Pharvaris Presents Data Highlighting the Potential for Deucrictibant to Prevent and Treat Bradykinin-Mediated Angioedema Attacks at the EAACI Congress

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ZUG, Switzerland, June 16, 2025 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to help address unmet needs of those living with bradykinin-mediated diseases such as hereditary angioedema (HAE) and acquired angioedema due to C1 inhibitor deficiency (AAE-C1INH), today announced a summary of data that were presented at the European Academy of Allergy and Clinical Immunology (EAACI) Congress 2025.

"Pharvaris embraced the opportunity to engage in scientific exchange with the HAE thought leader community during EAACI as we presented data supporting the differentiated profile of deucrictibant for the prophylactic and on-demand treatment of bradykinin-mediated angioedema attacks," said Berndt Modig, Chief Executive Officer of Pharvaris. "Building on our R&D call from last week, we shared data demonstrating the potential for deucrictibant to address the unmet needs of people living with bradykinin-mediated angioedema beyond HAE-1/2. Deucrictibant showed sustained attack reduction and improved quality of life measures in the randomized portion of the CHAPTER-1 study, which was maintained in the open-label extension study, as well as early-onset symptom relief and complete symptom resolution in a single dose in most attacks in our ongoing RAPIDe-2 on-demand long-term extension study. Finally, RAPIDe-3 is the first and only phase 3 on-demand study that will explore 'end-of-progression' as a new pre-specified endpoint, which is particularly meaningful for people living with HAE. Together with the outcomes from other study endpoints, we will be able to assess the full impact of deucrictibant on an HAE attack from start to end."

Details of the presentations are outlined below:
Prophylaxis
Long-Term Safety and Efficacy of Oral Deucrictibant for Prophylaxis in Hereditary Angioedema: Results of the CHAPTER-1 Open-Label Extension Study, a poster presentation by Emel Aygören-Pürsün, M.D.

- First-ever bradykinin B2 receptor antagonism mechanism-on-mechanism prophylactic/on-demand data supports potential for deucrictibant portfolio.
- The ongoing Phase 2 CHAPTER-1 open-label extension (OLE) study provides further evidence on the long-term safety and efficacy of oral deucrictibant for prevention of HAE attacks.
- The attack rate has remained low, irrespective of baseline attack rate, for over a year and a half in OLE participants.
- When evaluating mechanism-on-mechanism responses, the response to icatibant for on-demand treatment of breakthrough attacks appeared to be maintained when used for breakthrough attacks during prophylactic treatment with deucrictibant.

Long-Term Prophylactic Treatment with Oral Deucrictibant Improves Disease Control and Health-Related Quality of Life in Participants with Hereditary Angioedema in the CHAPTER-1 Open-Label Extension Study, a flash talk by Markus Magerl, M.D.

- The impact of deucrictibant treatment on health-related quality of life (HRQoL), disease control, and treatment satisfaction during the ongoing CHAPTER-1 OLE was evaluated.
- All of the participants who received deucrictibant reported clinically meaningful improvements in HRQoL at the end of the randomized portion of the trial, which was maintained up to the latest timepoint assessed at the time of data cutoff (week 62) of the OLE.
- All of the participants in the OLE reported well controlled HAE and a high level of satisfaction with treatment.

CHAPTER-3 Phase 3 Trial Design: Efficacy and Safety of the Oral Bradykinin B2 Receptor Antagonist Deucrictibant Extended-Release Tablet for Prophylaxis of Hereditary Angioedema Attacks, a flash talk by William Lumry, M.D.

- CHAPTER-3 is an ongoing, global, Phase 3 study designed to evaluate the efficacy and safety of once-daily, oral deucrictibant (40 mg/day) extended release (XR) tablet for prophylaxis of attacks in adolescents and adults with HAE.
- Results from the Phase 2 CHAPTER-1 study support the CHAPTER-3 study design.

Health-Related Quality of Life and Clinical Characteristics in People Living with Hereditary Angioedema Prescribed Long Term Prophylaxis Alone and On-Demand Treatment Alone, an oral presentation by Laurence Bouillet, M.D., Ph.D.

- A real-world cross-sectional survey was conducted to assess the relationship between treatment and outcomes of patients with HAE type 1/2 prescribed LTP or ODT alone in a real-world setting.
- 162 physicians reported data for 601 patients from Europe and the United States, collected via the Adelphi HAE Wave II Disease Specific Programme™ (DSP).
- Of the 601 patients, 41% were taking LTP, and 59% were taking ODT alone.
- Study results showed that patients with HAE prescribed LTP in the last 12 months experienced more mild attacks than moderate or severe attacks and had significantly better health related quality of life at the time of the survey compared with those prescribed ODT alone.

