



Pharvaris Reports Second Quarter 2024 Financial Results and Provides Business Update

August 14, 2024

- Alignment with regulatory agencies following End-of-Phase 2 meetings for the prophylactic development of deucricitbant; global startup activities of CHAPTER-3, pivotal Phase 3 study of deucricitbant for the prevention of hereditary angioedema (HAE) attacks, underway
- Enrollment of RAPIDe-3, a global pivotal Phase 3 study of deucricitbant for the on-demand treatment of HAE attacks, progressing as planned
- Executing from a strong financial position with cash and cash equivalents of €344 million as of June 30, 2024

ZUG, Switzerland, Aug. 14, 2024 (GLOBE NEWSWIRE) -- [Pharvaris](#) (Nasdaq: PHVS), a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to treat and prevent hereditary angioedema (HAE) attacks, today announced the financial results for the second quarter ended June 30, 2024, and provided a business update.

"Pharvaris supports the view of the HAE community that achievement of complete control of the disease and normalization of lives of people with HAE through long-term prophylaxis are the main goals of treatment in HAE. Obtaining alignment with regulatory agencies on our proposed global clinical development plan for deucricitbant as a prophylactic HAE treatment is an important milestone for the company," said Berndt Modig, Chief Executive Officer of Pharvaris. "RAPIDe-3 enrollment is progressing as planned, and CHAPTER-3 start-up activities are underway globally. Diligent execution of the RAPIDe-3 and the CHAPTER-3 pivotal clinical studies remains our top priority, with the goal of establishing differentiated data packages for deucricitbant in both on-demand and prophylaxis. Data from the ongoing open-label extensions in both on-demand and prophylaxis, as well as supplemental analyses from the RAPIDe-1 and CHAPTER-1 studies, will be presented at upcoming medical meetings. Pharvaris continues to operate from a strong financial position with a disciplined approach as we aspire to bring best-in-class oral therapies to the HAE community."

Recent Business Updates

Development Pipeline

- **Alignment with regulatory authorities achieved regarding design of CHAPTER-3, a global Phase 3 study of deucricitbant for the prophylactic treatment of HAE.** Pharvaris sought feedback and obtained alignment on key elements of a Phase 3 clinical study design during End-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA), the European Union Committee for Medicinal Products for Human Use (CHMP), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). CHAPTER-3 is planned as a randomized, double-blind, placebo-controlled Phase 3 study of orally administered deucricitbant extended-release tablets for the prophylactic treatment of HAE attacks. The study aims to enroll approximately 81 adult and adolescent participants (12 years and older) with HAE and randomize them in a 2:1 ratio to receive deucricitbant extended-release tablets (40 mg/day) or placebo once daily for 24 weeks. The primary endpoint of the study is to evaluate the efficacy of deucricitbant compared to placebo for prophylaxis against angioedema attacks as measured by the time-normalized number of investigator-confirmed HAE attacks during the 24-week treatment period. Other objectives of the study include evaluating additional clinically relevant outcomes, deucricitbant's safety and tolerability, pharmacokinetics, and its impact on health-related quality of life in the prophylactic setting.
- **Advancing RAPIDe-3 ([NCT06343779](#)), a global Phase 3 clinical study.** RAPIDe-3, a global pivotal Phase 3 study of deucricitbant immediate-release capsules for the on-demand treatment of HAE attacks is progressing as planned with a target enrollment of approximately 120 participants. The primary efficacy endpoint is time to onset of symptom relief, as measured by Patient Global Impression of Change (PGI-C) rating of at least "a little better" for two consecutive timepoints within 12 hours post-treatment. Other efficacy endpoints include time to End of Progression (EoP) in attack symptoms, substantial symptom relief, complete attack resolution, and proportion of attacks achieving symptom resolution with one dose of deucricitbant as measured by Patient Global Impression of Severity (PGI-S) and by Angioedema Symptom Rating Scale (AMRA).
- **Best-in-class properties of deucricitbant further substantiated at recent medical congresses.** Pharvaris presented data highlighting deucricitbant's unique pharmacological and clinical properties at the [CIIC Spring 2023 Conference](#), the [20th Annual Congress of International Drug Discovery Science and Technology \(IDDST\)](#); the [2024 Eastern Allergy Conference \(EAC\)](#); and [the European Academy of Allergy and Clinical Immunology \(EAACI\) Congress 2024](#). As part of the additional analyses presented at these congresses, one data highlight was a post-hoc analysis of the RAPIDe-1 data set which showed that [78.6% of the HAE attacks treated with deucricitbant in this study resolved within 24 hours](#). The full posters and presentation slides are available on the Investors section of the Pharvaris website at <https://ir.pharvaris.com/news-events/publications>.

