



Pharvaris Updates Timing of Topline Data Announcement for RAPIDe-3 Pivotal Phase 3 Study to the Fourth Quarter of 2025

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- Company expects to submit deucricitbant IR capsule NDA to the U.S. FDA for the on-demand treatment of HAE attacks in 1H2026

ZUG, Switzerland, July 10, 2025 (GLOBE NEWSWIRE) -- [Pharvaris](#) (Nasdaq: PHVS), a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to 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), updated the guidance for the disclosure of topline data from the ongoing RAPIDe-3 pivotal Phase 3 study evaluating deucricitbant immediate-release (IR) capsule for the on-demand treatment of HAE attacks. Pharvaris anticipates announcing topline data from RAPIDe-3 in the fourth quarter of 2025 and, pending positive data, expects to submit a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the first half of 2026.

"The attack data in RAPIDe-3 have continued to accrue following the achievement of target enrollment in the study; we now estimate that our RAPIDe-3 topline data announcement will be in the fourth quarter of this year," said Berndt Modig, Chief Executive Officer of Pharvaris. *"Our phase 3 data may provide evidence of deucricitbant IR's potential to address the desire of people living with HAE for an on-demand therapy that combines efficacy—from rapid end of progression to fast and complete resolution—and a favorable safety profile, with the convenience of a single-capsule oral dose."*

Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris, added, *"We aim to confirm the findings from our Phase 2 studies in a larger Phase 3 trial, RAPIDe-3. Importantly, this study is assessing the effects of deucricitbant for people with high unmet need beyond adults with HAE type 1 and 2, such as participants with HAE with normal C1 inhibitor and adolescents between 12 and 17 years and will be evaluating the effects of deucricitbant in treating laryngeal attacks. We want to thank the clinical trial participants, the investigators and their study site collaborators for their ongoing commitment to this important trial."*

RAPIDe-3 ([NCT06343779](#)) is a global Phase 3 study evaluating deucricitbant immediate-release capsule (20 mg) for the on-demand treatment of angioedema attacks in approximately 120 adult and adolescent (12 years and older) participants with HAE, including forms with C1 inhibitor deficiency and forms with normal C1INH. The primary endpoint is time to onset of symptom relief, as measured by Patient Global Impression of Change (PGI-C) rating of at least "a little better." Other endpoints include time to End of Progression (EoP) in attack symptoms, substantial symptom relief, complete symptom resolution and proportion of complete symptom resolution achieved with one dose of deucricitbant as measured by Patient Global Impression of Severity (PGI-S), PGI-C, and by Angioedema Symptom Rating Scale (AMRA), and incidence of treatment-emergent adverse events (TEAEs).

About Deucricitbant

Deucricitbant is a novel, potent, orally bioavailable small-molecule bradykinin B2 receptor antagonist currently in clinical development. Deucricitbant 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 deucricitbant 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. Deucricitbant has been granted orphan drug designation for the treatment of bradykinin-mediated angioedema 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 oral therapies 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 deucricitbant 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 deucricitbant immediate-release capsules and deucricitbant 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 deucricitbant 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 maintain an effective system of internal control over financial reporting; changes and uncertainty in general market conditions; disruptions at the FDA and other agencies; political conditions, such as the current war between Russia and Ukraine; economic conditions, including continuing inflation concerns; 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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