Pharvaris Doses First Patient in RAPIDe-1, a Phase 2 Study Evaluating PHVS416 for the On-Demand Treatment of HAE

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ZUG, Switzerland, Feb. 26, 2021 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a clinical-stage company focused on the discovery and development of novel oral bradykinin-B2-receptor antagonists for the treatment of hereditary angioedema (HAE) and other bradykinin-B2-receptor-mediated indications, today announced dosing of the first patient in RAPIDe-1, an on-demand Phase 2 study evaluating the efficacy, safety, and pharmacokinetics of PHVS416 in patients with HAE due to C1-Inhibitor Deficiency type 1 and 2.

“The initiation of this trial signifies another step towards developing an oral treatment for hereditary angioedema patients experiencing acute attacks,” said Berndt Modig, chief executive officer and co-founder of Pharvaris. “The importance of providing patients with treatment alternatives to injection cannot be overstated. We hope to confirm in HAE patients the compelling findings of our previous studies. This study will help to determine if our small-dosage oral softgel capsule provides safe, rapid, and convenient on-demand treatment of HAE attacks.”

RAPIDe-1 is a Phase 2 study evaluating the efficacy and safety of orally administered PHVS416 for the acute treatment of attacks in patients with HAE type 1 or 2. The study aims to enroll 54 adults, ages 18 to 75, at centers in North America and Europe. Eligible patients are randomized to one of three single doses of active and placebo. The study will compare symptom relief (skin pain, skin swelling, abdominal pain) during HAE attacks and safety of each dose of PHVS416 with placebo. PHVS416 is a softgel capsule formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor.

For more information on RAPIDe-1, please visit https://hae-rapide.com/ or https://clinicaltrials.gov/ct2/show/NCT04618211.

About PHVS416
PHVS416 is a softgel capsule formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris is developing this formulation to provide rapid exposure of attack-mitigating medicine in a convenient, small oral dosage form. PHVS416 is currently in Phase 2 clinical development for the on-demand treatment of HAE.

About PHA121
PHA121 (PHA-022121) is a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor that has completed Phase 1 clinical development for the treatment of HAE. PHA121 utilizes the same mechanism as icatibant, the leading therapy for on-demand treatment of HAE. Pharvaris is developing this novel small molecule for on-demand and prophylactic treatment of HAE and other bradykinin-mediated diseases through formulations optimized for each setting. Data from single- and multiple-ascending-dose Phase 1 studies in healthy volunteers demonstrate rapid exposure and predictable linear pharmacokinetics at doses up to 50 mg. In a bradykinin-challenge study in healthy volunteers, PHA121 showed significant inhibition of bradykinin-induced hemodynamic changes with an average composite EC_{50} of 2.4 ng/mL and EC_{85} of 13.8 ng/mL, approximately four-fold more potent than historical data for icatibant. Quantitative modeling indicates that single oral doses of PHA121 will maintain pharmacologically active drug levels for a substantially longer time than 30 mg of subcutaneous icatibant. PHA121 has been observed to be well-tolerated at all doses studied to date.

About HAE
Hereditary angioedema is a rare and potentially life-threatening genetic condition with symptoms that include episodes of debilitating and often painful swelling in the hands, feet, face (lips and tongue), gastrointestinal tract, urogenital region, or airways. Attacks are unpredictable in frequency, location, timing, and severity, with multiple types of triggers. According to scientific publications, patients experience a median of 14 attacks per year, and half of patients experience a potentially life-threatening airway attack at least once in their lifetime. Airway attacks are particularly dangerous and can lead to asphyxiation. If left untreated, attacks can last multiple days and are commonly painful, leading to multiple sick days and even hospitalization. According to HAE International (HAEi), the global umbrella organization for the world’s HAE patient groups, HAE affects from 1:50,000 to 1:10,000 individuals globally, or at least 6,600 patients in the U.S. and at least 8,900 patients in the EU.

About Pharvaris
Pharvaris is a clinical-stage company focused on bringing oral bradykinin-B2-receptor antagonists to patients. By targeting this clinically proven therapeutic target with novel small molecules, the Pharvaris team is advancing new alternatives to injected therapies for all sub-types of HAE and other bradykinin-mediated diseases. The company brings together executives with a breadth of expertise across pharmaceutical development and rare disorders, including HAE. For more information, visit https://pharvaris.com/.

Forward-looking Statements
This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. 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: the expected timing, progress, or success of our clinical development programs, especially for PHVS416 and PHVS719, which are in early-stage clinical trials; risks associated with the COVID-19 pandemic, which may adversely impact our business, preclinical studies, and clinical trials; 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; and, our ability to compete in the pharmaceutical industry and with competitive generic products.

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. 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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