

Pharvaris Provides Business Update and Outlines 2024 Strategic Priorities

January 5, 2024

- RAPIDe-3, a global Phase 3 clinical study of deucricitbant for the on-demand treatment of HAE, to initiate within 1H24
- Results of nonclinical rodent toxicology study submitted to the FDA
- Jochen Knolle, Ph.D., to transition to strategic advisor to the CEO and Executive Committee
- Company presentation at the J.P. Morgan Healthcare Conference

ZUG, Switzerland, Jan. 05, 2024 (GLOBE NEWSWIRE) -- [Pharvaris](#) (Nasdaq: PHVS), a clinical-stage company developing novel, oral bradykinin B2 receptor antagonists to treat and prevent hereditary angioedema (HAE) attacks, today provided business updates and outlined its strategic priorities for 2024.

"Pharvaris enters the new year having demonstrated deucricitbant's potential to be the preferred option for both the prevention and treatment of HAE attacks," said Berndt Modig, Chief Executive Officer of Pharvaris. "We are operating from a strong financial position and anticipate 2024 will be an important execution year for Pharvaris as we transition into a late-stage clinical company with the initiation of RAPIDe-3 expected within the first half. We have submitted the results of the nonclinical study to the FDA for review with respect to the clinical hold on the long-term prophylaxis program in the U.S. We are also preparing to initiate the global pivotal study, CHAPTER-3, for the prophylaxis against HAE attacks. In parallel, we will be building on our foundation for Pharvaris' long-term strategy as we invest in our commercial and product infrastructure to support our commitment to provide deucricitbant to people living with HAE."

Mr. Modig continued, "We are thankful to Jochen Knolle's vision and leadership over the past eight years. Jochen has been instrumental in the development of multiple therapies throughout his career, including icatibant and deucricitbant for the treatment of HAE. The next years will be incredibly important to the company, and Jochen's continued strategic guidance will be invaluable."

Business Updates and Company Highlights

Pipeline

- **Anticipated initiation of RAPIDe-3 within 1H2024.** RAPIDe-3 is a randomized, double-blind, placebo-controlled, cross-over Phase 3 study designed to evaluate the efficacy and safety of oral deucricitbant immediate-release capsules (PHVS416) for the on-demand treatment of HAE attacks. During the treatment phase, participants will self-administer double-blinded study drug (20 mg deucricitbant immediate-release capsule or placebo, in a crossover fashion) to treat a total of two qualifying attacks. The primary endpoint is time to onset of symptom relief, defined as a Patient Global Impression of Change (PGI-C) rating of at least "a little better" for two consecutive timepoints within 12 hours post-treatment. Secondary endpoints include assessments of time to end of progression of attack symptoms, substantial symptom relief, and symptom resolution, as defined by PGI-C, Patient Global Impression of Severity (PGI-S) and Angioedema symptom Rating scale (AMRA), as well as use of rescue medication. [Data](#) from a real-world study in HAE with standard-of-care treatments suggest the median time to symptom relief is similar when measured by AMRA-3 $\geq 20\%$ reduction from pre-treatment and with PGI-C "a little better" on two consecutive timepoints. Safety outcome measures include incidence of treatment-emergent adverse events. After RAPIDe-3 completion, participants may continue treatment with deucricitbant in an open-label extension study. In the RAPIDe-1 Phase 2 study, deucricitbant significantly reduced the time to onset of symptom relief and to resolution of HAE attacks, reduced use of rescue medication, and was well-tolerated.
- **Submission of nonclinical rodent toxicology data to the U.S. Food & Drug Administration (FDA) completed.** Pharvaris has submitted the results from the 26-week rodent toxicology study to the FDA. The study was intended to provide additional data to address the clinical hold on the IND of deucricitbant for long-term prophylaxis, and Pharvaris believes the study met its objective. Neither the nature nor timing of the response from FDA is certain.
- **Phase 2 CHAPTER-1 clinical study met its primary endpoint.** The primary endpoint of the [CHAPTER-1](#) study measured the time-normalized number of investigator-confirmed HAE attacks during the treatment period. The monthly attack rate was reduced by 84.5% ($p=0.0008$) compared to placebo in participants who received 40 mg/day of deucricitbant. In the analysis of the secondary endpoints, deucricitbant demonstrated clinically meaningful reductions in the occurrence of moderate and severe attacks and in the number of attacks treated with on-demand medication. Participants on deucricitbant treatment experienced a meaningful improvement in their quality of life as measured by patient global assessment of change (PGA-Change) and angioedema quality of life (AE-QoL) questionnaires. Throughout 12 weeks of treatment in CHAPTER-1, both the 20 mg/day and the 40 mg/day doses of deucricitbant were well-tolerated. The open-label portion of the CHAPTER-1 study is ongoing. Pharvaris is preparing to initiate CHAPTER-3, a global, pivotal study to evaluate deucricitbant for the prophylactic treatment of HAE attacks.

Corporate

- **Closing of \$300 million underwritten offering extends cash runway.** [The offering of \\$300 million](#) included participation

from General Atlantic, as well as other new and existing institutional investors. The proceeds of the financing will be used to support Pharvaris' ongoing research and development activities, product discovery expenses, as well as general corporate purposes and working capital. Pharvaris remains diligent in its operational management and now has a cash runway for at least two years.

