Pharvaris Presents Long-Term Clinical Data of Deucrictibant for the Prevention and Treatment of HAE Attacks at the 2025 AAAAI/WAO Joint Congress

March 3, 2025

- Reduced monthly HAE attack rate maintained for at least 1.5 years in CHAPTER-1 OLE study; median proportion of days with symptoms in OLE was further reduced to zero days
- All participants in CHAPTER-1 OLE who had reached week 62 reported improved health-related quality of life
- Ongoing RAPIDe-2 extension study includes efficacy data from seven upper airway, including laryngeal, attacks; median time to onset of symptom relief was 0.9 hours (N=7)
- In both extension studies, deucrictibant was generally well tolerated with no safety signals observed

ZUG, Switzerland, March 03, 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), highlighted safety and efficacy data of deucrictibant, which is currently being evaluated in two pivotal Phase 3 studies, following long-term dosing in the prophylactic and on-demand settings at the American Academy of Allergy, Asthma, & Immunology's Annual Scientific Meeting (AAAAI) and World Allergy Organization (WAO) Joint Congress, which was held from February 28–March 3, 2025, in San Diego, CA.

"Topline results of deucrictibant in both prophylactic and on-demand randomized clinical trials substantiate our belief in the mechanism and molecule to provide choice to those living with HAE; continued analyses of clinical outcomes and health-related quality of life measures from the extension studies, such as these presented at the 2025 AAAAI/WAO Joint Congress, help solidify our confidence in deucrictibant's ability to meet existing unmet needs in the HAE community," said Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris. "The safety and efficacy data of deucrictibant following long-term dosing in a prophylactic clinical setting is especially noteworthy. Participants experienced a median of zero days with attack symptoms each month, and enhanced quality-of-life, specifically within the observed HRQoL domains of the greatest improvement—'functioning' and 'fear and shame' —which are particularly relevant to people living with HAE."

Dr. Lu continued, "Additionally, we understand from the HAE community that there is a desire for an oral, on-demand therapy that can rapidly and completely treat any type of attack with a single dose. Although the sample size is small, in line with the rarity of these types of attacks, we are pleased to share data from seven upper airway, including laryngeal, attacks that were treated with deucrictibant; these safety and efficacy findings were consistent with those seen in the 328 non-upper airway attacks treated with deucrictibant showing rapid and complete symptom resolution with a single dose. The encouraging data from these extension studies further underscore our opportunity to potentially introduce a therapeutically meaningful oral therapy for the prevention and treatment of HAE attacks, the profile of which we aim to confirm with Phase 3 data."

Prophylactic Program: CHAPTER-1 Open-Label Extension (OLE)
An analysis of the ongoing OLE (Part 2) of the Phase 2 study of orally administered deucrictibant for the prophylactic treatment of HAE, CHAPTER-1 (NCT05047185), explores safety and effectiveness findings from 30 participants who received deucrictibant 40 mg/day for a mean treatment duration of 12.8 months (data snapshot from June 10, 2024). The maximum exposure to deucrictibant based on available study data at the time of data cutoff was 20.8 months in the OLE, and 23.7 months in the entire study. Deucrictibant was well-tolerated with no safety signals.

Ongoing treatment with deucrictibant resulted in sustained protection from HAE attacks, including total monthly attack rate, "moderate and severe" attack rate, and rate of attacks treated with on-demand medication remaining low during OLE. In a poster presentation, Marc A. Riedl, M.D., M.S. also shared that at the time of data cut-off the median proportion of days with symptoms in deucrictibant-treated participants in the OLE was zero each month after a mean treatment duration of 12.8 months.

When evaluating health-related quality of life (HRQoL), participants were asked to report their outcomes through two measures: Patient Global Assessment of Change (PGA-Change) and the Angioedema Quality of Life Questionnaire (AE-QoL). The data shared in a poster presentation by John Anderson, M.D showed that PGA-Change, HRQoL was improved at week 12 and as well as at week 62 compared to study baseline in participants treated with deucrictibant. AEQoL measurements showed a clinically meaningful improvement at week 4 compared to baseline, which was then maintained throughout treatment, with "functioning" and "fear/shame" being the domains with greatest changes.

On-Demand Program: RAPIDe-2 Extension Study
RAPIDe-2 (NCT05396105) is an ongoing two-part Phase 2/3 extension study, evaluating long-term safety and efficacy of orally administered deucrictibant immediate-release capsule for the on-demand treatment of HAE attacks. The analysis (cutoff date: June 10, 2024) was presented by Michael E. Manning, M.D., in a poster presentation and showed that deucrictibant was generally well-tolerated with no safety signals observed. The data set includes a total of 337 attacks, seven of which met the definition of an upper airway, including laryngeal, attack. Of these upper airway attacks, the time to onset of symptom relief, as measured by the Patient Global Impression of Change (PGI-C), was 0.9 hours (N=7) and was consistent with that of non-airway attacks (1.1 hours, N=328). The majority of upper airway attacks were treated with a single dose of deucrictibant (85.7%), which was similar to that of non-airway attacks treated with a with a single dose of deucrictibant (85.4%).

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, oral small-molecule bradykinin B2 receptor antagonist currently in clinical development. By inhibiting bradykinin signaling through the bradykinin B2 receptor, deucrictibant is being investigated for its potential to prevent the occurrence of HAE attacks and to treat the manifestations of attacks if/when they occur. Based on its chemical properties, Pharvaris is developing two formulations of deucrictibant for oral administration: an extended-release tablet to enable sustained absorption and efficacy in prophylactic treatment, and an immediate-release capsule to enable rapid onset of activity for on-demand treatment.

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 an oral therapy to prevent and treat HAE 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 studies in ongoing and future nonclinical studies and clinical trials; risks arising from epidemic diseases, such as the COVID-19 pandemic, 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 successfully remediate the material weaknesses in our internal control over financial reporting and to maintain an effective system of internal control over financial reporting; changes and uncertainty in general market, political and economic conditions, including as a result of inflation and the current conflict between Russia and Ukraine and the Hamas attack against Israel and the ensuing war; 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.

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