



## Pharvaris Reports First Quarter 2021 Financial Results and Provides Business Highlights

May 26, 2021

- **RAPIDe-1, Phase 2 on-demand study of PHVS416 for the treatment of HAE attacks proceeding**
- **HAE CHAPTER-1, Phase 2 prophylactic study of PHVS416 for prevention of HAE attacks, on-track to initiate in 2021**
- **Viviane Monges nominated to Board of Directors and as Chair of the Audit Committee**
- **Strong financial position with cash and cash equivalents of €238.3 million as of March 31, 2021**

ZUG, Switzerland, May 26, 2021 (GLOBE NEWSWIRE) -- [Pharvaris](#) (Nasdaq: PHVS), a clinical-stage company focused on the development and commercialization of novel oral bradykinin-B2-receptor antagonists for the treatment of hereditary angioedema (HAE) and other bradykinin-B2-receptor-mediated indications, today reported financial results for the first quarter ended March 31, 2021, and provided an update on recent business highlights.

"We continue to execute on a development strategy which we believe provides value to shareholders and patients, as demonstrated by the successful completion of our IPO in the first quarter of the year and the continued enrollment of our Phase 2 on-demand study of PHVS416, from which we plan to report data next year," said Berndt Modig, co-founder and chief executive officer of Pharvaris. "In order to meet the unmet need of many HAE patients demanding oral alternative therapies, we plan to initiate our HAE CHAPTER-1 Phase 2 prophylactic study of PHVS416 this year. Pharvaris remains committed to providing access to medicines for patients in need, and the recent appointment of Wim Souverijns to the executive team will guide our clinical development and enable us to prepare for the commercialization of our B2-receptor antagonists. Additionally, we have nominated Viviane Monges to join our board of directors as the chair of the audit committee, bringing diverse global financial experience to our team."

### Recent Business Highlights and Upcoming Milestones

#### *Pipeline*

- **Phase 2 on-demand study (RAPIDe-1) of PHVS416 proceeding.** In February 2021, Pharvaris announced that enrollment had commenced in its Phase 2 clinical study of PHVS416 for the on-demand treatment of HAE attacks.
- **Phase 2 prophylactic study (HAE CHAPTER-1) of PHVS416 to begin in 2021.** In addition to developing PHVS416 for the on-demand treatment of HAE attacks, the company plans to investigate the therapeutic potential of PHVS416 for the prophylactic prevention of HAE attacks. In April 2021, Pharvaris announced that an IND is active in the US with the FDA and expects to initiate the study in 2021.
- **Phase 1 pharmacokinetics study of PHVS719 to begin by the end of 2021.** PHVS719 is an extended-release formulation of PHA121 intended for use in the prophylactic treatment of HAE. The company expects to initiate a Phase 1 pharmacokinetics study by the end of 2021.

#### *Corporate*

- **Leadership team expansion.** In May 2021, the company announced the expansion of their leadership team through the appointment of Wim Souverijns, Ph.D., as chief community engagement & commercial officer. In this newly created role, Wim is responsible for engagement of key stakeholders across HAE as the company sets its regulatory, commercial, and market-access strategies.
- **Board of Directors nomination.** In May 2021, the company nominated Viviane Monges as a new member of the Board of Directors and Chair of the Audit Committee. Ms. Monges currently serves on the board of multiple pharmaceutical, biotechnology, and financial companies, including DBV Technologies, UCB, and Novo Holdings, and brings over 30 years of financial management experience from within the pharmaceutical industry and across several continents. Her appointment to the Board is expected to be formally confirmed at an upcoming general meeting of shareholders.
- **Preclinical data accepted for presentation at C1-Inhibitor Deficiency Angioedema Workshop.** The company will present preclinical data for PHA121 at the 12<sup>th</sup> C1-Inhibitor Deficiency Angioedema Workshop, to be held virtually from June 3-6, 2021. The abstract, titled "PHA-022121: Efficacy in a monkey bradykinin challenge model translated to human," has been accepted for oral presentation by Anne Lesage, Ph.D., chief early development officer of Pharvaris, in Session 1, Basic Research and Diagnostics, on June 4 at 9:45 a.m. CEST.
- **Completed initial public offering (IPO).** In February 2021, Pharvaris completed its IPO of 9,511,075 shares of common stock at a public offering price of \$20.00 per share, generating gross proceeds of \$190.2 million before deducting underwriting discounts and commissions and estimated offering expenses.

