Positive Results from CHAPTER-1 Phase 2 Study of Deucrictibant for the Prophylactic Treatment of HAE Attacks to be Presented at AAAAI 2024 Annual Meeting

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Antagonism of the bradykinin B2 receptor via treatment with deucrictibant resulted in statistically significant reduction in rate of HAE attacks

ZUG, Switzerland, Feb. 22, 2024 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a clinical-stage company developing novel, oral bradykinin B2 receptor antagonists to treat and prevent hereditary angioedema (HAE) attacks, today announced the upcoming presentation of two posters at the American Academy of Allergy, Asthma, & Immunology (AAAAI) 2024 Annual Scientific Meeting, to be held in Washington D.C. from February 23-26, 2024, at the Walter E. Washington Convention Center. The abstracts have been published in an online supplement to *The Journal of Allergy and Clinical Immunology* (JACI).

A poster, titled “Efficacy and Safety of Bradykinin B2 Receptor Antagonism with Oral Deucrictibant in Prophylaxis of Hereditary Angioedema Attacks: Results of CHAPTER-1 Phase 2 Trial,” will be presented by Marc A. Riedl, M.D., M.S., during the poster session on Friday, February 23, from 3:15-4:15 p.m. EST. CHAPTER-1 is a two-part, Phase 2 study evaluating the efficacy, safety, and tolerability of deucrictibant for long-term prophylaxis against angioedema attacks in HAE type 1 and type 2 (HAE-1/2). The study enrolled participants in Canada, Europe, the United Kingdom, and the United States. Eligible participants were between the ages of 18 and 75 years, diagnosed with HAE-1/2, were not receiving other prophylactic treatments, and experienced an average of at least one attack per month.

34 participants were treated with double-blinded study drug (placebo or deucrictibant, 20 or 40 mg/day) for 12 weeks of treatment. Analysis of the primary endpoint demonstrated that deucrictibant significantly reduced the monthly attack rate by 84.5% (p=0.0008) in participants dosed at 40 mg/day and 79.3% (p=0.0009) in participants dosed at 20 mg/day compared to placebo. Analyses of secondary endpoints demonstrated that treatment with deucrictibant reduced the occurrence of moderate and severe attacks and of attacks treated with on-demand medication compared to placebo, and a consistent reduction in monthly attack rate was observed with deucrictibant treatment regardless of baseline attack rate. Deucrictibant was well tolerated at both doses, and all reported treatment-related treatment-emergent adverse events (TEAEs) were mild in severity, and no serious TEAEs, no severe TEAEs leading to treatment discontinuation, study withdrawal, or death were reported.

“The CHAPTER-1 study results show that deucrictibant is the first oral therapy with the potential to provide injectable-like efficacy with a favorable safety profile to prevent HAE attacks,” said Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris. “These data validate the mechanism of deucrictibant to provide early and sustained protection from HAE attacks. Combined with the results of our Phase 2 on-demand study, RAPIDe-1, these results support the further development of deucrictibant, which could become the preferred option to both treat and prevent HAE attacks.”

A second poster, titled “Understanding the Reasons not to Treat All HAE Attacks and Patient Satisfaction for On-Demand Treatment (ODT). Results from the HAE Wave II Disease Specific Program™ (DSP™) 2023,” will be presented by Joan Mendivil, M.D., during the poster session on Friday, February 23, from 3:15-4:15 p.m. EST.

Dr. Lu continued, “Additionally, we continue to present data from a multi-country real-world study that explores the barriers people living with HAE face in their decision-making process as they determine whether to treat an attack with on-demand therapy or not. By better understanding and addressing these factors, we aspire to make our commitment to ‘pioneering science for patient choice’ a reality.”

About Deucrictibant
Deucrictibant is a potent, selective, and orally available antagonist of the bradykinin B2 receptor. By inhibiting bradykinin signaling through the bradykinin B2 receptor, deucrictibant has the potential to treat the clinical signs of an HAE attack and to prevent the occurrence of attacks. Based on its chemical properties, Pharvaris is developing two formulations of deucrictibant for oral administration; a capsule to enable rapid onset of activity for acute treatment, and an extended-release tablet to enable sustained absorption and efficacy in prophylactic treatment.

About Pharvaris
Building on its deep-seated roots in HAE, Pharvaris is a clinical-stage company developing novel, oral bradykinin B2 receptor antagonists to treat and prevent HAE attacks. By directly pursuing this clinically proven therapeutic target with novel small molecules, the Pharvaris team aspires to offer people with all sub-types of HAE efficacious, safe, and easy-to-administer alternatives to treat attacks, both on-demand and prophylactically. The company brings together the best talent in the industry with deep expertise in rare diseases and HAE. 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 (PHVS416) and deucrictibant extended-release tablets (PHVS719), which are in mid-stage global clinical trials; risks arising from epidemic diseases, such as the COVID-19 pandemic, which may adversely impact our business, nonclinical studies, and clinical trials; 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 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, 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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