# Pharvaris Reports Third Quarter 2024 Financial Results and Highlights Recent Business Updates

November 13, 2024

- Positive long-term extension data highlighting the differentiated profile of deucrictibant for the prevention and treatment of HAE attacks presented at recent medical congresses
- Intend to engage in clinical development of deucrictibant for the treatment of acquired angioedema due to C1-INH deficiency (AAE-C1INH)
- Initiation of CHAPTER-3 global pivotal Phase 3 clinical study of deucrictibant for the prophylactic treatment of HAE using once-daily extended-release tablet expected by YE2024
- Operating from a strong financial position with cash and cash equivalents of €305 million as of September 30, 2024

ZUG, Switzerland, Nov. 13, 2024 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to prevent and treat hereditary angioedema (HAE) attacks, today announced financial results for the third quarter ended September 30, 2024, and highlighted recent business updates.

"Enrollment in our pivotal Phase 3 on-demand study, RAPIDe-3, progresses as planned, and we are preparing for the initiation of our pivotal Phase 3 prophylaxis study, CHAPTER-3, by year-end," said Berndt Modig, Chief Executive Officer of Pharvaris. "Our recently presented positive long-term extension data from our CHAPTER-1 and RAPIDe-2 Phase 2 studies reinforces deucrictibant's differentiated profile and its potential to provide people living with HAE the tools to confidently control their condition. Together with the data from our randomized clinical trials, we believe deucrictibant's injectable-like efficacy, placebo-like tolerability, and oral convenience uniquely position it to address unmet need in both the prophylactic and on-demand HAE treatment settings. Our team is now focused on the successful execution of our Phase 3 HAE clinical studies."

**Recent Highlights and Clinical Study Updates**

*Development Pipeline*

- **Anticipated initiation of CHAPTER-3 (NCT06669754) by YE2024.** CHAPTER-3 is a randomized, double-blind, placebo-controlled Phase 3 study of orally administered deucrictibant extended-release tablet 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 deucrictibant extended-release tablet (40 mg/day) or placebo once daily for 24 weeks. The primary endpoint of the study is to evaluate the efficacy of deucrictibant 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, deucrictibant's safety and tolerability, pharmacokinetics and its impact on health-related quality of life measures in the prophylactic setting.
- **Enrollment in RAPIDe-3 (NCT06343779) is progressing as planned.** Advancement of RAPIDe-3, a global pivotal Phase 3 study of deucrictibant immediate-release capsule 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 deucrictibant as measured by Patient Global Impression of Severity (PGI-S) and by Angioedema Symptom Rating Scale (AMRA).
- **Presentations at Bradykinin Symposium 2024, HAEi Global Angioedema Forum, and American College of Allergy, Asthma, & Immunology (ACAAI) Annual Meeting highlighted positive long-term extension data for deucrictibant for both prophylactic and on-demand treatment.** Extension data confirm the observed safety and tolerability profile from Phase 2 randomized studies and further support the potential for deucrictibant to become a preferred therapy for the management of HAE. Long-term prophylaxis extension data of deucrictibant (CHAPTER-1 OLE) show attack reduction is maintained for over one year with open-label extension participants experienced a 93% reduction in attacks compared to baseline. Long-term on-demand extension data of deucrictibant immediate-release capsule (RAPIDe-2 OLE) show median onset of symptom relief in ~1.1 hours, with 85.8% of attacks resolving completely 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.
- **Announced plans to expand clinical development of deucrictibant into acquired angioedema due to C1-INH deficiency (AAE-C1INH) following publication of compelling data from an investigator-initiated trial.** Data in the July 2024 publication of the *Journal of Allergy and Clinical Immunology* explored the potential for deucrictibant to address the unmet medical need for effective and well-tolerated therapies for the prophylactic and on-demand treatment of AAE-C1INH. Currently, there are no approved therapies to address AAE-C1INH. A randomized, double-blind, placebo-controlled study was conducted by Investigators at the Amsterdam University Medical Center (Amsterdam UMC). Three persons living with AAE-C1INH were enrolled; the individual mean monthly attack rates were 2.0, 0.6, and 1.0 during the placebo period and

0.0 across all participants during treatment with deucrictibant. There were no severe adverse events and one self-limiting treatment-emergent adverse event (abdominal pain).

*Upcoming Investor Events and Presentations*

- **Evercore ISI's 7 th Annual HealthCONx Conference** (Miami, FL, December 3-5, 2024)
  **Format:** Fireside Chat
  **Date, time:** Wednesday, Dec. 4, 3:50-4:10 p.m. ET
- **Oppenheimer Movers in Rare Disease Summit** (New York, NY, December 12, 2024)
  **Format:** Panel: Elevator Pitches from Rare Disease Companies
  **Date, time:** Thursday, Dec. 12, 2:45-3:30 p.m. ET

Live audio webcasts of the Evercore fireside chat 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*

**Third Quarter 2024 Financial Results**

- **Liquidity Position.** Cash and cash equivalents were €305 million as of September 30, 2024, compared to €391 million as of December 31, 2023.
- **Research and Development (R&D) Expenses.** R&D expenses were €25.8 million for the quarter ended September 30, 2024, compared to €18.5 million for the quarter ended September 30, 2023.
- **General and Administrative (G&A) Expenses.** G&A expenses were €12.1 million for the quarter ended September 30, 2024, compared to €7.7 million for the quarter ended September 30, 2023.
- **Loss for the year.** Loss for the third quarter was €41.7 million, resulting in basic and diluted loss per share of €0.77 for the quarter ended September 30, 2024, compared to €23.6 million, or basic and diluted loss per share of €0.58, for the quarter ended September 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 Deucrictibant**

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

**About Pharvaris**

Pharvaris is a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to prevent and treat 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 prophylactically and on-demand. With positive data in both Phase 2 prophylaxis and on-demand studies in HAE, Pharvaris is encouraged to further develop deucrictibant. 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 deucrictibant for the prevention of HAE by year-end 2024. 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 deucrictibant immediate-release capsules and deucrictibant extended-release tablets, 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 produce sufficient amounts of drug product candidates for commercialization; 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 [including the Biosecure Act], 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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