Corporate

- **David Nassif, J.D., permanently named Chief Legal Officer.** Mr. Nassif has acted as interim Chief Legal Officer since June 2024 and was permanently appointed to the position, effective August 1, 2024, in addition to his role as the Chief Financial Officer of the Company. He holds a B.S. in finance and management information systems with honors from the

University of Virginia and a J.D. from the University of Virginia School of Law.

Upcoming Investor Events and Presentations

- **2024 Wedbush PacGrow Healthcare Conference.** New York, NY, August 13-14, 2024.
Format: Panel Presentation: “HAE Ya! The Changing Face of the HAE Therapeutic Landscape”
Participants: Berndt Modig, CEO
Date, time: Wednesday, August 14, 2024, 2:30 p.m. EDT
- **Morgan Stanley 22nd Annual Global Healthcare Conference.** New York, NY, September 4-6, 2024.
Format: Fireside Chat
Presenters: Berndt Modig, CEO, Morgan Conn, Ph.D., CBO, and David Nassif, J.D., CFO & CLO
Date, time: Friday, September 6, 2024, 11:30 a.m. EDT

Live audio webcasts of the Morgan Stanley presentation will be available on the Investors section of the Pharvaris website at: <https://ir.pharvaris.com/news-events/events-presentations>. The audio replay will be available on Pharvaris' website for 30 days following the presentation.

Financials

Second Quarter 2024 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €344 million as of June 30, 2024, compared to €391 million for December 31, 2023.
- **Research and Development (R&D) Expenses.** R&D expenses were €23.1 million for the quarter ended June 30, 2024, compared to €14.7 million for the quarter ended June 30, 2023.
- **General and Administrative (G&A) Expenses.** G&A expenses were €11.3 million for the quarter ended June 30, 2024, compared to €7.8 million for the quarter ended June 30, 2023.
- **Loss for the year.** Loss for the second quarter was €29.7 million, resulting in basic and diluted loss per share of €0.55 for the quarter ended June 30, 2024, compared to €21.9 million, or basic and diluted loss per share of €0.63, for the quarter ended June 30, 2023.

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 Deucricitbant

Deucricitbant is a novel, potent, oral small-molecule bradykinin B2 receptor antagonist. By inhibiting bradykinin signaling through the bradykinin B2 receptor, deucricitbant has the potential to treat the manifestations of an HAE attack and to prevent the occurrence of attacks. Based on its chemical properties, Pharvaris is developing two formulations of deucricitbant for oral administration: an immediate-release capsule to enable rapid onset of activity for on-demand treatment, and an extended-release tablet to enable sustained absorption and efficacy in prophylactic treatment.

About Pharvaris

Pharvaris is a late-stage biopharmaceutical 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 types of HAE effective, well-tolerated, and easy-to-administer alternatives to treat attacks, both on-demand and prophylactically. With positive data in both Phase 2 on-demand and prophylaxis studies in HAE, Pharvaris is encouraged to further develop deucricitbant. Pharvaris is currently enrolling a pivotal Phase 3 study for the on-demand treatment of HAE attacks and plans to initiate a pivotal Phase 3 study of deucricitbant for the prevention of HAE attacks in the coming months. 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; the expected timing, progress, or success of our clinical development programs, especially for deucricitbant immediate-release capsules (PHVS416) and deucricitbant extended-release tablets (PHVS719), which are in late-stage global clinical trials; our ability to replicate the efficacy and safety demonstrated in the RAPIDE-1 and CHAPTER-1 Phase 2 studies in ongoing and future nonclinical studies and 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 outcome and 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, 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, including with respect to existing therapies, emerging potentially competitive therapies 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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