Pharvaris Presents Pharmacodynamic Activity of Oral PHA121, Under Development for the Treatment of HAE, at the AAAAI Annual Meeting

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Single-dose treatment of PHA121 demonstrated effective bradykinin inhibition in healthy volunteers

ZUG, Switzerland, Feb. 19, 2021 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of innovative therapies, including novel, small molecule bradykinin-B2-receptor antagonists for the treatment of hereditary angioedema (HAE) and other bradykinin-B2-receptor-mediated indications, today announced the presentation of clinical data supporting the pharmacokinetic (PK) and pharmacodynamic (PD) profiles of PHA121 (PHA-022121) for the treatment of hereditary angioedema (HAE) at the 2021 American Academy of Allergy Asthma & Immunology (AAAAI) Virtual Annual Meeting, to be held Feb. 26 through March 1, 2021.

“The data from PHA121 continue to support our development plans to initiate studies in HAE patients this year,” said Berndt Modig, chief executive officer and co-founder of Pharvaris. “There remains an unmet medical need for highly effective oral therapies with favorable safety profiles. We will continue to evaluate PHA121 for both on-demand and prophylactic treatment of HAE through our soft-capsule formulation, PHVS416, and tablet formulation, PHVS719.”

Peng Lu, M.D., Ph.D., chief medical officer of Pharvaris, added, “Orally dosed PHA121 was rapidly absorbed and exceeded projected efficacious therapeutic thresholds within 15 minutes with or without food. Using bradykinin-challenge-induced surrogate markers, pharmacodynamic results suggest that PHA121 may provide longer pharmacological effect with a single oral dose than icatibant. We look forward to exploring the therapeutic potential of this compound in multiple clinical studies this year.”

PHA121 was orally administered in two double-blind, placebo-controlled single-ascending-dose studies up to 50 mg, with PK and safety observed for 72 hours. PD effects were evaluated with a nonlinear mixed-effect PK/PD model using 12 mg and 22 mg doses and compared to historical icatibant data. PK/PD analysis 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. 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.

Adverse events (AEs) were reported by 25% of the subjects in the combined group of all subjects treated with PHA121, identical to the 25% incidence with placebo. All AEs were mild or moderate, and subsided rapidly and completely. No clinically relevant changes in safety laboratory parameters, vital signs, and ECG parameters were observed.

A copy of the poster can be viewed on the investor section of our website.

About Pharvaris
Pharvaris (Nasdaq: PHVS) is a clinical-stage biopharmaceutical 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. Pharvaris brings together executives with a breadth of expertise across pharmaceutical development and rare disorders, including HAE.

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.

Investor Contact
Chad Rubin, Solebury Trout
crubin@soleburytrout.com

Media Contact
Maggie Beller, Russo Partners, LLC
maggie.beller@russopartnersllc.com
+1-646-942-5631