Pharvaris Reports First Quarter 2025 Financial Results and Provides Business Update

May 13, 2025

- Enrollment underway in CHAPTER-3, a pivotal Phase 3 study of deucrictibant for prophylaxis of HAE attacks; topline data expected in 2H2026
- Attack dataset continues to accumulate in RAPIDe-3, a pivotal Phase 3 study of deucrictibant for the on-demand treatment of HAE attacks, strengthening confidence in clinical timelines
- TQT study waivers received from FDA for both deucrictibant extended-release formulation and deucrictibant immediate-release formulation
- Pharvaris Management to host R&D call on June 4 at 8:00 a.m. ET (14.00 CET)

ZUG, Switzerland, May 13, 2025 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to help address unmet needs of those living with bradykinin-mediated diseases such as hereditary angioedema (HAE) and acquired angioedema due to C1 inhibitor deficiency (AAE-C1INH), today announced financial results for the first quarter ended March 31, 2025, and provided a business update.

"Our interactions with the HAE community combined with the regulatory receipt of orphan drug designation for deucrictibant in both the U.S. and EU, strengthen our belief that deucrictibant has the potential to address unmet needs of people living with all types of bradykinin-mediated angioedema, including those with HAE with normal C1 inhibitor and with AAE-C1INH," said Berndt Modig, Chief Executive Officer of Pharvaris. "We will detail our plans to expand the potential treatment opportunities of deucrictibant beyond people with HAE type 1/2 during an R&D call in June. We are diligently working to achieve our clinical, regulatory, and pre-commercial aspirations for 2025 and bring deucrictibant to people living with bradykinin-mediated angioedema, while maintaining our financial discipline."

Recent Business Updates
Development Pipeline

- **RAPIDe-3 (NCT06343779) attack dataset continues to accumulate.** RAPIDe-3, a pivotal global Phase 3 study evaluating deucrictibant immediate-release capsule (20 mg) for the on-demand treatment of HAE attacks in adults and adolescents (12 years and older), reached target enrollment in March 2025; the study continues to assess HAE attacks in approximately 120 participants.
- **Enrollment in CHAPTER-3 (NCT06669754) progressing as planned.** CHAPTER-3 is a randomized, double-blind, placebo-controlled Phase 3 study of orally administered deucrictibant extended-release tablet for the prophylaxis against angioedema attacks in adults and adolescents (12 years and older) with HAE. The study aims to enroll approximately 81 participants and randomize them in a 2:1 ratio to receive deucrictibant extended-release tablet (40 mg/day), which is the intended commercial dosage, or placebo, once daily for 24 weeks. Pharvaris anticipates announcing topline data of CHAPTER-3 in the second half of 2026. Data from a recent food effect study, which further supports that the extended-release tablet can be administered with or without food, will be presented at an upcoming medical congress.
- **Receipt of TQT (thorough QT) waivers.** Following review of preclinical and clinical data, the U.S. Food and Drug Administration (FDA) has accepted Pharvaris' TQT study waiver requests. These waivers apply to the prophylactic program (IND153097) for deucrictibant extended-release formulation and the on-demand program (IND155872) for deucrictibant immediate-release formulation. Previously, Pharvaris has presented clinical and nonclinical data demonstrating that deucrictibant has no evident effect on cardiovascular parameters.

Corporate

- **Company hosting R&D-focused update on June 4.** Pharvaris executives will be joined by key medical expert, Danny M. Cohn, M.D., Ph.D., to discuss the pathophysiology of bradykinin-mediated angioedema, the prevalence and unmet needs of those living with these conditions, Pharvaris' approach to addressing these unmet needs, and Pharvaris' biomarker approach to identification of those living with bradykinin-mediated angioedema and other diseases. To register, click here.

Upcoming Investor Events

- **Deucrictibant: Beyond HAE Type 1/2**, Pharvaris-hosted R&D Call
  Format: Management Call
  Date, time: Wednesday, June 4, 8:00 a.m. ET (14.00 CET)
- **46th Annual Goldman Sachs Global Healthcare Conference,** Loews Miami Beach Hotel, Miami Beach, FL, June 9-11, 2025
  Format: Fireside chat
  Date, time: Wednesday, June 11, 4:00 p.m. ET (22.00 CET)

A live audio webcast of the 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
First Quarter 2025 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €236 million as of March 31, 2025, compared to €281 million for December 31, 2024.
- **Research and Development (R&D) Expenses.** R&D expenses were €30.9 million for the quarter ended March 31, 2025, compared to €18.5 million for the quarter ended March 31, 2024.
- **General and Administrative (G&A) Expenses.** G&A expenses were €11.3 million for the quarter ended March 31, 2025, compared to €9.8 million for the quarter ended March 31, 2024.
- **Loss for the year.** Loss for the first quarter was €46.3 million, resulting in basic and diluted loss per share of €0.85 for the quarter ended March 31, 2025, compared to €28.0 million, or basic and diluted loss per share of €0.52, for the quarter ended March 31, 2024.

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, orally bioavailable small-molecule bradykinin B2 receptor antagonist currently in clinical development. Deucrictibant is being investigated for its potential to prevent the occurrence of bradykinin-mediated angioedema attacks and to treat the manifestations of attacks if/when they occur by inhibiting bradykinin signaling through the bradykinin B2 receptor. 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 as prophylactic treatment, and an immediate-release capsule to enable rapid onset of activity for on-demand treatment. Deucrictibant has been granted orphan drug designation by the U.S. Food and Drug Administration and orphan designation by the European Commission.

About Pharvaris
Pharvaris is a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to potentially address all types of bradykinin-mediated angioedema. Pharvaris intends to provide injectable-like efficacy™ and placebo-like tolerability with the convenience of an oral therapy to prevent and treat bradykinin-mediated angioedema attacks. With positive data in both Phase 2 prophylaxis and on-demand studies in HAE, Pharvaris is currently evaluating the efficacy and safety of deucrictibant in a pivotal Phase 3 study for the prevention of HAE attacks (CHAPTER-3) and a pivotal Phase 3 study for the on-demand treatment of HAE attacks (RAPIDe-3). 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, RAPIDe-2, and CHAPTER-1 Phase 2 and Phase 3 studies in ongoing and future nonclinical studies and clinical trials; risks arising from epidemic diseases, , which may adversely impact our business, nonclinical studies, and clinical trials; our ability to potentially use deucrictibant for alternative purposes, for example to treat C1-INH deficiency (AAE-C1INH); 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 conditions; disruptions at the FDA and other agencies; political conditions, such as the current war between Russia and Ukraine; economic conditions, including continuing inflation concerns; 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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