- Analysis suggests that both LTP and ODT play important roles in HAE management and corroborates international guidelines that recommend patients with HAE on LTP must always have ODT available at all times.

On-Demand

Long-Term Safety and Efficacy of Oral Deucrictibant for Treatment of Hereditary Angioedema Attacks: Results of the RAPIDe-2 Extension Study, a thematic poster session by Henriette Farkas, M.D., Ph.D., D.Sc.

- Following the closure of Part A of RAPIDe-2, a Phase 2/3 study of deucrictibant for the on-demand treatment of HAE attacks, an analysis of 465 attacks from 19 participants, including 14 upper airway attacks from seven participants, was conducted.
- The final results from Part A of the RAPIDe-2 extension are consistent with the Phase 2 RAPIDe-1 randomized study.
- Deucrictibant continued to be well tolerated across all doses with no treatment-related treatment-emergent adverse events reported.
- The median time to onset of symptom relief was 1.1 hours, and 97.8% of attacks achieved onset of symptom relief by 12 hours.
- The median time to complete attack resolution was 10.6 hours, and 86.9% of attack achieved complete resolution at 24 hours.
- Deucrictibant data shows single-dose durability without symptom reoccurrence in most HAE attacks treated.
    - 89.2% of the attacks that achieved symptom resolution at 24 hours were treated with a single dose of deucrictibant.

Safety and Efficacy of Oral Deucrictibant for Treatment of Upper Airway and Laryngeal Hereditary Angioedema Attacks: Results from the RAPIDe-2 Extension Study, a flash talk by Anna Valerieva, M.D., Ph.D.

- The final data from Part A of the RAPIDe-2 study showed that safety and efficacy outcomes of treatment with deucrictibant IR were consistent for both HAE attacks affecting the upper airways, including laryngeal attacks, and HAE attacks occurring in other locations.
- Deucrictibant was generally well tolerated with no treatment-related treatment-emergent adverse events reported across upper airway and non-upper airway attacks.
- Fourteen upper airway attacks were treated by 7 participants; the median time to onset of symptom relief, as measured by Patient Global Impression of Change (PGI-C) of “a little better”, was 1.4 hours (n=14) for upper airway attacks and 1.1 hours for non-upper airway attacks (n=451).
- Endpoint measurements taken throughout the span of an entire attack until and including complete resolution were similar for both upper airway and non-upper airway attacks.
- Importantly, 92.9% of the upper airway attacks were treated with a single dose of deucrictibant.

Expansion Beyond HAE

Clinical Validation of a Novel Kinin Biomarker Assay for Characterization of Bradykinin-Mediated Pathologies in U.S. Subjects with Hereditary Angioedema, a flash talk by Evangelia Pardali, Ph.D.

- Assays for an early and accurate diagnosis of bradykinin-mediated angioedema are lacking.
- Cold activation of plasma from people living with HAE resulted in increased levels of bradykinin compared to cold-activated plasma of healthy volunteers. The qualified kinin assay can be used to reliably characterize a bradykinin signature in people with recurrent angioedema and could become a key tool aiding identification, study, and management of bradykinin-mediated pathologies including bradykinin-mediated angioedema.
- As presented at the 14th C1-Inhibitor Deficiency and Angioedema Workshop, the performance of the assay does not depend on availability of “fresh” plasma samples and the assay can also be applied in biobank samples for identification of people with bradykinin-mediated angioedema.

Development of a Conceptual Model Supporting a Clinical Outcome Assessment Strategy for Acquired Angioedema due to C1 Inhibitor Deficiency, a thematic poster session by Andrea Zanichelli, M.D., Ph.D.

- There are currently no approved therapies for the treatment of AAE-C1INH attacks, nor patient-reported outcome measures validated in AAE-C1INH.
- Concept elicitation and cognitive interviews were performed to develop a conceptual model of AAE-C1INH that could reveal important disease concepts supporting a clinical outcome assessment strategy, as well as evaluating the comprehension and interpretation of PGI-C, PGI-Severity (PGI-S), patient global assessment of change (PGA-C), and PGA-Status (PGA-S), and explore perceptions of meaningful change using these measures.
- One hundred percent of participants considered PGI-C “better” to be a meaningful change four hours post-treatment.
- Epidemiologic data and cognitive interviews further elucidate the unmet needs in bradykinin-mediated angioedema.

