

Pharvaris Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

April 10, 2024

- RAPIDe-3, a global pivotal Phase 3 study of deucricitbant for the on-demand treatment of HAE attacks, is currently enrolling
- End-of-Phase 2 meeting scheduled to discuss development plan of deucricitbant for the prophylaxis of HAE attacks
- Strengthened executive committee with hiring of David Nassif, J.D., Chief Financial Officer, and Stefan Abele, Ph.D., as Chief Technical Operations Officer
- UK Innovation Passport awarded to deucricitbant for both the on-demand and prophylactic treatment of HAE attacks
- Ended 2023 with cash and cash equivalents of approximately €391 million

ZUG, Switzerland, April 10, 2024 (GLOBE NEWSWIRE) -- [Pharvaris](#) (Nasdaq: PHVS), a late-stage biopharmaceutical company developing novel, oral bradykinin B2 receptor antagonists to treat and prevent hereditary angioedema (HAE) attacks, today reported financial results for the fourth quarter and year ended December 31, 2023 and provided a business update.

"2024 is off to a strong start, supported by the incredible momentum we built in an impressive 2023—driven by a second positive data readout of deucricitbant that was validated by the support of our investors," said Berndt Modig, Chief Executive Officer of Pharvaris. "At the start of the year, the lift of the remaining hold on the prophylaxis program in the U.S. allowed us to progress with the global Phase 3 clinical development plans for deucricitbant for prevention of HAE attacks. As we move toward the initiation of CHAPTER-3, we hope to realize the promise of the proof-of-concept CHAPTER-1 data, which support deucricitbant's potential to be a best-in-class oral prophylactic therapy. We are pleased with the HAE community's excitement in RAPIDe-3, which is enrolling as planned; we will provide the anticipated timing of topline data as enrollment progresses and data is accumulated. Receipt of the Innovation Passport designation for deucricitbant in the UK reflects regulatory recognition of deucricitbant's innovation for better treatment options for people living with HAE."

Recent Business Updates and Highlights

Development Pipeline

- **Enrollment initiated in RAPIDe-3 ([NCT06343779](#)) a global Phase 3 clinical study.** Pharvaris is currently enrolling in RAPIDe-3, a global pivotal Phase 3 study of deucricitbant immediate-release capsule (PHVS416) for the on-demand treatment of HAE attacks. The primary efficacy endpoint is time to onset of symptom relief, as measured by Patient Global Impression of Change (PGI-C) of at least "a little better" for two consecutive timepoints within 12 hours post-treatment. Other efficacy endpoints include time to End of Progression (EoP) in attack symptoms within 12 hours as measured by PGI-C, substantial symptom relief, and proportion of attacks achieving symptom resolution with one dose of deucricitbant as measured by Patient Global Impression of Severity (PGI-S) and by Angioedema Symptom Rating Scale (AMRA).
- **End-of-Phase 2 meeting scheduled to align on prophylactic Phase 3 clinical development plan.** Pharvaris continues preparatory activities for CHAPTER-3, a global Phase 3 study of deucricitbant extended-release tablets (PHVS719) for the prophylactic treatment of HAE attacks. An End-of-Phase 2 meeting has been scheduled with the U.S. Food and Drug Administration (FDA), during which Pharvaris will seek feedback and alignment on the key elements of the proposed clinical development plan.
- **Deucricitbant awarded UK Innovation Passport.** The UK Innovative Licensing and Access Pathway (ILAP) Steering Group, which consists of the All Wales Therapeutics and Toxicology Centre (AWTTC), the Medicines and Healthcare products Regulatory Agency (MHRA), the National Institute for Health and Care Excellence (NICE), and the Scottish Medicines Consortium (SMC), has awarded an Innovation Passport to deucricitbant for the on-demand and prophylactic treatment of HAE attacks in people 12 years and older. The Innovation Passport is the entry point for the ILAP, which has a goal of accelerating the time to access to medicines in the UK, and receipt of the award activates the MHRA, NICE, SMC, and other agencies to develop a roadmap for regulatory and development milestones.
- **Clinical hold lifted.** Following review of data from a 26-week rodent toxicology study, the FDA lifted the clinical hold on the Investigational New Drug (IND) application for deucricitbant for the prophylaxis of HAE attacks.
- **Deucricitbant data presented at recent industry meetings.** Data supporting the ongoing development of deucricitbant for both the on-demand and prophylactic treatment of HAE attacks were presented at the [GA²LEN UCARE Conference 2023](#), the [American College of Allergy, Asthma & Immunology \(ACAAI\) 2023 Annual Scientific Meeting](#), [Western Society of Allergy, Asthma & Immunology \(WSAAI\) Annual Meeting 2024](#), the [American Academy of Allergy, Asthma & Immunology \(AAAAI\) 2024 Annual Meeting](#), the [3rd National Congress of the Italian Network for Hereditary and Acquired Angioedema \(ITACA\)](#), and the [2024 HAE International \(HAEi\) Regional Conference Americas](#). Highlights of presentations include top-line data from the [CHAPTER-1 study](#), the design of the [RAPIDe-3 study](#), deucricitbant's ability to [reduce the time to EoP of HAE attacks](#), and a [comparison](#) of various patient-reported outcome (PRO) instruments.

