PHARVARIS

Assessment of AAE-C1INH Disease Burden and Validation of Clinical Trial Endpoints Published in Frontiers in Immunology

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- People with AAE-C1INH experience frequent misdiagnoses, emergency medical events, and wide-ranging impact on physical, emotional, and social well-being
- Study results informed the design and endpoint selection of the ongoing Phase 3 CREAATE study

ZUG, Switzerland, Aug. 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 angioedema, such as hereditary angioedema (HAE) and acquired angioedema due to C1 inhibitor deficiency (AAE-C1INH), today announced that results from the first in-depth qualitative study assessing the experiences of people with AAE-C1INH and validating relevant patient-reported outcome (PRO) measures have been published in *Frontiers in Immunology*. The study findings directly informed the design of and endpoint selection for the ongoing Phase 3 CREAATE study (NCT07266805) investigating deucrictibant for the prophylaxis and on-demand treatment of AAE-C1INH attacks.

"People living with AAE-C1INH face a profoundly challenging disease, including struggling through misdiagnoses, often due to lack of awareness of AAE-C1INH. Attacks are often painful, cause significant discomfort, and can limit functioning—disrupting daily life and creating a considerable burden," said Danny M. Cohn, M.D., Ph.D., Department of Vascular Medicine, Amsterdam UMC (an accredited center of ACARE) and principal investigator in CREAATE. *"Despite this, there are currently no therapies approved for the prevention or treatment of AAE-C1INH attacks. This study is an important step forward, capturing the patient experience in a rigorous way and helping to ensure that clinical studies evaluate outcomes that are truly meaningful to patients."*

The study represents the first in-depth qualitative assessment in AAE-C1INH, an ultra-rare and serious disease with no approved therapies for the prevention or treatment of bradykinin-mediated angioedema attacks. Findings provide foundational insights into disease burden and establish a framework to support the selection of clinical endpoints for clinical trials in this condition.

Interviews with people diagnosed with AAE-C1INH characterized disease manifestations, the impact on daily life, and perspectives on treatment benefit. Study results demonstrated that AAE-C1INH imposes a significant and multifaceted burden on patients, with participants reporting frequent, painful swelling attacks that disrupt daily functioning, often following prolonged initial periods of misdiagnosis and emergency care. Interviews also revealed broad impact across physical, emotional, social, and work-related domains, with individuals commonly unable to carry out routine activities, travel, or maintain employment during attacks. All participants relied on off-label therapies, underscoring the unmet needs associated with the absence of approved treatment options.

The study evaluated the relevance and interpretability of established PRO instruments, including the Patient Global Impression of Change (PGI-C), Patient Global Impression of Severity (PGI-S), and Patient Global Assessment (PGA) measures, in the AAE-C1INH population. Results demonstrated that these tools are meaningful and applicable for assessing treatment benefits in this disease context, helping to define clinically relevant thresholds for symptom improvement and resolution. Importantly, the study showed that a PGI-C rating of "better" was most consistently deemed meaningful across all participants at time points of up to 4 hours post treatment.

Peng Lu, M.D., Ph.D., President of Pharvaris, added, *"these findings represent an important step forward in building a rigorous, patient-centered evidence base in AAE-C1INH. Aligned with guidance from the U.S. Food and Drug Administration (FDA), capturing the patient experience and defining meaningful changes in patient-centered outcomes strengthens the scientific foundation for the evaluation of treatment benefit in this underserved population. These insights directly informed our clinical trial design, ensuring our programs measure outcomes that truly matter to patients and enable us to advance our broader goal of developing effective, well-tolerated therapies that address unmet needs for people living with bradykinin-mediated angioedema*."

The full publication can be found here: Angioedema due to acquired C1 inhibitor deficiency: patient experience, conceptual disease model, and assessment of patient-reported outcome measures

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 outcome of regulatory approvals, including the outcome of our NDA 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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