The posters are available on the Investors section of the Pharvaris website at: https://ir.pharvaris.com/news-events/events-presentations.

About Deucrictibant

Deucrictibant is a novel, potent, orally bioavailable small-molecule bradykinin B2 receptor antagonist currently in clinical development. Deucrictibant is being investigated for its potential to prevent the occurrence of bradykinin-mediated angioedema attacks and to treat the manifestations of attacks if/when they occur by inhibiting bradykinin signaling through the bradykinin B2 receptor. Pharvaris is developing two formulations of deucrictibant for oral administration: an extended-release tablet to enable sustained absorption and efficacy as prophylactic treatment, and an immediate-release capsule to enable rapid onset of activity for on-demand treatment. Deucrictibant has been granted orphan drug designation for the treatment of bradykinin-mediated angioedema by the U.S. Food and Drug Administration and orphan designation by the European Commission.

About Pharvaris

Pharvaris is a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to potentially address all types of bradykinin-mediated angioedema. Pharvaris intends to provide injectable-like efficacy™ and placebo-like tolerability with the convenience of oral therapies to prevent and treat bradykinin-mediated angioedema attacks. With positive data in both Phase 2 prophylaxis and on-demand studies in HAE, Pharvaris is currently evaluating the efficacy and safety of deucrictibant in a pivotal Phase 3 study for the prevention of HAE attacks (CHAPTER-3) and a pivotal Phase 3 study for the on-demand treatment of HAE attacks (RAPIDe-3). For more information, visit https://pharvaris.com/.

Forward Looking Statements

This press release contains certain forward-looking statements that involve substantial risks and uncertainties. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements relating to our future plans, studies and trials, and any statements containing the words “believe,” “anticipate,” “expect,” “estimate,” “may,” “could,” “should,” “would,” “will,” “intend” and similar expressions. These forward-looking statements are based on management’s current expectations, are neither promises nor guarantees, and involve known and unknown risks, uncertainties and other important factors that may cause Pharvaris’ actual results, performance or achievements to be materially different from its expectations expressed or implied by the forward-looking statements. Such risks include but are not limited to the following: uncertainty in the outcome of our interactions with regulatory authorities, including the FDA; the expected timing, progress, or success of our clinical development programs, especially for deucrictibant immediate-release capsules and deucrictibant extended-release tablets, which are in late-stage global clinical trials; our ability to replicate the efficacy and safety demonstrated in the RAPIDe-1, RAPIDe-2, and CHAPTER-1 Phase 2 and Phase 3 studies in ongoing and future nonclinical studies and clinical trials; risks arising from epidemic diseases, which may adversely impact our business, nonclinical studies, and clinical trials; our ability to potentially use deucrictibant for alternative purposes, for example to treat C1-INH deficiency (AAE-C1INH); the outcome and timing of regulatory approvals; the value of our ordinary shares; the timing, costs and other limitations involved in obtaining regulatory approval for our product candidates, or any other product candidate that we may develop in the future; our ability to establish commercial capabilities or enter into agreements with third parties to market, sell, and distribute our product candidates; our ability to compete in the pharmaceutical industry, including with respect to existing therapies, emerging potentially competitive therapies and with competitive generic products; our ability to market, commercialize and achieve market acceptance for our product candidates; our ability to produce sufficient amounts of drug product candidates for commercialization; our ability to raise capital when needed and on acceptable terms; regulatory developments in the United States, the European Union and other jurisdictions; our ability to protect our intellectual property and know-how and operate our business without infringing the intellectual property rights or regulatory exclusivity of others; our ability to manage negative consequences from changes in applicable laws and regulations, including tax laws (including the Biosecure Act), our ability to maintain an effective system of internal control over financial reporting; changes and uncertainty in general market conditions; disruptions at the FDA and other agencies; political conditions, such as the current war between Russia and Ukraine; economic conditions, including continuing inflation concerns; and the other factors described under the headings “Cautionary Statement Regarding Forward-Looking Statements” and “Item 3. Key Information—D. Risk Factors” in our Annual Report on Form 20-F and other periodic filings with the U.S. Securities and Exchange Commission. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. While Pharvaris may elect to update such forward-looking statements at some point in the future, Pharvaris disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing Pharvaris’ views as of any date subsequent to the date of this press release.

Contact Maggie Beller Executive Director, Head of Corporate and Investor Communications maggie.beller@pharvaris.com