PHARVARIS

Phase 3 Study Results Highlighting Deucrictibant's Rapid and Sustained Efficacy in Treating HAE Attacks Published in The Lancet

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- Results from RAPIDe-3 demonstrate that treatment with deucrictibant IR resulted in faster time to onset of symptom relief (1.28 hours) and to complete symptom resolution (11.95 hours)
- Deucrictibant IR showed a well-tolerated safety profile
- NDA and MAA of deucrictibant IR for the on-demand treatment of HAE attacks under review by regulatory authorities

ZUG, Switzerland, Oct. 08, 2026 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a late-stage biopharmaceutical company developing oral bradykinin B2 receptor antagonists to help address unmet needs of those living with bradykinin-mediated angioedema, such as hereditary angioedema (HAE) and acquired angioedema due to C1 inhibitor deficiency (AAE-C1INH), today announced that results of RAPIDe-3, a phase 3, global, randomized, double-blind, placebo-controlled crossover study evaluating oral deucrictibant immediate-release (IR) capsule (20 mg) for the on-demand treatment of HAE attacks in adolescents and adults have been published in *The Lancet* (Journal Impact Factor: 109.0).

"Bradykinin B2 receptor antagonism is a validated and reliable mechanism currently being widely used for the on-demand treatment of HAE attacks," said Marc A. Riedl, M.D., M.S., Professor of Medicine, Clinical Director of the U.S. Hereditary Angioedema Association (HAEA) Angioedema Center at the University of California San Diego (UCSD), principal RAPIDe-3 study investigator, and lead Author of the publication. *"The results of the RAPIDe-3 study demonstrate that deucrictibant IR, an orally-administered bradykinin B2 receptor antagonist, rapidly ended attack progression and accelerated the time to complete symptom resolution. Publication in* The Lancet, *one of the world's highest-impact academic journals, maximizes the visibility of these data to a global network of clinicians, researchers, and patients. If approved, deucrictibant IR will be the first approved oral bradykinin B2 receptor antagonist, with the potential to address unmet needs of people living with HAE by providing reliable symptom relief and resolution with a single convenient oral capsule."*

RAPIDe-3 (NCT06343779) met its primary endpoint and all 11 secondary endpoints with high statistical significance. Deucrictibant IR achieved End of Progression™[1] (EoP) of attack symptoms, symptom relief, and complete symptom resolution significantly faster than placebo, with most attacks being adequately controlled with a single capsule. Deucrictibant IR was well tolerated with no safety signals observed. Results were consistent across subgroups of participants defined according to age, geographic location, HAE type (including HAE with normal C1 inhibitor), use of long-term prophylaxis, and attack severity and location (including non-severe laryngeal attacks).

Peng Lu, M.D., Ph.D., President of Pharvaris, added, *"the consistent results from RAPIDe-3 across subgroups underscores the clinical relevance of antagonizing the bradykinin B2 receptor, a downstream target that stops the effects of excess bradykinin regardless of the pathways through which it is generated. These findings represent the first pivotal step in Pharvaris' broader clinical development strategy of investigating deucrictibant across both on-demand and prophylactic settings with the goal of delivering new treatment options that may address unmet medical needs of those living with bradykinin-mediated angioedema."*

The full article can be found here: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(26)01296-1/fulltext

Results of the RAPIDe-3 study are consistent with results of RAPIDe-1, which were published in April 2026 in *The Lancet Haematology*. An open-label extension study of deucrictibant IR for the on-demand treatment of HAE attacks, RAPIDe-2 (NCT05396105), is ongoing. An expanded access program (EAP) (NCT07759141) for deucrictibant IR for the on-demand treatment of HAE attacks is also available to people in U.S. meeting eligibility requirements.

A New Drug Application (NDA) for deucrictibant IR for the on-demand treatment of HAE attacks is currently under review with the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of April 23, 2027. A Marketing Authorization Application (MAA) for deucrictibant IR for on-demand treatment of HAE attacks is also currently under review with the European Medicines Agency (EMA).

[1] The term End of Progression is a registered trademark of Pharvaris GmbH.

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,” “estimate,” “may,” “could,” “should,” “would,” “will” 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; the outcome of regulatory approvals, including the outcome of our NDA and MAA for the on-demand treatment of acute attacks of HAE; our ability to replicate the efficacy and safety demonstrated in the RAPIDe-1, RAPIDe-2, RAPIDe-3, CHAPTER-1, and CHAPTER-3 Phase 2 and Phase 3 studies in ongoing and future nonclinical studies and clinical trials, such as CREAATE; 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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