Pharvaris Reports Second Quarter 2022 Financial Results and Provides Business Update

September 12, 2022

- Formal letters received from FDA relating to the previously announced hold on clinical studies of PHA121 in the U.S.
- Top-line data anticipated in 4Q22 for RAPIDe-1, a global Phase 2 study of PHVS416 for the acute treatment of HAE attacks ongoing outside the U.S.
- Executing from a strong financial position with cash and cash equivalents of €201 million as of June 30, 2022

ZUG, Switzerland, Sept. 12, 2022 (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 reported financial results for the second quarter ended June 30, 2022, and provided a business update.

"Pharvaris is dedicated to bringing therapeutic alternatives to people living with HAE and we maintain our belief in the potential of PHA121. Our team is committed to working with the FDA to resolve the hold on clinical trials involving PHA121 in the U.S. and we deeply appreciate the patience of the HAE community during this time," said Berndt Modig, Chief Executive Officer of Pharvaris. "Having evaluated the impact of the clinical hold, we anticipate announcing top-line Phase 2 data for RAPIDe-1 in the fourth quarter of this year. As we work to address the FDA's concerns and continue interactions with other regulatory authorities, we maintain a disciplined operational approach with our strong cash position expected to provide runway through the first quarter of 2024."

Recent Business Updates

- Pharvaris announced that it has received formal clinical hold letters from the U.S. Food and Drug Administration (FDA). This follows the previously announced verbal notification of a hold on the clinical trials of PHA121 in the U.S. under Investigational New Drug (IND) applications for the on-demand and prophylactic treatment of HAE attacks. The FDA requested that Pharvaris conduct an additional long-term rodent toxicology study and update the Investigator's Brochure. The letters stated that the nonclinical observations are unlikely due to B2 receptor antagonism. Pharvaris plans to request a Type A meeting to discuss on-demand and prophylactic proposals to address the clinical holds.
- **RAPIDe-1, a global Phase 2 study of PHVS416 for the on-demand treatment of HAE, continues evaluating enrolled patients outside the U.S. with top-line data anticipated in 4Q22.** The previously announced target enrollment of 72 people with HAE across 33 sites in Canada, Europe, Israel, the UK, and the U.S. was achieved. Subsequent to the clinical hold, the company continues to evaluate PHVS416 for HAE attacks in patients enrolled outside the U.S. The goal of RAPIDe-1 is to assess PHVS416 as an oral acute treatment of HAE attacks by comparing safety and symptom relief (skin pain, skin swelling, and abdominal pain) during HAE attacks across three doses and placebo. The primary endpoint of RAPIDe-1 is the change of the composite of the three measured symptoms (skin pain, skin swelling and abdominal pain) using a visual analogue scale (VAS-3) four hours after treatment. One of the measured symptoms must have a VAS score of 30 before treatment to be considered a qualified HAE attack. Other key secondary endpoints include the time to onset of symptom relief, as well as safety and tolerability. Given the current dataset of evaluable attacks, Pharvaris anticipates announcing top-line data in the fourth quarter of 2022.
- **Working with country-specific regulatory authorities regarding ongoing CHAPTER-1 Phase 2 study of PHVS416 for the prophylactic treatment of HAE attacks**. Pharvaris has notified country-specific regulatory authorities in Canada, Europe, Israel, and the UK of the clinical hold in the U.S. When the company has more clarity regarding the impact of the U.S. clinical hold and additional feedback from global regulatory authorities, Pharvaris will provide guidance on the timing of announcing top-line data for the CHAPTER-1 trial. The study is designed to enroll 30 patients globally in CHAPTER-1 with a goal of evaluating proof of concept of PHVS416 for oral prophylaxis against HAE attacks. The safety and efficacy of two doses and placebo will be evaluated by comparing the number of investigator-confirmed attacks during participants' 12-week treatment period. Data from this study is expected to inform design of an anticipated Phase 3 study utilizing PHVS719, an extended-release formulation of PHA121.
- **Strengthened executive team.** With the appointment of Joan Schmidt, J.D., as Chief Legal Officer, effective June 2022, the company further strengthened its capabilities in legal, compliance, and governance.
- **Held Annual Meeting of Shareholders and appointed Elisabeth Björk, M.D., and Anne Marie de Jonge Schuermans, Ph.D., to the Board of Directors**. On June 29, 2022, the company held an Annual Meeting of Shareholders at which all proposals were approved. Dr. Björk and Dr. de Jonge Schuermans were appointed as Non-Executive Directors.

Upcoming Events

- Pharvaris will attend the upcoming Morgan Stanley 20th Annual Global Healthcare Conference, which is being held in New York from September 12-14, 2022. Mr. Modig and Morgan Conn, Ph.D., Chief Business Officer, will participate in a fireside chat on Monday, September 12, at 4:15 p.m. ET. A live audio webcast will be available on the Investors section of the Pharvaris website at https://ir.pharvaris.com/news-events/events-presentations. A replay will be available on Pharvaris'

website for 30 days following the fireside chat.

Second Quarter 2022 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €201 million as of June 30, 2022, compared to €209 million as of December 31, 2021. The net cash position reflects increased operating expenses, offset by favorable foreign exchange effects.
- **Research and Development (R&D) Expenses.** R&D expenses were €13.7 million for the quarter ended June 30, 2022, compared to €8.1 million for the quarter ended June 30, 2021.
- **General and Administrative (G&A) Expenses.** G&A expenses were €7.7 million for the quarter ended June 30, 2022, compared to €4.7 million for the quarter ended June 30, 2021.
- **Loss for the period.** Loss for the quarter ended June 30, 2022 was €12.6 million, or basic and diluted loss per share of €0.38, compared to €15.2 million, or basic and diluted loss per share of €0.46, for the quarter ended June 30, 2021.

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 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 fast and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form. In healthy volunteers, a single dose of PHVS416 showed rapid exposure exceeding predicted therapeutically efficacious levels within 15 minutes. 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. 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. In clinical studies, PHA121 has been observed to be well-tolerated at all doses studied to date.

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 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 hold 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 hold; risks associated with the COVID-19 pandemic, which may adversely impact our business, nonclinical 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; changes in general market, political and economic conditions, including as a result of 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.

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