

KalVista Pharmaceuticals Presents Data at Eastern Allergy Conference 2024 and the Japanese Dermatological Association 2024

Jun 06, 2024

- US subgroup in the phase 3 KONFIDENT trial demonstrates median time to treatment of 38 minutes and time to beginning of symptom relief 1.3 hours -

 Despite growing use of long-term prophylaxis therapies in the US on-demand treatment prescription volumes stay stable and non-prescription healthcare costs for management of HAE remain substantial –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jun. 6, 2024-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), today announced that it presented the US subgroup analysis from the sebetralstat phase 3 KONFIDENT trial and real-world claims and patient survey data at the Eastern Allergy Conference (EAC) 2024, as well as the Japanese subgroup from KONFIDENT at the 123rd Annual Meeting of the Japanese Dermatological Association (JDA) 2024. KONFIDENT is the first pivotal phase 3 trial to include Japanese sites in an HAE development program.

The following presentations occurred at EAC 2024:

- Sebetralstat for On-demand Treatment of Hereditary Angioedema Attacks: US Subgroup Analysis from the Doubleblind, Placebo-controlled Phase 3 KONFIDENT Trial: Daniel Soteres, Asthma & Allergy Associates P.C., Colorado Springs, Colorado, United States. (Poster presentation)
 - Median time from attack onset to administration was 38 minutes (IQR 5-124) for the US subgroup (78 attacks), which compares favorably to the median time to treatment of 41 minutes (IQR 6-140) in the overall trial population
 - Median time to beginning of symptom relief for 300 mg in the US subgroup was 1.28 hours (IQR 0.77-3.12), which also compares favorably to the 300 mg median time to beginning of symptom relief of 1.61 hours (IQR 0.78-7.04) for the overall trial population
- Trends in volume of on-demand hereditary angioedema treatments in the US: A retrospective analysis of a large multi-payer claims database: Daniel Soteres, Asthma & Allergy Associates P.C., Colorado Springs, Colorado, United States. (Poster presentation)
 - Despite the advent of multiple non-androgen LTPs since 2017, the overall trend in the total number of claims reimbursed and quantity dispensed for on-demand treatments has remained stable in the US
 - Average year-over-year variability in the total number of on-demand syringes and vials dispensed per quarter has remained within 3% and 10%, respectively, of baseline from Q3 2018 Q3 2023
- Healthcare Costs Among Commercially Insured Patients with Hereditary Angioedema Managed with Long-term Prophylaxis: a Retrospective US Claims Database Analysis: Daniel Soteres, Asthma & Allergy Associates P.C., Colorado Springs, Colorado, United States. (Poster presentation)
 - Claims database analysis revealed that HAE-related non-pharmacy resource utilization costs among patients receiving non-androgen LTP were substantial, averaging >\$641,000 in HAE healthcare costs per patient per year
 - Approximately one-third of patients receiving non-androgen LTP had ≥1 HAE-related ER visits during follow-up (33%), and nearly one-quarter (22%) had ≥1 HAE-related home health visit
- Real-World Impact of Treated Hereditary Angioedema Attacks on Patients' Quality of Life: Maeve O'Connor, Allergy, Asthma, & Immunology Relief of Charlotte, Charlotte, NC, United States. (Poster presentation)
 - Attacks occurring among patients receiving non-androgen LTP and those receiving on-demand treatment only similarly impact physical and social quality of life (QoL)
 - Attacks treated in <1 hour were associated with a lower impact on QoL
- Real-world Impact of Treated Hereditary Angioedema Attacks on Patients' Employment and Work Productivity:
 - Maeve O'Connor, Allergy, Asthma, & Immunology Relief of Charlotte, Charlotte, NC, United States. (Poster presentation)
 o HAE attacks among patients receiving non-androgen LTP and those receiving on-demand treatment only similarly impacted the work lives of employed patients resulting in impairments in their ability to work, substantial absenteeism, reduced productivity, and presenteeism among those who were able to work
- Burden of the Untreated Attacks and its Impact on Social, Mental and Physical Health: Maeve O'Connor, Allergy, Asthma, & Immunology Relief of Charlotte, Charlotte, NC, United States. (Poster presentation)
 - Patients, including those taking LTP, reported that untreated HAE attacks often progressed in severity, migrated to other locations, and were associated with social isolation and impact on physical/mental health
 - 70% of patients indicated that their last untreated attack had an impact on their energy levels; 55% and 22% of LTP and on-demand only patients, respectively, felt reluctant to go out in public

The following presentation occurred at the Annual Meeting of the JDA 2024:

• Sebetralstat KONFIDENT Is the First Phase 3 On-demand HAE Trial to Include Japanese Sites: Daisuke Honda, Chiba University Graduate School of Medicine, Chiba, Japan. (Poster presentation)

- Despite the relatively small number of attacks that were treated in the subgroup of Japanese KONFIDENT participants, primary endpoint results were consistent with those observed in the overall trial population
- Among Japanese participants, sebetralstat was well tolerated with no treatment-related TEAEs, no serious or severe TEAEs, and no TEAEs leading to study discontinuation

"We have observed exceptional consistency of results across subgroups in the KONFIDENT trial including attack severity, location, treatment paradigm (with or without long-term prophylaxis) and geography," said Ben Palleiko, CEO of KalVista Pharmaceuticals. "This data further highlights that patients on LTP generally continue to have attacks, and that those attacks have similar impact as on-demand only users, showing the continued unmet need although it is not generally recognized. In parallel, claims data also highlight that on-demand prescription volumes have remained stable despite the introduction of subcutaneous and oral long-term prophylaxis options. Sebetralstat has the potential to transform the management of HAE."

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

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 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-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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240606656084/en/

KalVista Pharmaceuticals, Inc. Jarrod Aldom Vice President, Corporate Communications (201) 705-0254 jarrod.aldom@kalvista.com

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

Source: KalVista Pharmaceuticals, Inc.