### First Quarter 2021 Financial Results

- **Liquidity Position.** Cash and cash equivalents were €238.3 million for the quarter ended March 31, 2021, compared to €98.6 million for the year ended December 31, 2020.
- **Research and Development (R&D) Expenses.** R&D expenses were €8.1 million for the quarter ended March 31, 2021,

compared to €2.4 million for the quarter ended March 31, 2020.

- **General and Administrative (G&A) Expenses.** G&A expenses were €3.8 million for the quarter ended March 31, 2021, compared to €0.8 million for the quarter ended March 31, 2020.
- **Loss for the period.** Loss for the quarter ended March 31, 2021 was €6.0 million, or basic and diluted loss per share of €0.66, for the quarter ended March 31, 2021, compared to loss for the quarter ended March 31, 2020 of €3.3 million, or basic and diluted loss per share of €0.68 for the quarter ended March 31, 2020.

#### **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 Pharvaris**

Pharvaris is a clinical-stage company focused on bringing oral bradykinin-B2-receptor antagonists to patients. By targeting this clinically proven therapeutic target with novel small molecules, the Pharvaris team is advancing new alternatives to injected therapies for all sub-types of HAE and other bradykinin-mediated diseases. The Company brings together executives with a breadth of expertise across pharmaceutical development and rare disorders, including HAE. For more information, visit <https://pharvaris.com/>.

#### **About PHVS416**

PHVS416 is a softgel capsule formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris is developing this formulation to provide rapid exposure of attack-mitigating medicine in a convenient, small oral dosage form. PHVS416 is currently in Phase 2 clinical development for the on-demand treatment of HAE.

#### **About PHVS719**

PHVS719 is an extended-release tablet formulation containing PHA121, a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor. Pharvaris is developing this formulation to provide sustained exposure of attack-preventing medicine in a convenient, small oral dosage form. PHVS719 is currently in preclinical development for the prophylactic treatment of HAE.

#### **About PHA121**

PHA121 (PHA-022121) is a highly potent, specific, and orally bioavailable competitive antagonist of the bradykinin B2 receptor that has completed Phase 1 clinical development for the treatment of HAE. PHA121 utilizes the same mechanism as icatibant, the leading therapy for on-demand treatment of HAE. Pharvaris is developing this novel small molecule for on-demand and prophylactic treatment of HAE and other bradykinin-mediated diseases through formulations optimized for each setting. Data from single- and multiple-ascending-dose Phase 1 studies in healthy volunteers demonstrate rapid exposure and predictable linear pharmacokinetics at doses up to 50 mg. In a bradykinin-challenge study in healthy volunteers, PHA121 showed significant inhibition of bradykinin-induced hemodynamic changes with an average composite EC<sub>50</sub> of 2.4 ng/mL and EC<sub>85</sub> of 13.8 ng/mL, approximately four-fold more potent than historical data for icatibant. Quantitative modeling indicates that single oral doses of PHA121 will maintain pharmacologically active drug levels for a substantially longer time than 30 mg of subcutaneous icatibant. PHA121 has been observed to be well-tolerated at all doses studied to date.

#### **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 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: the expected timing, progress, or success of our clinical development programs, especially for PHVS416 and PHVS719, which are in early-stage clinical trials; risks associated with the COVID-19 pandemic, which may adversely impact our business, preclinical studies, and clinical trials; 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 PHVS416 and PHVS719, 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 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 weakness in our internal control over financial reporting and to maintain an effective system of internal control over financial reporting; and the other factors described under the heading "Risk Factors" in our registration statement on Form 20-F and other periodic filings with the 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.

#### **Investor Contact**

Sarah McCabe  
[sarah.mccabe@sternir.com](mailto:sarah.mccabe@sternir.com)  
+1-212-362-1200

#### **Media Contact**

Maggie Beller, Russo Partners, LLC

[maggie.beller@russopartnersllc.com](mailto:maggie.beller@russopartnersllc.com)

+1-646-942-5631