Pharvaris Outlines 2025 Strategic Priorities

January 13, 2025

- Initiated CHAPTER-3, the pivotal Phase 3 study of deucrictibant for prophylaxis against hereditary angioedema (HAE) attacks in 2024; topline data anticipated in 2H2026
- Enrollment in RAPIDe-3, the pivotal Phase 3 study of deucrictibant for the on-demand treatment of HAE attacks, continuing as planned; topline data anticipated in 1Q2026
- Study initiation of deucrictibant for the treatment of acquired angioedema due to C1-INH deficiency (AAE-C1INH) anticipated in 2025
- Operating from a strong financial position with estimated cash runway into 3Q2026
- Company presentation at the J.P. Morgan Healthcare Conference

ZUG, Switzerland, Jan. 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 (AAE), today outlined its strategic priorities for 2025.

"This year is paramount to Pharvaris as we continue clinical development of deucrictibant to help address unmet needs for those living with bradykinin-mediated angioedema," said Berndt Modig, Chief Executive Officer of Pharvaris. "Pharvaris is committed to generating robust clinical data to build a compelling package supporting deucrictibant's efficacy and safety profile. Our team is focused on the execution of two Phase 3 clinical studies in HAE, the expansion of our pipeline into AAE, and preparations for commercialization of deucrictibant pending regulatory submission and approval; we have significant resources in place to support these strategic investments and provide value for our shareholders."

2025 Strategic Priorities
Long-term Prophylaxis of HAE Attacks

- **Initiated CHAPTER-3 (NCT06669754), a global pivotal Phase 3 study, evaluating deucrictibant for the prophylactic treatment of HAE attacks; topline data anticipated 2H2026.** 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 with HAE and randomize them in a 2:1 ratio to receive deucrictibant extended-release tablet (40 mg/day), which is currently the intended commercial dosage, 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. Pharvaris anticipates announcing topline data of CHAPTER-3 in the second half of 2026.
- **Prophylactic open-label extension study CHAPTER-4 (NCT06679881) on track to initiate in 1Q2025.** CHAPTER-4 is a long-term, open-label extension study of orally administered deucrictibant extended-release tablet (40 mg/day) for the prophylactic treatment of HAE attacks. Participants in the open-label extension study are 12 years or older, have been diagnosed with HAE, and may either have rolled over from the CHAPTER-3 randomized clinical study, may transition to CHAPTER-4 after participating in the long-term extension study of Phase 2 prophylactic study using the twice-daily deucrictibant immediate-release capsule (CHAPTER-1 Part 2, NCT05047185), or may qualify following an eligibility confirmation via screening period. The intention of the study is to evaluate the tolerability and efficacy of deucrictibant extended-release tablet in the prophylactic treatment of HAE attacks.

On-demand Treatment of HAE Attacks

- **Topline data from RAPIDe-3 (NCT06343779), a global Phase 3 study evaluating deucrictibant for the treatment of HAE attacks, anticipated 1Q2026.** Advancement of RAPIDe-3, a global pivotal Phase 3 study of deucrictibant immediate-release capsule (20 mg) for the on-demand treatment of HAE attacks in adults and adolescents (12 years and older), 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). Pharvaris anticipates announcing topline data of RAPIDe-3 in the first quarter of 2026.
- **Phase 2/3 open-label extension, RAPIDe-2 (NCT05396105), of deucrictibant immediate-release capsule for the treatment of HAE attacks ongoing.** All participants from RAPIDe-2 Part A, the dose-blinded open-label extension study of RAPIDe-1 (NCT04618211), as well as participants who have completed RAPIDe-3, have or will be offered to enter Part

B, the open-label extension study of deucrictibant immediate-release capsule (20 mg), which is the dose being used in RAPIDe-3 and currently the intended commercial dosage. The intention of the study is to evaluate the tolerability and efficacy of deucrictibant immediate-release capsule in the on-demand treatment of HAE attacks.

Clinical Development of Deucrictibant in AAE-C1 INH

- **Clinical development plans of deucrictibant in acquired angioedema due to C1-INH deficiency (AAE-C1INH) underway.** Currently, there are no approved therapies to address AAE-C1INH[1]. Pharvaris has engaged stakeholders, including the U.S. Food and Drug Administration (FDA), for feedback on a clinical development plan designed to evaluate the potential of deucrictibant to address an unmet medical need for therapies for the treatment of AAE-C1INH; Pharvaris intends to initiate a clinical study in 2025 pending feedback from regulators.