- **Jochen Knolle, Ph.D., co-founder of Pharvaris, transitions to strategic advisor to the CEO and Executive Committee.** Dr. Knolle, who served as Pharvaris' Chief Scientific Officer and Chief Operating Officer since the company's inception, is named as an author or inventor on numerous publications and patents, including for the approved therapeutics quinapril, a marketed ACE inhibitor, and icatibant. Under his leadership, Pharvaris succeeded in identifying deucricitbant, a long-sought-after oral B2 receptor antagonist with sub-nanomolar *in vitro* potency that utilizes the same mechanism of action as icatibant with a distinctly different chemical structure. Deucricitbant is being developed as two different oral formulations, optimized either for rapid exposure and onset of activity for the acute treatment of HAE attacks or through sustained exposure for preventive treatment of HAE.

Dr. Knolle stated, "It has been a privilege working with the HAE community throughout my career. The approval of icatibant as an acute treatment for HAE attacks shifted the paradigm of treatment for people living with HAE, and I anticipate that deucricitbant will have an equally important impact on the HAE community. I look forward to continuing to contribute to the strategic transformation of Pharvaris in my new capacity."

Upcoming Presentations

- **42nd Annual J.P. Morgan Healthcare Conference.** San Francisco, CA, January 8-11, 2024.
 - **Format:** Company Presentation
 - Presenter:** Berndt Modig
 - Date, time:** Thursday, January 11, 2024, 9:00-9:40 a.m. PST (12:00-12:40 p.m. EST)
- **20th BioCapital Europe Conference.** Amsterdam, Netherlands, February 8, 2024.
 - **Format:** Live In-Person Presentation
 - Presenter:** Berndt Modig
 - Date, time:** Thursday, February 8, 4:00-4:20 p.m. CET (10:00-10:20 a.m. EST)
- **Oppenheimer 34th Annual Healthcare Life Sciences Conference.** Virtual, February 13-14, 2024.
 - **Format:** Fireside Chat
 - Presenter:** Berndt Modig and Morgan Conn, Ph.D.
 - Date, time:** Wednesday, February 14, 2024, 8:30-9:10 a.m. EST
- **American Academy of Allergy, Asthma & Immunology (AAAAI) 2024 Annual Meeting.** Washington, DC, February 23-26, 2024. Details for the accepted poster presentations at AAAAI are as follows:
 - **Title:** Efficacy and Safety of Bradykinin B2 Receptor Antagonism with Oral Deucricitbant in Prophylaxis of Hereditary Angioedema Attacks: Results of CHAPTER-1 Phase 2 Trial
 - Presenter:** Marc A. Riedl, M.D., M.S.
 - Date, time:** Friday, February 23, 2024, 3:15-4:15 p.m. EST
 - **Title:** Understanding the Reasons not to Treat All HAE Attacks and Patient Satisfaction for on-Demand Treatment (ODT). Results from the HAE Wave II Disease Specific Program™ (DSP™) 2023
 - Presenter:** Joan Mendivil, M.D.
 - Date, time:** Friday, February 23, 2024, 3:15-4:15 p.m. EST

Live audio webcasts of the J.P. Morgan and Oppenheimer presentations will be available on the Investors section of the Pharvaris website at: <https://ir.pharvaris.com/news-events/events-presentations>. The audio replays will be available on Pharvaris' website for 30 days following the presentation.

About Deucricitbant

Deucricitbant is a potent, selective, and orally available antagonist of the bradykinin B2 receptor. By inhibiting bradykinin signaling through the bradykinin B2 receptor, deucricitbant has the potential to treat the clinical signs of an HAE attack and to prevent the occurrence of attacks. Based on its chemical properties, Pharvaris is developing two formulations of deucricitbant for oral administration; a capsule to enable rapid onset of activity for acute treatment, and an extended-release tablet to enable sustained absorption and efficacy in prophylactic treatment.

About Pharvaris

Building on its deep-seated roots in HAE, Pharvaris is a clinical-stage company developing novel, oral bradykinin B2 receptor antagonists to treat and prevent HAE attacks. By directly pursuing this clinically proven therapeutic target with novel small molecules, the Pharvaris team aspires to offer people with all sub-types of HAE efficacious, safe, and easy-to-administer alternatives to treat attacks, both on-demand and prophylactically. The company brings together the best talent in the industry with deep expertise in rare diseases and HAE. 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 with respect to the clinical hold on prophylactic deucricitab in the U.S.; the expected timing, progress, or success of our clinical development programs, especially for deucricitab immediate-release capsules (PHVS416) and deucricitab extended-release tablets (PHVS719), which are in mid-stage global clinical trials; risks arising from epidemic diseases, such as the COVID-19 pandemic, which may adversely impact our business, nonclinical studies, and clinical trials; the expected timing and results of the rodent toxicology study and our ability to resolve any issues to the satisfaction of the FDA or any regulatory agency in a timely manner; the 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 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, 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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