Pharvaris Presents Deucrictibant Clinical Data and Analysis of Endpoints for Trials of On-demand Treatment of HAE at the GA²LEN UCARE Conference 2023

December 8, 2023

ZUG, Switzerland, Dec. 08, 2023 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent hereditary angioedema (HAE) attacks, today announced the presentation of one oral session and two posters at the Global Allergy and Asthma Excellence Network (GA²LEN) Urticaria Centers of Reference and Excellence (UCARE) Conference, being held from December 7-9, 2023, at the Rebouças Convention Center in São Paulo, Brazil.

Prof. Markus Magerl, M.D., presented an oral session titled "Treatment of HAE Attacks with Deucrictibant: RAPIDe-1 Phase 2 Trial Results" on Friday, December 8, 11:18-11:26 a.m. BST (9:18-9:26 a.m. EST). RAPIDe-1, a pivotal Phase 2 trial of deucrictibant immediate-release capsule (PHVS416) in the on-demand treatment HAE attacks, showed that deucrictibant capsules rapidly reduced time to the onset of symptom relief and to the resolution of HAE attacks, substantially reduced use of rescue medication and was well-tolerated at all dose levels.

Prof. Marcus Maurer, M.D., presented a poster titled "Early-Onset Response to Treatment of Hereditary Angioedema Attacks with Deucrictibant" on Friday, December 8, 7:00-8:00 p.m. BST (5:00-6:00 p.m. EST). Primary and *post-hoc* analyses of the RAPIDe-1 study were conducted to evaluate end of progression (EoP) and symptom relief in response to treatment of HAE attacks with PHVS416. In a post-hoc analysis of RAPIDe-1 data, EoP of angioedema manifestations, which represents the first event documenting treatment response and the first evidence of attacks evolving towards relief and resolution, was achieved at a median time of 25 or 26 minutes after treatment with deucrictibant capsules versus 20 hours for placebo. The onset of symptom relief was achieved at approximately two hours and clinically meaningful improvement within two hours after administration of deucrictibant.

Dr. Danny M. Cohn, M.D., presented a poster titled "Analyzing Symptom Relief Definitions in HAE Using AMRA and PGI-C/PGI-S" on Friday, December 8, 7:00-8:00 p.m. BST (5:00-6:00 p.m. EST). This poster details findings from a study performed in the U.S. assessing the content validity and psychometric properties of the three-item Angioedema symptom Rating scale (AMRA-3), a numeric rating scale derived from the three-symptom composite visual analogue scale (VAS-3). Results suggest that the median time to symptom relief of an AMRA-3 ≥20% reduction from pre-treatment is comparable with achieving a Patients' Global Impression of Change (PGI-C) "a little better" on two consecutive timepoints.

"A key secondary endpoint of RAPIDe-1 was the time to ≥30% change in VAS-3; today, Dr. Cohn presented data collected from the assessment of on demand stand-of-care treatments, suggesting that time to achieve a 20% change in AMRA-3—a derivative of VAS-3—is comparable to the time tc achieve an improvement of 'a little better' on PGI-C," said Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris. "These findings, combined with the consistent results of RAPIDe-1 across the primary and all key secondary endpoints, provide confidence in the robustness of the dataset that can be generated through a pivotal Phase 3 study, such as RAPIDe-3. Additionally, we have been exploring other *post-hoc* analyses from RAPIDe-1 to assess additional outcomes that are clinically meaningful to the reduction of the morbidity of HAE, such as those that yielded the compelling data on the time to end of progression presented at the GA²LEN UCARE Conference."

About deucrictibant immediate-release capsule (PHVS416)
Deucrictibant immediate-release capsule (PHVS416) is an investigational drug intended to treat attacks of hereditary angioedema (HAE) containing deucrictibant, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris aims to develop the immediate-release capsule formulation to provide rapid and reliable symptom relief, through rapid exposure of attack-mitigating therapy in an easy-to-administer, small oral dosage form.

About Pharvaris
Building on its deep-seated roots in HAE, Pharvaris is a clinical-stage 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 sub-types of HAE efficacious, safe, and easy-to-administer alternatives to treat attacks, both on-demand and prophylactically. The company brings together the best talent in the industry with deep expertise in rare diseases and HAE. 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 with respect to the clinical hold on prophylactic deucrictibant in the U.S.; the expected timing, progress, or success of our clinical development programs, especially for PHVS416 (immediate-release deucrictibant capsules) and PHVS719 (extended-release deucrictibant tablets), which are in mid-stage global 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 expected timing and results of the rodent toxicology study and our ability to resolve any issues to the satisfaction of the FDA or any regulatory agency in a timely manner; the 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 PHVS416 and PHVS719, 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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