# Pharvaris Reports Third Quarter 2021 Financial Results and Provides Business Highlights

November 10, 2021

- **RAPIDe-1, Phase 2 on-demand study of PHVS416 for the treatment of HAE attacks, proceeding; topline data reaffirmed for 2022**
- **CHAPTER-1, Phase 2 prophylactic study of PHVS416 for the prevention of HAE attacks, recruiting; topline data expected in 2022**
- **PHVS719 Phase 1 pharmacokinetics study initiating this month**
- **Executing from a strong financial position with cash and cash equivalents of €218.6 million as of September 30, 2021**

ZUG, Switzerland, Nov. 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 reported financial results for the third quarter ended September 30, 2021, and provided an update on recent business highlights.

"This quarter we continued to execute on our robust clinical development strategy as we seek to advance novel treatments for HAE patients that offer efficacy without compromising on convenience," said Berndt Modig, co-founder and chief executive officer of Pharvaris. "We continue enrolling patients in RAPIDe-1, our Phase 2 on-demand study of PHVS416, and have begun recruiting in CHAPTER-1, our Phase 2 prophylactic study of PHVS416 for the prevention of HAE attacks. We expect to report top-line data, including efficacy and safety, for both studies in 2022. This month, in the PHVS719 program for HAE prophylaxis we also expect to initiate dosing in a Phase 1 pharmacokinetic study designed to assess the bioavailability of extended-release formulation."

**Recent Pipeline and Business Highlights and Upcoming Milestones**

- **Phase 2 on-demand study (RAPIDe-1) of PHVS416 proceeding toward data readout in 2022.** In February 2021, Pharvaris announced that dosing had commenced in its Phase 2 clinical study of PHVS416 for the on-demand treatment of HAE attacks. The company reaffirms guidance for reporting topline efficacy and safety data from this study in 2022. Pharvaris is conducting RAPIDe-1 at 33 sites in Canada, Europe, Israel, the UK, and the US.
- **Phase 2 prophylactic study (HAE CHAPTER-1) of PHVS416 recruiting.** In addition to developing PHVS416 for the on-demand treatment of HAE attacks, the company plans to investigate the therapeutic potential of the PHVS416 formulation of PHA121 for the prophylactic prevention of HAE attacks. In April 2021, Pharvaris announced that an IND was in effect in the US. Patient recruitment has begun and the study is expanding to Canada, Europe, Israel, and the UK. Pharvaris anticipates reporting topline safety and efficacy data from this study in 2022.
- **Phase 1 pharmacokinetics study of PHVS719 initiating shortly.** PHVS719 is under development as an extended-release formulation of PHA121 intended for use in the prophylactic treatment of HAE. Dosing of a Phase 1 pharmacokinetics study to assess the bioavailability of the extended-release formulation is expected to begin this month.
- **Expanding corporate capabilities.** With Wim Souverijns joining as Chief Community Engagement and Commercial Officer to engage with patient advocacy groups, clinicians, and payers, in the third quarter the company further strengthened capabilities in Community Engagement and Commercialization, as well as CMC, Clinical, and organizational development.

**Third Quarter 2021 Financial Results**

- **Liquidity position.** Cash and cash equivalents were €218.6 million as of September 30, 2021, compared to €98.6 million as of December 31, 2020.
- **Research and Development (R&D) expenses.** R&D expenses were €9.0 million for the quarter ended September 30, 2021, compared to €5.1 million for the quarter ended September 30, 2020.
- **General and Administrative (G&A) expenses**. G&A expenses were €4.4 million for the quarter ended September 30, 2021, compared to €1.2 million for the quarter ended September 30, 2020.
- **Loss for the period.** Loss for the quarter ended September 30, 2021 was €9.1 million, or basic and diluted loss per share of €0.39, for the quarter ended September 30, 2021, compared to loss for the quarter ended September 30, 2020 of €6.4 million, or basic and diluted loss per share of €1.32 for the quarter ended September 30, 2020.

**Note on International Financial Reporting Standards (IFRS)**
Pharvaris is a Foreign Private Issuer and prepares and reports consolidated financial statements and financial information in accordance with IFRS as issued by the International Accounting Standards Board. Pharvaris maintains its books and records in the Euro currency.

**About RAPIDe-1**
The RAPIDe-1 study is a clinical research study for people who have been diagnosed with HAE. The main purpose of the study is to find out how effective three different doses of the study drug, PHVS416, are in relieving symptoms associated with HAE attacks. Researchers developed the study drug in the form of soft capsules which are taken orally and could be a more convenient alternative to an injection into a vein or under the skin for

resolving HAE attacks. For more information, visit https://hae-rapide.com/, https://hae-rapide.us/, or https://clinicaltrials.gov/ct2/show/NCT04618211.

**About HAE CHAPTER-1**
The HAE CHAPTER-1 study is a clinical research study for people who have been diagnosed with HAE. The main purpose of the study is to evaluate two different doses of the study drug, PHVS416, in preventing HAE attacks. Researchers developed the study drug in the form of soft capsules which are taken orally and could be a more convenient alternative to an injection into a vein or under the skin for preventing HAE attacks. For more information, visit https://haechapter-1.com or https://clinicaltrials.gov/show/NCT05047185.

**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 fast and reliable symptom relief when patients want, through 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 an easy way to prevent attacks with sustained exposure of attack-preventing medicine in a convenient, small oral dosage form. PHVS719 is currently entering Phase 1 clinical 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. Data from single- and multiple-ascending-dose Phase 1 studies in healthy volunteers demonstrate rapid exposure and 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 pharmacological effectiveness 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 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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