Positive Phase 2 Data from RAPIDe-1 Study of PHVS416 for the On-Demand Treatment of HAE Attacks Highlighted at the 2023 HAEi Regional Conference APAC

March 18, 2023

ZUG, Switzerland, March 18, 2023 (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 an oral presentation of positive data from its Phase 2 RAPIDe-1 study of PHVS416 for the on-demand treatment of attacks at the 2023 HAEi Regional Conference APAC, taking place in Bangkok, Thailand, on March 17-19, 2023.

Presentation Details

- **Title:** Efficacy and Safety of Bradykinin B2 Receptor Inhibition with Oral PHVS416 in Treating Hereditary Angioedema Attacks: Results of RAPIDe-1 Phase 2 Trial
- **Presenter:** Marc A. Riedl, M.D., M.S., Professor of Medicine, Clinical Director of the US Hereditary Angioedema Association (HAEA) Angioedema Center at the University of California San Diego (UCSD), and Clinical Service Chief for Allergy/Immunology at UCSD
- **Date, Time:** Saturday, March 18, 11:35 a.m. ICT (12:35 a.m. EDT)

Dr. Riedl commented, “Currently approved on-demand therapies for HAE attacks are administered intravenously or subcutaneously and can be associated with treatment burden. The time required for preparation and administration, as well as potential occurrence of pain, discomfort, or other injection site reactions can lead to treatment delays or untreated HAE symptoms. An unmet need exists for on-demand oral therapies that are effective and well-tolerated, and that may reduce the treatment burden, enabling prompt administration as recommended by clinical guidelines. The consistent results across all endpoints in the RAPIDe-1 trial provide evidence supporting the efficacy and well-tolerated profile of PHVS416 in treating HAE attacks and provide a foundation for its further development as a potential on-demand therapy.”

RAPIDe-1 is a Phase 2, double-blind, placebo-controlled, randomized, cross-over, dose-ranging trial of PHVS416, the oral softgel capsule formulation of PHA121, for the treatment of HAE type 1 and type 2 (HAE-1/2) attacks. The trial enrolled participants in Canada, Europe, Israel, the United Kingdom, and the United States. Eligible participants were between the ages of 18 and 75 years, diagnosed with HAE type I or II and experienced three or more attacks in the last four months or two or more attacks in the last two months prior to screening.

74 participants were enrolled and 62 of them experienced 147 qualifying HAE attacks that were treated with double-blinded study drug (either placebo or PHVS416 10, 20, or 30 mg doses). Analysis of the primary endpoint demonstrated that PHVS416 significantly ($p<0.0001$; nominal p value for 10 mg dose) reduced attack symptoms measured as change in the mean 3-symptom composite (skin pain, skin swelling, abdominal pain) visual analogue scale (VAS-3) score during HAE attacks, at four hours compared with placebo (LS mean difference of change in VAS-3: -16.75, -15.02, and -16.28 for PHVS416 10, 20 and 30 mg, respectively, vs. placebo). All key secondary efficacy endpoints were also met. Participants on PHVS416 also used substantially less rescue medication compared to placebo (10 mg=18.9%, 20 mg=10.7%, 30 mg=6.5%, placebo=60.8%). PHVS416 was generally well tolerated with three treatment-related adverse events (TRAEs) reported for one PHVS416 30-mg-treated attack (2.8%) and one TRAE reported for one placebo-treated attack (1.9%).

The presentation slides will be available on the Investors section of the Pharvaris website at: https://ir.pharvaris.com/news-events/events-presentations.

About PHVS416
PHVS416 is an investigational softgel capsule formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris aims to develop this formulation to provide rapid and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form. PHVS416 is currently in Phase 2 clinical development outside the U.S. for the on-demand and proof-of-concept prophylactic treatment of HAE.

About Pharvaris
Pharvaris is a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent HAE attacks, building on its deep-seated roots in HAE. By directly targeting this clinically proven therapeutic target with novel small molecules, the Pharvaris team aspires to offer people with all sub-types of HAE safe, effective, and convenient 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 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 with respect to the clinical holds on PHA121 clinical trials in the U.S.; the expected timing, progress, or success of our clinical development programs, especially for PHVS416 and PHVS719, which are in mid-stage global clinical trials and are currently on hold in the U.S. as a result of the clinical holds; risks arising from epidemic diseases, such as the COVID-19 pandemic, which may adversely impact our business, nonclinical studies, and clinical trials; the timing of our rodent toxicology study; the 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 PHVS416 and PHVS719, 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

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 weakness 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 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 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
Maryann Cimino
Director of Corporate Relations
maryann.cimino@pharvaris.com
+1-617-710-7305