Pharvaris Reports Third Quarter 2023 Financial Results and Provides Business Update

November 2, 2023

- Top-line data from Phase 2 CHAPTER-1 prophylactic study anticipated by YE2023
- Participated in an End-of-Phase 2 meeting with the FDA; initiation of global Phase 3 clinical study (RAPIDe-3) anticipated within 1H2024
- Cash and cash equivalents of €158 million as of September 30, 2023

ZUG, Switzerland, Nov. 02, 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 third quarter ended September 30, 2023 and provided a business update.

"We appreciate the FDA's ongoing communication and collaboration, including our recent productive End-of-Phase 2 meeting, and anticipate initiating RAPIDe-3, our global Phase 3 on-demand study of PHVS416, within the first half of 2024," said Berndt Modig, Chief Executive Officer of Pharvaris. "Pharvaris remains committed to resolving the U.S. clinical hold on deucrictibant for the prophylactic treatment of HAE, and we are on track to submit the non-clinical rodent data to the FDA by the end of the year. Top-line data from CHAPTER-1, a Phase 2 proof-of-concept study of deucrictibant, potentially the first B2-receptor antagonist for long-term prophylaxis in HAE, is anticipated to be announced by the end of the year. Pharvaris' financial position allows us to 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 deucrictibant for the long-term prophylactic treatment of HAE attacks, expected to be announced by the end of 2023.** CHAPTER-1, which is currently on hold in the U.S., was designed to enroll approximately 30 patients globally with a goal of evaluating deucrictibant as an oral long-term prophylactic treatment against HAE attacks, using PHVS416 (immediate-release deucrictibant capsules) as proof of concept. The efficacy and safety of deucrictibant (10 mg and 20 mg, twice-daily) 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 the design of an anticipated Phase 3 study utilizing PHVS719, a once-daily extended-release formulation of deucrictibant. Pharvaris anticipates announcing top-line data of CHAPTER-1 by the end of 2023.
- **Participated in End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA).** Pharvaris participated in an End-of-Phase 2 meeting with the FDA, during which Pharvaris sought feedback and aligned on the key elements of a proposed Phase 3 clinical study for PHVS416. Globally, Pharvaris is working on study startup activities with clinical site investigators and staff, and expects to initiate RAPIDe-3 within the first half of 2024.
- **Results of nonclinical toxicology study on-track to be submitted to the FDA by the end of 2023.** The IND of deucrictibant for long-term prophylaxis remains on hold in the U.S. Pharvaris anticipates submitting the results of the 26-week nonclinical rodent toxicology study, which is intended to provide additional data to address the remaining clinical hold in the U.S., to the FDA by the end of 2023.
- **Clinical deucrictibant data presented at recent medical and patient meetings, supporting ongoing clinical development of deucrictibant.** Pharvaris presented data from clinical studies at the 2023 Hereditary Angioedema International (HAEi) Regional Conference EMEA, the 18th German Allergy Congress, the Consortium of Independent Immunology Clinics (CIIC) Fall 2023 Conference, and the Asia Pacific Association of Allergy, Asthma, and Clinical Immunology (APAAACI) and Allergy and Clinical Immunology Society of Singapore (ACIS) APAAACI 2023 International Conference. The slides from the oral presentations and the posters are available on the Investors section of the Pharvaris website.

Third Quarter 2023 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €158 million as of September 30, 2023, compared to €162 million for December 31, 2022.
- **Research and Development (R&D) Expenses.** R&D expenses were €18.5 million for the quarter ended September 30, 2023, compared to €14.1 million for the quarter ended September 30, 2022.
- **General and Administrative (G&A) Expenses**. G&A expenses were €7.7 million for the quarter ended September 30, 2023, compared to €8.3 million for the quarter ended September 30, 2022.
- **Loss for the year.** Loss for the third quarter was €23.6 million, resulting in basic and diluted loss per share of €0.58 for the quarter ended September 30, 2023, compared to €8.5 million, or basic and diluted loss per share of €0.25, for the quarter ended September 30, 2022.

Upcoming Events

American College of Allergy, Asthma & Immunology (ACAAI) 2023 Annual Scientific Meeting. Anaheim, CA, November 9-13, 2023. Two abstracts have been accepted for ePoster presentation with accompanying audio voiceover. Details are as follows:

- **Title:** Deucrictibant immediate-release capsule reduces time to end of progression of hereditary angioedema attacks' manifestations
  Presenter: Marc A. Riedl, M.D., M.S.
  Date/Time: Friday, November 10, 5:15-5:30 p.m. PST (8:15-8:30 p.m. EST)
- **Title:** Reasons not to treat HAE attacks and satisfaction for on-demand treatment
  Presenter: Joan Mendivil, M.D.
  Date/Time: Saturday, November 11, 12:20-12:35 p.m. PST (3:20-3:35 p.m. EST)

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 deucrictibant capsules)
PHVS416 (immediate-release deucrictibant capsules) is an investigational drug intended to treat attacks of hereditary angioedema (HAE) containing deucrictibant, 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 an easy-to-administer, small oral dosage form.

About PHVS719 (extended-release deucrictibant tablets)
PHVS719 (extended-release deucrictibant tablets) is an investigational drug intended to prevent attacks of hereditary angioedema (HAE) containing deucrictibant, 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 an easy to administer, 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 pursuing this clinically proven therapeutic target with novel small molecules, the Pharvaris team aspires to offer people with all sub-types of HAE efficacious, safe, and easy-to-administer 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 hold on prophylactic deucrictibant in the U.S.; the expected timing, progress, or success of our clinical development programs, especially for PHVS416 (immediate-release deucrictibant capsules) and PHVS719 (extended-release deucrictibant tablets), which are in mid-stage global clinical trials; 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 and our ability to resolve any issues to the satisfaction of the FDA or any regulatory agency in a timely manner; 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 Hamas attack against Israel and the ensuing war; 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 U.S. 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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