KalVista Pharmaceuticals Presents New Sebetralstat Data at the 2024 American College of Allergy Asthma and Immunology

Oct 28, 2024

–Phase 3 trial data show that early treatment is correlated with shorter attack duration–

– Rigorous comparison of Phase 3 results for oral sebetralstat and pivotal trial results of IV recombinant C1-inhibitor for on-demand treatment of HAE attacks shows no differences in time to beginning of symptom relief –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Oct. 28, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today announced the presentation of new sebetralstat data at the American College of Allergy Asthma and Immunology (ACAAI) taking place in Boston, MA from October 24 - 28, 2024.

Tim Craig, DO, Professor, Departments of Medicine and Pediatrics, Division of Pulmonary, Allergy and Critical Care Medicine, Penn State Health, and KONFIDENT investigator, presented data on the **Correlation of Time to Treatment with Attack Duration in the Sebetralstat KONFIDENT Phase 3 Trial** that showed complete attack resolution was achieved faster in attacks that were treated earlier (1st quartile) compared with those treated later (4th quartile).

“This is the first time in a Phase 3 on-demand trial where we can see that treating attacks within minutes versus hours has a meaningful impact on clinical outcomes. While injectable on-demand therapies are effective, there are numerous barriers patients face that lead to delay or denial of HAE on-demand treatment,” said Dr. Craig. “These data help to clarify the potential value of sebetralstat if approved: reduced burden enabling patients to treat attacks early and achieve earlier symptom relief and shorter attack duration.”

William Lumry, MD, Medical Director AARA Research Center, Dallas and KONFIDENT investigator, presented data on the **Substantial Reduction of HAE Symptom Burden in the Sebetralstat Phase 3 KONFIDENT Trial** which showed that among attacks that had progressed to at least moderate severity on the Patient Global Impression of Severity (PGI-S) prior to treatment, those treated with sebetralstat 300mg (n=49, *P*=0.002) and sebetralstat 600mg (n=52, *P*=0.034) achieved a faster reduction in substantial symptom burden (reduction in PGI-S to “mild”) than with placebo (n=46), with median times of 5.0 hours, 5.2 hours, and >12 hours, respectively.

“All other clinical trial designs for on-demand therapy have required attacks to be at least moderate in severity to be eligible to treat. This changed with the sebetralstat Phase 2 and 3 trials which, consistent with modern HAE guidelines, instructed patients to treat attacks early. Despite this, approximately half of attacks progressed in severity prior to treatment,” said Dr. Lumry. “Among these more severe attacks, which were treated somewhat later, sebetralstat reduced symptom burden to “mild” significantly faster than placebo, with a median time of approximately 5 hours for sebetralstat vs >12 hours for placebo.”

The following are details for the additional ePoster - Meet the Author data presentations at ACAAI 2024:

- **Indirect Treatment Comparison of Oral Sebetralstat and Intravenous rhC1-INH as On demand Treatments for Hereditary Angioedema:** H. Henry Li, Institute for Asthma and Allergy, Chevy Chase, MD, USA
  - The network meta-analysis (NMA) fixed effects model found no significant differences in time to beginning of symptom relief between sebetralstat 300mg and IV-rhC1-INH 50 IU/kg (HR [95% CI] 0.96 [0.42-2.15] to 1.19 [0.58-2.45]).
  - After adjusting for baseline attack severity, matching-adjusted indirect comparison showed numerically favorable results with sebetralstat versus IV-rhC1-INH.
- **On-demand Treatment of Laryngeal Hereditary Angioedema Attacks with Sebetralstat: Pooled Analysis from KONFIDENT and KONFIDENT-S:** Emel Aygören-Pürsün, University Hospital Frankfurt, Goethe University Frankfurt, Frankfurt, Germany
  - Pooled Analysis from KONFIDENT and KONFIDENT-S included 16 laryngeal attacks treated with sebetralstat 600mg. Median time to treatment was 8 minutes.
  - Median time to beginning of symptom relief was 1.5 hours; median time to reduction in severity was 1.7 hours; median time to complete attack resolution was 9.7 hours.
- **Patient-Reported Anxiety Impacts Utilization of Injectable On-demand Treatment of Hereditary Angioedema Attacks:** Cristine Radojicic, Duke University School of Medicine, Durham, NC, USA
  - The survey highlighted patients with Type I/II HAE who reported waiting 2.4 hours to treat their HAE attack after recognizing the initial onset of the attack.
  - Those who were experiencing anxiety related to their injectable on-demand treatment were most likely to delay or not treat attacks.

“The HAE community has long sought a less invasive treatment option that combines needed efficacy with lower treatment burden. These presentations continue to demonstrate that sebetralstat has the potential to provide injectable-like efficacy in a pill,” said Ben Palleiko, CEO of KalVista Pharmaceuticals. “If approved, sebetralstat will be the only on-demand treatment option that will have demonstrated the ability to enable compliance with treatment guidelines that call for early treatment of attacks, regardless of severity or location.”

Links to all posters and presentations can be found on the KalVista website under Publications.

About Sebetralstat
Discovered and developed entirely by the scientific team at KalVista, sebetralstat is a novel, investigational oral plasma kallikrein inhibitor for the on-demand treatment of hereditary angioedema (HAE). Sebetralstat 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 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 location affected. All currently approved on-demand treatment options require either intravenous or subcutaneous administration.

About KalVista Pharmaceuticals, Inc.
KalVista Pharmaceuticals, Inc. is a global pharmaceutical company whose mission is to develop and deliver life-changing oral medicines for people affected by rare diseases with significant unmet need. Sebetralstat, our novel, investigational candidate for the oral, on-demand treatment of hereditary angioedema, is under regulatory review by the U.S. FDA with a PDUFA goal date of June 17, 2025. In addition, we have completed marketing authorization application (MAA) submissions for sebetralstat to the European Medicines Agency as well as the United Kingdom, Switzerland, Australia, and Singapore, and we anticipate filing a MAA in Japan in late 2024. For more information, please visit www.kalvista.com or follow 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 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, 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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