- **Strengthened executive team.** Stefan Abele, Ph.D., joined Pharvaris as Chief Technical Operations Officer in November 2023, furthering the company's capabilities in chemistry, manufacturing, and controls (CMC) activities, supply chain, intellectual property, and project management. Effective April 15, 2024, David Nassif, J.D., will join Pharvaris as Chief Financial Officer and will be responsible for refining and implementing Pharvaris' corporate financial strategy and activities including financial reporting and operations. In April 2024, Peng Lu, M.D., Ph.D., was promoted to Head of Research & Development and Chief Medical Officer, as Pharvaris strategically strengthens the continuity between research and clinical development for various pipeline programs.
- **Held Extraordinary Meeting of Shareholders.** On March 6, 2024, the company held an Extraordinary General Meeting of Shareholders at which all proposals were approved.

Upcoming Investor Presentations

The Citizens JMP Life Sciences Conference. New York, NY, May 13-14, 2024.

- **Format:** Fireside Chat
Presenter: Berndt Modig and Morgan Conn, Ph.D.
Date, time: Monday May 13, 2024, 9:30 a.m. EDT

BofA Securities Health Care conference 2024. Las Vegas, NV, May 14-16, 2024.

- **Format:** Company Presentation
Presenter: Morgan Conn, Ph.D.
Date, time: Thursday May 16, 2024, 8:00 a.m. PDT (11:00 a.m. EDT)

Live audio webcasts of the 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.

Financials

Fourth Quarter and Full Year 2023 Financial Results

- **Liquidity Position.** Cash and cash equivalents were approximately €391 million as of December 31, 2023, compared to approximately €162 million for December 31, 2022.
- **Research and Development (R&D) Expenses.** R&D expenses were €18.6 million for the fourth quarter and €65.6 million for the full year of 2023, compared to €15.7 million for the fourth quarter and €57.4 million for the full year of 2022.
- **General and Administrative (G&A) Expenses.** G&A expenses were €8.6 million for the fourth quarter and €31.3 million for the full year of 2023, compared to €7.8 million for the fourth quarter and €29.3 million for the full year of 2022.
- **Loss for the year.** Loss for the fourth quarter of 2023 was €32.7 million, resulting in basic and diluted loss per share of €0.74. For the full year of 2023, loss was €101 million, resulting in basic and diluted loss per share of €2.63 per share. This compares to €39.2 million, or basic and diluted loss per share of €1.16, for the fourth quarter of 2022 and €76.3 million, or basic and diluted loss per share of €2.27, for the full year of 2022.

Note on International Financial Reporting Standards (IFRS)

Pharvaris is a Foreign Private Issuer and prepares and reports consolidated financial statements and financial information in accordance with IFRS as issued by the International Accounting Standards Board. Pharvaris maintains its books and records in the Euro currency.

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 late-stage biopharmaceutical 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; the expected timing, progress, or success of our clinical development programs, especially for deucricitbant immediate-release capsules (PHVS416) and deucricitbant extended-release tablets (PHVS719), which are in late-stage global clinical trials; our ability to replicate the efficacy and safety demonstrated in the RAPIDe-1 and CHAPTER-1 Phase 2 study in ongoing and future nonclinical studies and 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 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 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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