X, Facebook and Instagram.

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, information relating to our business and business plans, the success of our efforts to commercialize EKTERLY® (sebetralstat), our ability to successfully obtain foreign regulatory approvals for sebetralstat, including approval by the EC, our expectations about the timing of the EC’s final decision, our expectations about the safety and efficacy of sebetralstat and our other product candidates, the timing of clinical trials and their results, our ability to commence clinical studies or complete ongoing clinical studies, including our KONFIDENT-S and KONFIDENT-KID trials, and the ability of EKTERLY to treat HAE. 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, 2025, 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.

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

Molly Cameron
Director, Corporate Communications
(978) 339-3378
molly.cameron@kalvista.com

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