Pharvaris Presents Clinical Data on Oral PHA121 Supporting the Prophylactic Treatment of Hereditary Angioedema at the EAACI Annual Congress 2021

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- **Multiple doses of PHA121 were well-tolerated and showed a favorable pharmacokinetic profile for prophylactic treatment of HAE**

ZUG, Switzerland, July 10, 2021 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a clinical-stage company focused on the development and commercialization of novel oral 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 multiple-dose safety and pharmacokinetic (PK) profile of PHA121 (PHA-022121) for the treatment of hereditary angioedema (HAE) at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2021, being held virtually from July 10-16, 2021.

The double-blind, randomized, placebo-controlled, multiple ascending dose study included 38 male and female healthy volunteers. PHA121 was orally administered after standardized meals twice daily (BID) for 10 days in four sequential dosing cohorts, ranging from 12 to 50 mg, with safety and PK assessments during treatment and follow-up for 72 hours after the last dose. PHA121 was well-tolerated up to the highest dose of 50 mg BID. All reported treatment-emergent adverse events (TEAEs) were mild in intensity and resolved completely. The total incidence and type of AEs was comparable between active and placebo groups.

The data also show that PHA121 was well absorbed with median times to reach peak plasma levels within 1.00 to 1.75 hours after dosing with standard meals. On both Day 1 and Day 10, plasma exposure of PHA121 increased approximately dose-proportionally over the dose range from 12 to 50 mg with a mean half-life ranging from 4.8 to 7.3 hours after Day 10. At steady state, which was generally reached within three days of treatment, plasma levels of PHA121 remained consistently above the therapeutic threshold EC85 for all doses (as determined in a human bradykinin challenge previously described).

"The pharmacokinetic profile demonstrated in this study suggests that the therapeutic effect of PHA121 can be achieved as early as the first day of dosing, with steady-state plasma levels achieved within three days. PHA121 was well-tolerated in healthy volunteers up to 50 mg dosed twice a day for 10 days," said Peng Lu, M.D., Ph.D., chief medical officer of Pharvaris. "Coupled with our bradykinin challenge data, which has shown potent inhibition of bradykinin-induced hemodynamic effects, the PK and safety data observed in this study supports future development to assess the efficacy and safety of prophylactic use of PHA121 in HAE patients."

Berndt Modig, chief executive officer and co-founder of Pharvaris added, "Bradykinin-B2-receptor antagonism has been demonstrated to be effective in treating acute HAE attacks but is currently not available as oral treatment. Pharvaris remains committed to providing patients with oral alternatives both for on-demand and prophylactic treatment in HAE via our softgel capsule formulation, PHVS416, and extended-release tablet formulation, PHVS719."

A copy of the e-poster, titled "Multiple dose administration of PHA-022121, an orally available, bradykinin B2 receptor antagonist is well tolerated and shows a favorable pharmacokinetic profile for prophylactic treatment of HAE," can be viewed on the Investor section of the company's website at https://ir.pharvaris.com/news-events/events-presentations.

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 PHVS719
PHVS719 is an extended-release tablet formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris is developing this formulation to provide sustained exposure of attack-preventing medicine in a convenient, small oral dosage form. PHVS719 is currently in preclinical development for the prophylactic 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.

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 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: 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; 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; and the other factors described under the heading “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.

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