NICE Recommends EKTERLY®▼ (sebetralstat) the First Oral, On-Demand Treatment Option for Hereditary Angioedema (HAE) Attacks

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The National Institute for Health and Care Excellence (NICE) has issued final draft guidance recommending sebetralstat, within its marketing authorisation, as an oral, on-demand option for the treatment of HAE attacks in adults and adolescents aged 12 years and older on the National Health Service (NHS) in England and Wales.

FRAMINGHAM, Mass. & SALISBURY, England--(BUSINESS WIRE)--Nov. 25, 2026-- KalVista Pharmaceuticals, Inc. ("KalVista"), a company of the Chiesi Group, welcomed a decision by the National Institute for Health and Care Excellence (NICE) to recommend sebetralstat, within its marketing authorisation, as an oral option for the on-demand treatment of hereditary angioedema (HAE) attacks in adult and adolescent patients aged 12 years and older on the National Health Service (NHS) in England and Wales.[1]

HAE is a rare genetic disease that causes unpredictable, painful attacks of tissue swelling in various locations of the body that can be life-threatening depending on the area affected.[2] It is estimated to affect 1,000 to 1,500 people across the United Kingdom.[3] Sebetralstat works by blocking plasma kallikrein, which is a protein that plays a key role in swelling in HAE attacks.[4]

The recommendation is informed by results from the phase 3 KONFIDENT clinical trial, randomised, double-blind, placebo-controlled, three-way cross-over design, published in the New England Journal of Medicine.[5]

Across the study, 110 patients treated a total of 264 attacks. These included 87 attacks treated with sebetralstat 300 mg and 84 treated with placebo. Attacks ranged in severity from mild to very severe and occurred in all anatomical locations.[4] An additional dose could be taken if needed following initial treatment of an attack. The primary efficacy endpoint was the time to beginning of symptom relief, assessed using the Patient Reported Global Impression of Change (PGI-C), which required patients to assess their attack symptoms using a seven-point scale ("much worse" to "much better"). To achieve the primary endpoint, a patient had to report a positive and sustained response on the PGI-C within 12 hours. There was a statistically significant faster time to the beginning of symptom relief for 300 mg sebetralstat (Bonferroni adjusted $p<0.0001$) compared to placebo. The median time to the beginning of symptom relief was 1.61 hours (95% CI: 1.28 - 2.27) with sebetralstat 300 mg, compared with 6.72 hours (95% CI: 2.33 - NE) with placebo (NE = not evaluable at 12 hours).

In clinical studies used for registration, 1,945 HAE attacks have been treated with sebetralstat. The most common adverse reaction in HAE patients treated with sebetralstat is headache (reported by 9.2% of patients). The reported events of headache were generally mild to moderate in severity, non-serious and resolved without any further intervention.

About Hereditary Angioedema (HAE)
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.[3] 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.[2] 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.[6,7]

About EKTERLY® (sebetralstat)
EKTERLY (sebetralstat) is a competitive, reversible inhibitor of plasma kallikrein and is indicated for the treatment of hereditary angioedema (HAE) attacks in adult and adolescents aged 12 years and older.

For complete product information, please see the Summary of Product Characteristics that can be found on https://products.mhra.gov.uk/.

About KalVista Pharmaceuticals, Inc.
KalVista, a company of the Chiesi Group, is a global pharmaceutical company dedicated to delivering oral therapies for people affected by rare diseases with significant unmet needs. The KalVista team discovered and developed sebetralstat for hereditary angioedema (HAE) and continues to work closely with the global HAE community to improve treatment and care worldwide. As part of Chiesi Global Rare Diseases, a Chiesi Group business unit established to deliver innovative therapies and solutions for people living with rare diseases, KalVista is building on its expertise in HAE and contributing to a shared mission to help underserved rare disease communities live their most fulfilling lives.

For more information, please visit www.kalvista.com and www.chiesi.uk.com

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