Pharvaris Announces FDA Lifting of the Clinical Hold of Deucrictibant for the Prophylactic Treatment of HAE Attacks

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ZUG, Switzerland, Jan. 22, 2024 (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 U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Investigational New Drug (IND) application for deucrictibant for the prophylactic treatment of HAE attacks following review of data from a 26-week rodent toxicology study.

"The lift of the clinical hold in the U.S. enables us to progress the global development of deucrictibant for long-term prophylaxis, including resuming the open-label portion of CHAPTER-1, our Phase 2 proof-of-concept study of deucrictibant for the prevention of HAE attacks, in the U.S.," said Berndt Modig, Chief Executive Officer of Pharvaris. "We are pleased to have worked collaboratively with the FDA to address the requests of the agency with the submission of additional nonclinical data, and we appreciate the agency's comments and recommendations regarding study conduct. We will request an End-of-Phase 2 meeting with the FDA to align on key elements of CHAPTER-3, the anticipated global Phase 3 study of deucrictibant extended-release tablets (PHVS719) for the prophylactic treatment of HAE attacks."

In August 2022, the FDA placed clinical studies of deucrictibant, including CHAPTER-1, on hold. Pharvaris notified ex-U.S. country-specific regulatory authorities of the clinical hold in the U.S., and the regulatory status of deucrictibant outside the U.S. was not affected. In June 2023, Pharvaris announced the FDA's removal of the clinical hold of deucrictibant for the on-demand treatment of HAE in the U.S. following FDA review of data from a preplanned interim analysis of a 26-week rodent toxicology study. In December 2023, Pharvaris announced positive top-line clinical data from the Phase 2 CHAPTER-1 study of deucrictibant for the prophylactic treatment of HAE attacks.

About Deucrictibant
Deucrictibant is a potent, selective, and orally available antagonist of the bradykinin B2 receptor. By inhibiting bradykinin signaling through the bradykinin B2 receptor, deucrictibant has the potential to treat the clinical signs of an HAE attack and to prevent the occurrence of attacks. Based on its chemical properties, Pharvaris is developing two formulations of deucrictibant for oral administration; a capsule to enable rapid onset of activity for acute treatment, and an extended-release tablet to enable sustained absorption and efficacy in prophylactic treatment.

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; the expected timing, progress, or success of our clinical development programs, especially for deucrictibant immediate-release capsules (PHVS416) and deucrictibant extended-release tablets (PHVS719), 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 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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