



Pharvaris Reports First Quarter 2022 Financial Results and Provides Business Highlights

May 11, 2022

- Target enrollment achieved in RAPIDe-1, Phase 2 on-demand study of PHVS416 for the treatment of HAE attacks; top-line data anticipated in 4Q22
- Enrollment underway in HAE CHAPTER-1, proof-of-concept Phase 2 prophylactic study using PHVS416 for the prevention of HAE attacks; top-line data anticipated in 4Q22
- RAPIDe-2, long-term extension on-demand study of PHVS416 for the treatment of HAE attacks, on-track to initiate in 2H22
- Continue to execute from a strong financial position with cash and cash equivalents of €194.8 million as of March 31, 2022

ZUG, Switzerland, May 11, 2022 (GLOBE NEWSWIRE) -- [Pharvaris](#) (Nasdaq: PHVS), a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent HAE attacks, building on its deep-seated roots in hereditary angioedema (HAE), today reported financial results for the first quarter ended March 31, 2022, and provided an update on recent business highlights.

"We met our operational goals for PHVS416 for the on-demand treatment of HAE attacks and have reached our target patient enrollment in the RAPIDe-1 Phase 2 study," said Berndt Modig, chief executive officer of Pharvaris. "We sincerely thank the HAE patients and HAE community, investigators, and site staff across the globe who are participating in this trial, as well as our outstanding team. Pharvaris is also enrolling patients in CHAPTER-1, a proof-of-concept Phase 2 clinical trial using PHVS416 for the prophylactic treatment of HAE attacks. We continue to collaborate with the HAE community to further understand how our clinical research can address remaining unmet needs in HAE."

Recent Business Highlights and Updates

- **Target enrollment achieved for Phase 2 on-demand study (RAPIDe-1) of PHVS416.** RAPIDe-1, a Phase 2 clinical study of PHVS416 for the on-demand treatment of HAE attacks, has reached its target enrollment and continues to assess HAE attacks across 33 clinical sites in Canada, Europe, Israel, the UK and the U.S. Top-line data from the study is anticipated to be available in the fourth quarter of 2022.
- **Enrollment ongoing in Phase 2 prophylactic study (HAE CHAPTER-1) of PHVS416.** HAE CHAPTER-1, a proof-of-concept Phase 2 clinical trial using PHVS416 for the prophylactic treatment of HAE attacks, is enrolling across clinical sites in Canada, Europe, Israel, the UK and the U.S. Top-line data from the study are anticipated in the fourth quarter of 2022.
- **RAPIDe-2 expected to initiate in 2022.** RAPIDe-2, a long-term extension study evaluating PHVS416 for the on-demand treatment of people with HAE, is expected to initiate in the second half of 2022.

First Quarter 2022 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €194.8 million as of March 31, 2022, compared to €209.4 million as of December 31, 2021.
- **Research and Development (R&D) Expenses.** R&D expenses were €13.5 million for the quarter ended March 31, 2022, compared to €8.1 million for the quarter ended March 31, 2021.
- **General and Administrative (G&A) Expenses.** G&A expenses were €5.9 million for the quarter ended March 31, 2022, compared to €3.8 million for the quarter ended March 31, 2021.
- **Loss for the period.** Loss for the quarter ended March 31, 2022 was €16.0 million, or basic and diluted loss per share of €0.48, for the quarter ended March 31, 2022 compared to loss for the quarter ended March 31, 2021 of €6.0 million, or basic and diluted loss per share of €0.66 for the quarter ended March 31, 2021.

Upcoming Events

- BofA 2022 Healthcare Conference, presentation at 10:00 am PDT/1:00 pm EDT on May 12, 2022 in Las Vegas, NV
- Kinin2022 Conference, symposium ("Tailored drug development for patients living with HAE") with Anne Lesage, Ph.D., Chief Early Development Officer, on June 7, 2022

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 softgel 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 softgel 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. 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 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 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 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 EC₅₀ of 2.4 ng/mL and EC₈₅ 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 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 more 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: the expected timing, progress, or success of our clinical development programs, especially for PHVS416 and PHVS719, which are in mid-stage clinical trials; 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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