Pharvaris Reports Third Quarter 2022 Financial Results and Provides Business Update

December 8, 2022

- Announced positive top-line data for RAPIDe-1, a global Phase 2 study of PHVS416 for the on-demand treatment of HAE attacks
- Participated in a Type A meeting with the FDA regarding the previously announced holds on the clinical studies of PHA121 in the U.S.
- Top-line data from CHAPTER-1, a global proof-of-concept Phase 2 study of PHVS416, anticipated 2H2023
- Executing from a strong financial position with cash and cash equivalents of €198 million as of September 30, 2022

ZUG, Switzerland, Dec. 08, 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 third quarter ended September 30, 2022, and provided a business update.

“The results of the RAPIDe-1 study affirm our confidence in our clinical development program in HAE,” said Berndt Modig, Chief Executive Officer of Pharvaris. “Pharvaris is fully committed to resolving the clinical holds on PHA121 in the U.S., and we appreciate the opportunity to meet with the FDA in the recent Type A meeting and to work with the agency on next steps. To date, the regulatory status for our studies outside the U.S. remains unchanged. Top-line data from CHAPTER-1, a proof-of-concept study of PHVS416 for the prophylactic treatment of HAE, is anticipated in the second half of 2023. Pharvaris has a strong financial position and will continue to operate with a disciplined approach as we aspire to bring best-in-class oral therapies to the HAE community.”

Recent Business Updates

- **Announcement of positive RAPIDe-1 data.** Today Pharvaris announced top-line Phase 2 data demonstrating statistically significant results of PHVS416 as an oral on-demand treatment for HAE attacks. Additional details can be found in the news release.
- **Pharvaris continues to engage with the FDA to resolve the holds on PHA121 clinical trials in the U.S.** Following the previously announced receipt of the formal letters regarding the holds on PHA121 clinical trials in the U.S., Pharvaris attended a Type A meeting with the U.S. Food and Drug Administration (FDA). During the meeting, Pharvaris proposed potential paths to resolve the clinical holds for each of the on-demand and prophylactic programs. The company will provide additional information following receipt of the formal meeting minutes.
- **CHAPTER-1, a global Phase 2 study of PHVS416 for the prophylactic treatment of HAE attacks, top-line data is anticipated 2H2023.** All active sites outside of the U.S. continue to enroll participants in the CHAPTER-1 clinical study. After being notified of the clinical holds in the U.S., Pharvaris notified country-specific regulatory authorities in Canada, Europe, Israel, and the UK regarding the clinical holds in the U.S. To date, the regulatory status of the CHAPTER-1 study outside the U.S. remains unchanged. Based on our current assumptions regarding ex-U.S. regulatory status and enrollment, Pharvaris anticipates announcing top-line data from the CHAPTER-1 trial in 2H2023. The study is designed to enroll 30 patients globally with a goal of evaluating proof of concept of PHVS416 as an 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 proof-of-concept study is expected to inform design of an anticipated Phase 3 study utilizing PHVS719, an extended-release formulation of PHA121.
- **Presentations of preclinical and clinical data supporting development of PH121 at industry meetings.** Data detailing PHA121’s pharmacokinetic (PK), pharmacodynamic (PD) and safety profile, as well as initial bioavailability and absorption data for the softgel capsule formulation, PHVS416, and extended-release tablet formulation, PHVS719, were presented at the Bradykinin Symposium in September, the HAEi Global Leadership Workshop in October, and the American College of Allergy, Asthma and Immunology (ACAAI) Annual Scientific Meeting in November. In healthy volunteer clinical studies, PHA121 was shown to be well-tolerated with a favorable PK/PD profile up to the highest dose tested. PHVS416 has been shown to achieve a rapid onset of exposure in humans, which is desirable for the on-demand treatment of HAE. PHVS719 has been shown to sustain therapeutic exposure, which supports its use in the prophylactic treatment of HAE.
- **Strengthened Executive Committee.** With the promotion of Annick Deschoolmeester to Chief Human Resources Officer, Pharvaris continues to strengthen its Executive Committee. Since joining Pharvaris as the Head of Human Resources in September 2021, Ms. Deschoolmeester has had a substantial impact on the organization and has been instrumental in positioning Pharvaris for its next stage in scale and impact.

Third Quarter 2022 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €198 million as of September 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 €14.1 million for the quarter ended September 30,

2022, compared to €9.0 million for the quarter ended September 30, 2021.

- **General and Administrative (G&A) Expenses.** G&A expenses were €8.3 million for the quarter ended September 30, 2022, compared to €4.4 million for the quarter ended September 30, 2021.
- **Loss for the period.** Loss for the quarter ended September 30, 2022, was €8.5million, or basic and diluted loss per share of €0.25, compared to €9.1 million, or basic and diluted loss per share of €0.28, for the quarter ended September 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 rapid and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form. PHVS416 is currently in Phase 2 clinical development outside the U.S. for the on-demand and proof-of-concept prophylactic treatment of HAE.

About PHVS719
PHVS719 is an investigational 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 in Phase 1 clinical development for the prophylactic treatment of HAE. In healthy volunteers, a single dose of PHVS719 was well tolerated with an extended-release profile supporting once-daily dosing.

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 safe, effective and convenient alternatives to treat attacks, for 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 holds 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 holds; 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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