Business Updates
Corporate

- **Expansion of Pharvaris team to support deucrictibant launch preparedness, as well as business growth and planning.** Chris Wilson joined Pharvaris as the Vice President of Sales & Marketing, North America, bringing a wealth of expertise in HAE product commercialization and executing strategic sales and marketing initiatives. Christa Milley joined Pharvaris as the Vice President, Head of Business Development, bringing an extensive deal sheet that demonstrates her track record of identifying, evaluating, structuring, negotiating, and executing deals to support our corporate development strategy.
- **HAE treatment experience and burden of disease data presented at recent medical congresses.** Data from the Adelphi Disease Specific Programme™, a real-world cross-sectional survey of physicians and people living with HAE, were presented in two oral presentations at the Spanish Society of Allergology and Clinical Immunology (SEAIC) International Symposium and a poster at the BSI Clinical Immunology Network (BSI-CIPN) Conference. One oral presentation characterized the treatment of HAE airway attacks, detailing the considerable pain, fatigue, and emotional distress experienced; despite the potential consequences, approximately one-third of HAE airway attacks were not treated, underscoring the importance for people with HAE to align with clinical guidelines to carry on-demand therapy, as well as highlighting the need for portable therapies. The second oral presentation investigated the burden of disease in people living with HAE and their caregivers in Europe, concluding that people with HAE who reported a greater need for caregiver support—driven by the support for medication management—experienced significant impairment in activity and a reduced quality of life.
  The poster presented at BSI-CIPN characterized the experience of people living with HAE in the United Kingdom with current treatments, all of whom were prescribed injectable on-demand medications. The most common unmet need associated with currently prescribed long-term prophylactic and on-demand medications was a desire for a different route of administration. This analysis highlights the unmet need for novel oral options.

Upcoming Participation at Investor Conferences

- **43rd Annual J.P. Morgan Healthcare Conference.** San Francisco, CA, January 13-16, 2025.
  - **Format:** Company Presentation
    Presenter: Berndt Modig, CEO
    Date, time: Wednesday, January 15, 2025, 5:15-5:55 p.m. PST (8:15-8:55 p.m. EST)
- **Oppenheimer 35th Annual Healthcare Life Sciences Conference.** Virtual, February 11-12, 2025.
  - **Format:** Fireside Chat
    Presenters: Berndt Modig, CEO; Wim Souverijns, Ph.D., CCO; Peng Lu, M.D., Ph.D., CMO
    Date, time: Wednesday, February 12, 2025, 9:20-9:50 a.m. EST

Live audio webcasts of the J.P. Morgan and Oppenheimer presentations will be available on the Investors section of the Pharvaris website at: https://ir.pharvaris.com/news-events/events-presentations. The audio replays will be available on Pharvaris' website for 30 days following the presentation.

Upcoming Presentations at Medical Congresses

- **American Academy of Allergy, Asthma & Immunology (AAAAI) 2025 Annual Meeting.** San Diego, CA, February 28-March 4, 2025. Details for the accepted poster presentations at AAAAI are as follows:
  - **Title:** Long-Term Safety and Efficacy of Oral Deucrictibant for Prophylaxis in Hereditary Angioedema: Results of the CHAPTER-1 Open-Label Extension Study
    Presenter: Marc A. Riedl, M.D., M.S.
    Date, time: Sunday, March 2, 2025, 9:45-10:45 a.m. PST (12:45-1:45 p.m. EST)
  - **Title:** Long-Term Prophylactic Treatment with Oral Deucrictibant Improves Health-Related Quality of Life of Patients with Hereditary Angioedema: CHAPTER-1 Open-Label Extension Study
    Presenter: John Anderson, M.D.

Date, time: Sunday, March 2, 2025, 9:45-10:45 a.m. PST (12:45-1:45 p.m. EST)

- **Title:** Long-Term Safety and Efficacy of Oral Deucrictibant for Treatment of Hereditary Angioedema Attacks: Results of the RAPIDe-2 Extension Study
  Presenter: Michael E. Manning, M.D.
  Date, time: Sunday, March 2, 2025, 9:45-10:45 a.m. PST (12:45-1:45 p.m. EST)

The posters will be available on the Investors section of the Pharvaris website at: https://ir.pharvaris.com/news-events/events-presentations.

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 potentially address all types of bradykinin-mediated angioedema. Pharvaris has the ambition to provide injectable-like efficacy and placebo-like tolerability with the convenience of an oral therapy to prevent and treat HAE attacks. With positive data in both Phase 2 prophylaxis and on-demand studies in HAE, Pharvaris is currently evaluating the efficacy and tolerability 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 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; 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, 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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[1] Petersen et al. *J Allergy Clin Immunol* July 2024.

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