Pharvaris Announces Phase 3 Clinical Study Design for Recently Initiated RAPIDe-3 Study, and Presents Quality-of-Life Improvement and Caregiver Behavior Data at Two Recent HAE Congresses

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- The company announced the initiation of RAPIDe-3, the Phase 3 clinical trial evaluating the efficacy and safety of deucrictibant immediate-release capsule (PHVS416) for the treatment of HAE attacks

ZUG, Switzerland, March 18, 2024 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to treat and prevent hereditary angioedema (HAE) attacks, presented at two recent congresses: the 3rd National Congress of the Italian Network for Hereditary and Acquired Angioedema (ITACA) and the 2024 HAE International (HAEi) Regional Conference Americas.

"We are committed to the continued advancement of our clinical development program of deucrictibant to fulfill unmet needs of current HAE treatment," said Berndt Modig, Chief Executive Officer of Pharvaris. "In collaboration with regulatory authorities we have designed a robust global study to assess the efficacy and safety of deucrictibant, a molecule which we believe has the potential to be best-in-class for both the prevention and treatment of HAE attacks."

Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris, added, "We hear from the HAE community that rapid onset and complete resolution of angioedema attacks with a single, easy-to-administer oral pill remains a high unmet need. The RAPIDe-3 study is designed to assess the effectiveness of deucrictibant in addressing that unmet need. To our knowledge, Pharvaris has been the first and only company to include and statistically power the novel endpoint 'End of Progression' in a pivotal study to show the first point at which medicine stops the worsening of the symptoms of an HAE attack, recognized by people living with HAE and physicians, and which could differentiate deucrictibant from other HAE therapies. We are also presenting quality-of-life data from our prophylaxis study, CHAPTER-1, and a real-world, cross-sectional survey, both of which continue to inform us of the unmet needs in the HAE community and how deucrictibant could potentially address those needs."

The design of the Phase 3 RAPIDe-3 study was showcased for the first time in two posters on Friday. One titled "Design of RAPIDe-3 Phase 3 Trial: Efficacy and Safety of the Oral Bradykinin B2 Receptor Antagonist Deucrictibant Immediate-Release Capsule in Treatment of Hereditary Angioedema Attacks" was presented by Mauro Cancian, M.D., Ph.D., at the ITACA meeting and the second, titled " Efficacy and Safety of the Oral Bradykinin B2 Receptor Antagonist Deucrictibant Immediate-Release Capsule in Treatment of Hereditary Angioedema Attacks: RAPIDe-3 Phase 3 Trial Design" was presented by Anete Grumach, M.D., Ph.D., at the HAEi Americas Congress. RAPIDe-3 is a randomized, double-blind, placebo-controlled, crossover study, which is designed to enroll approximately 120 adolescent and adult participants globally. The primary efficacy endpoint is time to onset of symptom relief, as measured by Patient Global Impression of Change (PGI-C) of at least "a little better" for two consecutive timepoints within 12 hours post-treatment. Other efficacy endpoints include time to End of Progression (EoP) in attack symptoms within 12 hours as measured by PGI-C, and proportion of attacks achieving symptom resolution with one dose of deucrictibant as measured by Patient Global Impression of Severity (PGI-S).

In a poster titled "Prophylactic Treatment with Oral Deucrictibant Improves Health-Related Quality of Life of Patients with Hereditary Angioedema" presented by Andrea Zanichelli, M.D., Ph.D., on Friday at the ITACA meeting, two health-related quality of life (HRQoL) outcomes were measured in participants from CHAPTER-1, a double-blinded, placebo-controlled Phase 2 study evaluating the efficacy and safety of deucrictibant for the prevention of HAE attacks. The data illustrates that HRQoL is negatively impacted, including functional and psychological impairment, in people with HAE. Analyses of CHAPTER-1 study data provide evidence that prophylactic treatment with oral deucrictibant for 12 weeks improved HRQoL for people living with HAE, in addition to significant reduction of attacks.

In a poster titled "Need for Caregiver Support for People Living with Hereditary Angioedema in European Countries," also presented by Andrea Zanichelli, M.D., Ph.D., on Friday at the ITACA meeting, the Adelphi HAE Disease Specific Programme™ (DSP™) examined caregiver suppor requirements among people living with HAE in some European countries, as well as the impact of their condition on their HRQoL and ability to work.

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 late-stage biopharmaceutical 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 late-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.

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