Pharvaris Announces Orphan Designation Granted to Deucrictibant by the European Commission

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ZUG, Switzerland, April 01, 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 due to C1 inhibitor deficiency (AAE-C1INH), today announced that the European Commission (EC) has granted orphan designation to its investigational drug, deucrictibant, for the treatment of bradykinin-mediated angioedema.

The U.S. Food and Drug Administration (FDA) previously granted orphan drug designation to deucrictibant for the treatment of bradykinin-mediated angioedema in March 2022.

"Today, we are diligently executing our phase 3 development program evaluating the efficacy and safety of deucrictibant in HAE. By granting deucrictibant orphan designation for the treatment of bradykinin-mediated angioedema, the European regulators are acknowledging deucrictibant's ability as a bradykinin B2 receptor antagonist to address the unmet needs associated with any bradykinin-mediated angioedema condition," said Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris. "By blocking the effects of bradykinin, the ultimate culprit inducing angioedema attacks, regardless of its source, deucrictibant has the potential to offer a broader-acting option to address the unmet need associated with bradykinin-mediated angioedema diseases, beyond HAE. To provide further evidence for that hypothesis, we are currently discussing a pivotal trial in AAE-C1INH with regulators."

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 is being investigated for its potential to prevent the occurrence of bradykinin-mediated angioedema attacks and to treat the manifestations of attacks 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 as prophylactic treatment, and an immediate-release capsule to enable rapid onset of activity for on-demand treatment. Deucrictibant has been granted orphan drug designation by the U.S. Food and Drug Administration and orphan designation by the European Commission.

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 intends to provide injectable-like efficacy and placebo-like tolerability with the convenience of an oral therapy to prevent and treat bradykinin-mediated angioedema attacks. With positive data in both Phase 2 prophylaxis and on-demand studies in HAE, Pharvaris is currently evaluating the efficacy and safety 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 and Phase 3 studies in ongoing and future nonclinical studies and clinical trials; risks arising from epidemic diseases, 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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