Pharvaris Announces FDA Acceptance of New Drug Application for Deucrictibant IR for On-Demand Treatment of Hereditary Angioedema Attacks

July 6, 2026

- If approved, deucrictibant will be the first oral bradykinin B2 receptor antagonist to treat HAE attacks
- NDA includes positive data from successful clinical program demonstrating rapid relief and sustained response to resolution of HAE attack symptoms and a well-tolerated safety profile
- PDUFA action date set for April 23, 2027

ZUG, Switzerland, July 06, 2026 (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 U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for deucrictibant immediate-release (IR) capsule (20 mg) for the on-demand treatment (ODT) of Hereditary Angioedema (HAE) attacks. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of April 23, 2027.

“After 10 years of dedicated effort by the team at Pharvaris, this FDA acceptance of deucrictibant IR’s NDA represents a major milestone in our journey to develop a differentiated therapy with the potential to improve the standard of care for people living with HAE,” said Berndt Modig, Chief Executive Officer of Pharvaris. “Pharvaris has a deep scientific legacy in bradykinin B2 receptor antagonism, a clinically proven therapeutic approach for HAE attack treatment. By leveraging this trusted mechanism and its chemical properties, deucrictibant IR has the potential to be an oral on-demand medicine that addresses unmet needs of those living with HAE. In clinical studies, treatment of HAE attacks with deucrictibant IR resulted in rapid time to onset of symptom relief and accelerated time to complete symptom resolution. With the build out of our commercial infrastructure already underway, Pharvaris is poised for a successful launch of deucrictibant IR, if approved.”

Pharvaris’ NDA details a comprehensive clinical development program for deucrictibant IR, including data from the treatment of over 1,300 HAE attacks. RAPIDe-3 (NCT06343779), a global, pivotal, placebo-controlled Phase 3 study of deucrictibant IR for the on-demand treatment of attacks in participants 12 years and older with HAE, including those with HAE with normal C1 inhibitor, met the primary and all 11 secondary efficacy endpoints with statistical significance. Results from RAPIDe-3 demonstrated the rapid and sustained efficacy of deucrictibant IR in treating HAE attacks; the median time to onset of symptom relief was 1.28 hours, to End of Progression™ (EoP) was 17.48 minutes, and to complete resolution of attack symptoms was 11.95 hours. Deucrictibant IR demonstrated a well-tolerated safety profile. Deucrictibant was granted orphan drug designation by the FDA in 2022.

About Deucrictibant
Deucrictibant is a novel, potent, orally bioavailable small-molecule bradykinin B2 receptor antagonist currently in clinical development. 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 by inhibiting bradykinin signaling through the bradykinin B2 receptor. 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 for the treatment of bradykinin-mediated angioedema by the U.S. Food and Drug Administration, the European Commission, and Swissmedic.

About Pharvaris
Pharvaris is a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to help address unmet needs in bradykinin-mediated conditions, including all types of bradykinin-mediated angioedema. Pharvaris’ aspiration is to offer therapies with injectable-like efficacy™, a well-tolerated profile, and the convenience of oral administration to prevent and treat bradykinin-mediated angioedema attacks. By delivering on this aspiration, Pharvaris aims to provide a new standard of care in bradykinin-mediated angioedema. 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,” “hope,” “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, RAPIDe-3, and CHAPTER-1 Phase 2 and Phase 3 studies in ongoing and future nonclinical studies and clinical trials, such as CHAPTER-3, and CREAATE; the timing and outcome of regulatory approvals, including the timing and outcome of our planned submission of an NDA with the FDA in the first half of 2026 for the on-demand treatment of acute attacks of HAE; 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 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 maintain an effective system of internal control over financial reporting; changes and uncertainty in general market conditions; disruptions at the FDA and other agencies; changes and uncertainty in general market, political and economic conditions, including as a result of inflation and geopolitical conflicts; changes in regulations and customs, tariffs and trade barriers; 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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