Pharvaris Announces FDA Removal of Clinical Hold of Deucrictibant for the On-Demand Treatment of HAE

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ZUG, Switzerland, June 26, 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 U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Investigational New Drug (IND) application for deucrictibant for the on-demand treatment of HAE following review of data from a preplanned interim analysis of the ongoing 26-week nonclinical study. Pharvaris expects to submit data from the 26-week nonclinical study by the end of 2023 to address the remaining hold on the IND application for deucrictibant for prophylactic treatment of HAE.

"The lift of the clinical hold on our on-demand clinical trials enables us to continue development of PHVS416 (deucrictibant immediate-release capsules) in the U.S., including resuming RAPIDe-2, our extension study for acute treatment of attacks," said Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris. "Our team plans to request an end of Phase 2 meeting with the agency and is preparing for RAPIDe-3, our global Phase 3 study of PHVS416 for the on-demand treatment of HAE, to include U.S. sites. The 26-week nonclinical study to address the remaining hold on prophylactic deucrictibant in the U.S. is still progressing and we plan to submit the data from that study to the FDA by the end of the year. Based on current enrollment, we confirm that top-line data from CHAPTER-1, our Phase 2 proof-of-concept study of PHVS416 for the prophylactic treatment of HAE, remains on track to be announced by the end of the year."

About Pharvaris
Building on its deep-seated roots in hereditary angioedema (HAE), Pharvaris is a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent HAE attacks. By directly targeting this clinically proven therapeutic target with novel small molecules, the Pharvaris team aspires to offer people with all sub-types of HAE safe, effective, and convenient 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 the Offering and the use of proceeds therefrom, 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 associated with the COVID-19 pandemic, which may adversely impact our business, nonclinical studies, and clinical trials; 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 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 weakness in our internal control over financial reporting and to maintain an effective system of internal control over financial reporting; changes in general market, political and economic conditions, including as a result of the current conflict between Russia and Ukraine; 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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