Pharvaris Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

April 5, 2023

- Top-line data from CHAPTER-1, a proof-of-concept Phase 2 study of PHVS416 for the prophylactic treatment of HAE, anticipated in 2H2023
- 26-week non-clinical toxicology study intended to address the clinical holds in the U.S. initiated; submission of study results anticipated by YE2023
- Adoption of deucrictibant as the global nonproprietary name for PHA121
- Executing from a strong financial position with cash and cash equivalents of €162 million as of December 31, 2022

ZUG, Switzerland, April 05, 2023 (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 fourth quarter and year ended December 31, 2022 and provided a business update.

“Our first in-patient data readout of deucrictibant in people living with HAE was a significant milestone for the company. The positive outcome of the RAPIDe-1 clinical study, announced in December 2022, demonstrates the potential of PHVS416 to offer meaningful improvement over the standard of care for people living with HAE in their on-demand treatment of attacks. With the non-clinical study underway, we believe we have a path forward to address the remaining clinical holds in the U.S.,” said Berndt Modig, Chief Executive Officer of Pharvaris. “We anticipate important milestones this year, including the announcement of top-line Phase 2 CHAPTER-1 data, the activation of our first ex-U.S. clinical sites for a Phase 3 on-demand study, and the submission of our non-clinical toxicology data to the FDA. The unique clinical insights of the Pharvaris team and our strong financial position have enabled us to effectively execute toward our goals; we 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

- **Top-line data from CHAPTER-1, a global Phase 2 study of PHVS416 for the prophylactic treatment of HAE attacks, anticipated in 2H2023.** CHAPTER-1 is currently on hold in the U.S. All CHAPTER-1 sites outside of the U.S. continue to recruit participants in the study. Based on the Company’s current assessment of the ex-U.S. regulatory status and enrollment rates, Pharvaris anticipates announcing top-line data in the second half of 2023.
- **Non-clinical toxicology study has been initiated with study results anticipated by YE2023.** Pharvaris has aligned with the U.S. Food and Drug Administration (FDA) regarding the design of the 26-week rodent toxicology study, which is intended to provide additional data to address the clinical holds in the U.S. Pharvaris has initiated the study and anticipates submitting the results from this study by the end of 2023.
- **RAPIDe-1 has completed its last patient’s last visit.** Pharvaris has completed the placebo-controlled evaluation of on-demand attacks in RAPIDe-1. Positive top-line data from RAPIDe-1 were announced in December 2022. The final analysis included the two remaining U.S. participants who had rejoined the trial following agreement from the FDA to partially lift the hold of on-demand treatment. RAPIDe-2, a long-term extension study of PHVS416 for the on-demand treatment of HAE, is underway outside the U.S. for eligible participants.
- **RAPIDe-3 study initiation readiness underway.** Pharvaris has begun preparatory activities for RAPIDe-3, a Phase 3 study of PHVS416 for the on-demand treatment of people living with HAE.
- **Presentations of data from the RAPIDe-1 clinical study highlighted at recent industry meetings.** Data from the Phase 2 RAPIDe-1 study of PHVS416 for the on-demand treatment of HAE attacks were presented in February 2023 at the American Academy of Allergy Asthma & Immunology (AAAAI) Annual Meeting and in March 2023 at the 2023 HAEi Regional Conference APAC. The presentations highlighted the consistent results across all endpoints and assessments in the RAPIDe-1 trial supporting the efficacy and tolerability profile of PHVS416 in treating HAE attacks. The data provide support for the further development of PHVS416 as a potential on-demand therapy to address the unmet need of people living with HAE.
- **Adoption of deucrictibant as the approved global nonproprietary name for PHA121.** The World Health Organization’s (WHO) International Nonproprietary Names (INN) Expert Committee and the United States Adopted Names (USAN) Council of the American Medical Association (AMA) have adopted deucrictibant (doo-KRIK-ta-bant) as the nonproprietary name for PHA121, Pharvaris’ bradykinin B2 receptor antagonist. Based on naming guidelines, the name describes deucrictibant’s deuterium by using the prefix “deu-“ and its ability to antagonize the bradykinin B2 receptor by using the stem “-tibant.”

Fourth Quarter and Full Year 2022 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €162 million as of December 31, 2022, compared to €209 million for December 31, 2021.
- **Research and Development (R&D) Expenses.** R&D expenses were €15.7 million for the fourth quarter and €57.4 million

for the full year of 2022, compared to €10.7 million for the fourth quarter and €35.8 million for the full year of 2021.

- **General and Administrative (G&A) Expenses**. G&A expenses were €7.8 million for the fourth quarter and €29.3 million for the full year of 2022, compared to €5.5 million for the fourth quarter and €18.3 million for the full year of 2021.
- **Loss for the year.** Loss for the fourth quarter was €39.2 million, resulting in basic and diluted loss per share of €1.16. For the full year, loss was €76.3 million, resulting in basic and diluted loss per share of €2.27 per share. This compares to €12.3 million, or basic and diluted loss per share of €0.37, for the fourth quarter and €42.7 million, or basic and diluted loss per share of €1.40, for the full year of 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 deucrictibant (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 deucrictibant (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, 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 relating to our future plans, studies and trials, and any 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 deucrictibant (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 arising from epidemic diseases, such as the COVID-19 pandemic, which may adversely impact our business, nonclinical studies, and clinical trials; the expected timing and results of the rodent toxicology study; 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 weaknesses in our internal control over financial reporting and to maintain an effective system of internal control over financial reporting; changes and uncertainty in general market, political and economic conditions, including as a result of inflation and 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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