



Pharvaris Reports First Quarter 2023 Financial Results and Provides Business Update

May 8, 2023

- Top-line data from CHAPTER-1, a proof-of-concept Phase 2 study of PHVS416 (immediate-release deucricitibant capsules) for the prophylactic treatment of HAE, anticipated by YE2023
- Executing from a strong financial position with cash and cash equivalents of €135 million as of March 31, 2023

ZUG, Switzerland, May 08, 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 first quarter ended March 31, 2023 and provided a business update.

"The Pharvaris team has made strong progress advancing our key studies and initiatives toward meaningful year-end milestones, including the anticipated reporting of topline CHAPTER-1 data and the submission of newly generated non-clinical toxicology data to the FDA to address the clinical holds in the U.S.," said Berndt Modig, Chief Executive Officer of Pharvaris. "The data [presented](#) at the C1-inhibitor Deficiency and Angioedema Workshop provide additional insights into the therapeutic profile of deucricitibant as potential treatment for HAE and other bradykinin-mediated diseases."

Recent Business Updates

- **Top-line data from CHAPTER-1, a global Phase 2 study of PHVS416 (immediate-release deucricitibant capsules) for the prophylactic treatment of HAE attacks, anticipated by YE2023.** 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 by the end of 2023.
- **Non-clinical toxicology study ongoing.** A 26-week rodent toxicology study, which is intended to provide additional data to address the clinical holds in the U.S., is ongoing; the results from which Pharvaris anticipates submitting to the U.S. Food and Drug Administration (FDA) by the end of 2023.
- **Clinical and non-clinical deucricitibant data presented at a recent medical meeting supports ongoing clinical development.** Pharvaris presented data from clinical and non-clinical studies in two oral and three poster presentations at the 13th C1-inhibitor Deficiency and Angioedema Workshop, which was held from May 4-7, 2023, in Budapest, Hungary. Details of the presentations were included in a recent [press release](#). The posters and slides from the oral presentations are available on the [Investors section of the Pharvaris website](#).

First Quarter 2023 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €135 million as of March 31, 2023, compared to €162 million for December 31, 2022.
- **Research and Development (R&D) Expenses.** R&D expenses were €13.7 million for the quarter ended March 31, 2023, compared to €13.5 million for the quarter ended March 31, 2022.
- **General and Administrative (G&A) Expenses.** G&A expenses were €7.3 million for the quarter ended March 31, 2023, compared to €5.9 million for the quarter ended March 31, 2022.
- **Loss for the year.** Loss for the first quarter was €22.6 million, resulting in basic and diluted loss per share of €0.67, for the quarter ended March 31, 2023, compared to €16.0 million, or basic and diluted loss per share of €0.48, for the quarter ended March 31, 2022.

Upcoming Events

BofA Securities 2023 Healthcare Conference. Las Vegas, May 9-11, 2023. Morgan Conn, Ph.D., Chief Business Officer, and Wim Souverijns, Ph.D., Chief Community Engagement and Commercial Officer, will present a corporate overview on Wednesday, May 10, at 4:35 p.m. PDT (Thursday, May 11, at 1:35 a.m. CEST). 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 90 days following the presentation.

European Academy of Allergy & Clinical Immunology (EAACI) Hybrid Congress 2023. Hamburg, Germany, June 9-11, 2023. Two abstracts have been accepted for presentation during the "flash talks on angioedema" Flash Talks:

- **Title:** Treatment with Oral Administered Bradykinin B2 Receptor Inhibitor PHVS416 Improves Hereditary Angioedema Attack Symptoms
Abstract Number: 001557
Date/Time: Sunday, June 11, 14:10 CEST (8:10 a.m. EDT)
Presenter: Emel Ayyören-Pürsün, M.D., University Hospital Frankfurt
- **Title:** Efficacy and Safety of Oral Administered Bradykinin B2 Receptor Inhibitor PHVS416 in Treatment of Hereditary Angioedema Attacks: Topline Results of RAPIDE-1 Phase 2 Trial
Abstract Number: 001510

Date/Time: Sunday, June 11, 14:30 CEST (8:30 a.m. EDT)

Presenter: Marcus Maurer, M.D., Charité Universitätsmedizin Berlin

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 (immediate-release deucricitibant capsules)

PHVS416 (immediate-release deucricitibant capsules) is an investigational medicine intended to treat acute attacks of hereditary angioedema (HAE) containing deucricitibant, 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 (extended-release deucricitibant tablets)

PHVS719 (extended-release deucricitibant tablets) is an investigational medicine intended to prevent attacks of hereditary angioedema (HAE) containing deucricitibant, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris is developing this formulation to provide 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

Building on its deep-seated roots in HAE, Pharvaris is a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent HAE attacks. 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 deucricitibant 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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