

Pharvaris Reports Second Quarter 2023 Financial Results and Provides Business Update

August 7, 2023

- Enrollment completed in Phase 2 CHAPTER-1 prophylactic study; top-line data anticipated by YE2023
- Clinical hold lifted on deucricitbant for the on-demand treatment of HAE; initiation of global Phase 3 clinical study (RAPIDe-3) anticipated by YE2023
- Completed \$70 million private placement; cash and cash equivalents of €179 million as of June 30, 2023

ZUG, Switzerland, Aug. 07, 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 second quarter ended June 30, 2023 and provided a business update.

"The completion of enrollment in our Phase 2 CHAPTER-1 prophylactic HAE study, provides momentum as Pharvaris prepares to announce our first in-patient prophylactic clinical data by the end of the year," said Berndt Modig, Chief Executive Officer of Pharvaris. "Resolving the on-demand clinical hold of deucricitbant enables us to proceed with the clinical development of deucricitbant for the on-demand treatment of HAE; we intend to initiate our global Phase 3 on-demand study by the end of the year. We are focused on resolving the remaining clinical hold on deucricitbant for the long-term prophylactic treatment of HAE in the U.S. We appreciate the ongoing support of our external partners, including the investors in our most recent financing, which we believe demonstrates excitement for the Pharvaris story, confidence in our team's ability to execute against key initiatives, and the need for oral therapies for the treatment of HAE that are efficacious, safe, and easy to administer."

Recent Business Updates

- **CHAPTER-1, a global Phase 2 study of deucricitbant for the prophylactic treatment of HAE attacks, has completed the enrollment.** CHAPTER-1, which is currently on hold in the U.S., was designed to enroll approximately 30 patients globally with a goal of evaluating deucricitbant as an oral prophylaxis against HAE attacks, using PHVS416 (immediate-release deucricitbant capsules) as proof of concept. The efficacy and safety of deucricitbant (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 deucricitbant. Pharvaris anticipates announcing top-line data of CHAPTER-1 by the end of 2023.
- **Clinical hold lifted on deucricitbant for the on-demand treatment of HAE.** Following review of data from a preplanned interim analysis of the ongoing 26-week nonclinical study, the U.S. Food and Drug Administration (FDA) lifted the clinical hold on the Investigational New Drug (IND) application for deucricitbant for the on-demand treatment of HAE. The resolution of the hold has enabled Pharvaris to resume RAPIDe-2 in the U.S., an extension study of RAPIDe-1 evaluating PHVS416 for the on-demand treatment of HAE attacks.
- **RAPIDe-3 anticipated initiation by YE2023.** An End-of-Phase 2 meeting has been scheduled with the FDA, during which Pharvaris will seek feedback and alignment on the key elements of a proposed Phase 3 clinical study for PHVS416. Globally, Pharvaris has been working on study startup activities with clinical site investigators and staff, and upon alignment with regulators, is prepared to initiate RAPIDe-3 by the end of 2023.
- **Nonclinical toxicology study ongoing.** The IND of deucricitbant for long-term prophylaxis remains on hold in the U.S. A 26-week nonclinical rodent toxicology study, which is intended to provide additional data to address the remaining hold in the U.S., is ongoing. Pharvaris anticipates submitting the results of this nonclinical study to the FDA by the end of 2023.
- **Closing of \$70 million private placement extends cash runway.** Pharvaris announced a [placement financing of approximately \\$70 million](#), which was led by General Atlantic and venBio Partners with participation from Bain Capital Life Sciences, Foresite Capital, and Venrock Healthcare Capital Partners. The proceeds of the financing will be used to support Pharvaris' ongoing research and development activities, as well as general corporate purposes and working capital.
- **Clinical and non-clinical deucricitbant data presented at recent medical and patient meetings, supporting ongoing clinical development of deucricitbant.** Pharvaris presented data from clinical and non-clinical studies at the [13th C1-inhibitor Deficiency and Angioedema Workshop](#), the [European Academy of Allergy & Clinical Immunology \(EAACI\) Hybrid Congress 2023](#), and the [2023 U.S. HAEA National Summit](#). The slides from the oral presentations and the posters are available on the [Investors section of the Pharvaris website](#).

Second Quarter 2023 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €179 million as of June 30, 2023, compared to €162 million for December 31, 2022.
- **Research and Development (R&D) Expenses.** R&D expenses were €14.7 million for the quarter ended June 30, 2023, compared to €13.7 million for the quarter ended June 30, 2022.
- **General and Administrative (G&A) Expenses.** G&A expenses were €7.8 million for the quarter ended June 30, 2023, compared to €7.7 million for the quarter ended June 30, 2022.

- **Loss for the year.** Loss for the second quarter was €21.9 million, resulting in basic and diluted loss per share of €0.63 for the quarter ended June 30, 2023, compared to €12.6 million, or basic and diluted loss per share of €0.38, for the quarter ended June 30, 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 PHVS416 (immediate-release deucricitbant capsules)

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

PHVS719 (extended-release deucricitbant tablets) is an investigational drug intended to prevent attacks of hereditary angioedema (HAE) containing deucricitbant, 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 deucricitbant in the U.S.; the expected timing, progress, or success of our clinical development programs, especially for PHVS416 (immediate-release deucricitbant capsules) and PHVS719 (extended-release deucricitbant 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 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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