Pharvaris Presents Clinical and Non-Clinical Data Supporting HAE Development Program at the 2024 ACAAI Annual Scientific Meeting

October 24, 2024

Data from randomized clinical studies and long-term extension studies support deucrictibant's potential best-in-class profile, detailing its injectable-like efficacy, placebo-like tolerability, and oral convenience

ZUG, Switzerland, Oct. 24, 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 data from seven posters that will be presented at the 2024 Annual Scientific Meeting of the American College of Allergy, Asthma & Immunology (ACAAI).

Pharvaris mourns our distinguished colleague, Prof. Marcus Maurer, who passed away during the development and finalization of these posters.

"The totality of data supporting deucrictibant's potential best-in-class profile in both prophylaxis and on-demand remains consistent and provides compelling validation for its continued clinical development," said Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris. "The data presented at ACAAI continue to clinically derisk deucrictibant and contribute to excitement for deucrictibant to become a preferred therapy in HAE."

The CHAPTER-1 Phase 2 data provide proof of the efficacy and safety of deucrictibant for the prevention of HAE attacks and support its further development as a potential prophylactic therapy for HAE, which will be presented by H. James Wedner, M.D. Specifically, Dr. Wedner explores deucrictibant's ability to decrease the median percentage of days with symptoms to 1.7% (40 mg/day) from 14.6% (placebo).

Results of the ongoing CHAPTER-1 open-label extension study provide further evidence on the long-term safety and efficacy of deucrictibant for prevention of HAE attacks and support further development of deucrictibant as a potential prophylactic therapy for HAE, which will be presented by John Anderson, M.D. Importantly, approximately 80% of participants achieved at least a 90% reduction in attack rate relative to the study baseline (as studied in the randomized clinical trial).

Pharvaris' confidence in the design of both the prophylactic and on-demand Phase 2 and Phase 3 studies is supported by nonclinical data in the bradykinin (BK) challenge model in non-human primates (NHPs). The pharmacokinetic and pharmacodynamic (PK/PD) profile of deucrictibant in the NHP BK challenge was shown to be predictive of the human PK/PD in the human BK challenge, as presented by Juan Bravo, Ph.D. Successful predictions of efficacious dosing of deucrictibant in humans were obtained following in-house modeling of nonclinical data, in line with the Phase 2 clinical studies of deucrictibant for both the prophylactic and the on-demand treatment of HAE attacks.

The posters from ACAAI and a replay of the investor event are 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. 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 on-demand and prophylactically. 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 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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