Pharvaris Participates in the Kinin 2022 Conference

June 7, 2022

Pharvaris' tailored drug development approach to enable treatment of people living with all types of hereditary angioedema (HAE) presented at satellite symposium

ZUG, Switzerland, June 07, 2022 (GLOBE NEWSWIRE) -- Pharvaris (Nasdaq: PHVS), a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent HAE attacks, building on its deep-seated roots in hereditary angioedema (HAE), today announced the presentation of its development program at the Kinin 2022 Conference, to be held June 5-8, 2022, in Annecy, France. The satellite symposium titled, "Tailored drug development for patients living with HAE," was delivered on Tuesday, June 7, at 13:00 CEST by Anne Lesage, Ph.D., chief early development officer at Pharvaris.

The satellite symposium explored the attributes and mechanism of HAE; the pharmacodynamic (PD) and pharmacokinetic (PK) characteristics of Pharvaris' novel, orally bioavailable, highly potent and selective B2 receptor antagonist; and, preclinical and clinical data supporting Pharvaris' development strategy of two oral therapies for both the on-demand and prophylactic treatment of all HAE attacks.

"The data presented at Kinin 2022 demonstrate that our molecule shows rapid onset of effect, and, relative to icatibant, higher potency in a surrogate endpoint and longer half-life which may lead to more effective symptom mitigation," said Dr. Lesage. "Bradykinin-B2-receptor antagonism is effective in treating HAE but is currently unavailable as an oral treatment. Pharvaris is designing oral product candidates for both on-demand use, and prophylactic use, in the form of softgel PHVS416 capsules and extended-release PHVS719 tablets, respectively. The data presented in the satellite symposium support the development strategy implemented by Pharvaris to prevent and treat painful HAE attacks through a convenient oral route of administration."

Berndt Modig, chief executive officer of Pharvaris, added, "We continue to advance our therapeutic pipeline to better understand the product profile of each of our candidates. The Phase 2 RAPIDe-1 study investigating PHVS416 for the on-demand treatment of HAE attacks has reached target patient enrollment, and we continue to enroll patients in our ongoing Phase 2 CHAPTER-1 clinical trial for the prophylactic treatment of HAE attacks. At Pharvaris, we remain committed to providing people living with HAE additional treatment alternatives."

As presented in the satellite symposium, Pharvaris is developing oral products that are highly potent, specific, and orally bioavailable competitive antagonists of the bradykinin B2 receptor, which utilize the same mechanism as icatibant, the leading therapy for on-demand treatment of HAE. Preclinical in vitro studies demonstrate PHA121, the active ingredient in PHVS416 and PHVS719, is 25-fold more potent than icatibant at competing with the endogenous human B2 receptor, and preclinical in vivo data demonstrate oral PHA121 inhibits bradykinin with longer duration and faster onset than subcutaneous icatibant. Phase 1 studies in healthy volunteers demonstrate oral pre-treatment with PHA121 blocks the effect of bradykinin-induced hemodynamic changes. Additional data on PHA121 gut absorption and fecal excretion in animal models confirm high oral bioavailability and low excretion. Together, studies in vitro, ex vivo, and in vivo demonstrate that PHA121 is 20- to 25-fold more potent than icatibant.

The presentation will be available on the Investors section of the Pharvaris website at: https://ir.pharvaris.com/news-events/events-presentations for 30 days.

About PHVS416
PHVS416 is an investigational 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 fast and reliable symptom relief when patients want, through rapid exposure of attack-mitigating medicine in a convenient, small oral dosage form. In healthy volunteers, a single dose of PHVS416 showed rapid exposure exceeding predicted therapeutically efficacious levels within 15 minutes. PHVS416 is currently in Phase 2 clinical development for the on-demand treatment of HAE.

About PHVS719
PHVS719 is an investigational 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 an easy way to prevent attacks with sustained exposure of attack-preventing medicine in a convenient, small oral dosage form. PHVS719 is currently in Phase 1 clinical development for the prophylactic treatment of HAE. In healthy volunteers, a single dose of PHVS719 was well tolerated with an extended-release profile supporting once-daily dosing.

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 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_{50} of 2.4 ng/mL and EC_{85} 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 pharmacological effectiveness 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.

About Pharvaris
Pharvaris is a clinical-stage company developing novel, oral bradykinin-B2-receptor antagonists to treat and prevent HAE attacks, building on its deep-seated roots in HAE. By directly targeting this clinically proven therapeutic target with novel small molecules, the Pharvaris team aspires to offer people with all sub-types of HAE more effective and convenient 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 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 mid-stage clinical trials; risks associated with the COVID-19 pandemic, which may adversely impact our business, nonclinical 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; changes in general market, political and economic conditions, including as a result of the current conflict between Russia and Ukraine; 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 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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