Pharvaris Announces Phase 1 Clinical Data of PHA121, an Oral B2 Receptor Antagonist Under Development for the Treatment of Hereditary Angioedema

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Data demonstrate the oral bioavailability of PHA121, which was well-tolerated across multiple ascending doses

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ZUG, Switzerland, Jan. 27, 2021 /PRNewswire/ -- Pharvaris, a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of innovative therapies, including novel, small molecule bradykinin-B2-receptor antagonists for the treatment of hereditary angioedema (HAE) and other bradykinin-B2-receptor-mediated indications, today announced clinical data from its Phase 1 multiple-ascending-dose study demonstrating PHA121's pharmacokinetics and tolerability. PHA121 was well tolerated at all doses studied, with approximately dose-proportional exposure.

"We are encouraged by these results to continue development of PHA121 as an oral treatment for hereditary angioedema," said Berndt Modig, Chief Executive Officer and co-founder of Pharvaris. "In 2021, we will explore the therapeutic potential of PHA121 for both acute and prophylactic treatment of HAE. Our upcoming Phase 2 studies will utilize PHVS416, a soft capsule formulation containing PHA121."

The Phase 1 randomized, double-blind, placebo-controlled, multiple ascending dose trial examined the safety, tolerability, and pharmacokinetics of PHA121 in healthy volunteers. The trial included 38 healthy subjects dosed twice daily (BID) for 10 days in four sequential dosing cohorts, ranging from 12 to 50 mg. During the study, PHA121 was well tolerated up to the highest dose of 50 mg BID. All reported treatment-emergent adverse events (TEAEs) were mild in intensity and resolved completely. The total incidence and type of TEAEs were similar between active drug and placebo groups. Lab safety, vital signs, and ECG parameters remained well within normal limits in all subjects. The pharmacokinetic profile suggests that therapeutic drug levels of PHA121 were achieved in day 1 and steady-state plasma concentrations were reached within 72 hours.

About PHVS416
PHVS416 is a soft capsule formulation containing PHA121 (PHA-022121), 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.

About PHA121
PHA121 (PHA-022121) is a highly potent, specific, and orally bioavailable competitive antagonist of the human bradykinin B2 receptor currently in 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 disease through formulations optimized for each setting.

About HAE
Hereditary angioedema is a rare and potentially life-threatening genetic condition with symptoms that include episodes of debilitating and often painful swelling in the hands, feet, face (lips and tongue), gastrointestinal tract, urogenital region, or airways. Attacks are unpredictable in frequency, location, timing, and severity, with multiple types of triggers. Patients experience a median of 14 attacks per year, and half of patients experience a potentially life-threatening airway attack at least once in their lifetime, according to published reports. Airway attacks are particularly dangerous and can lead to asphyxiation. If left untreated, attacks can last multiple days and are commonly painful, leading to multiple sick days and even hospitalization. According to HAE International (HAEi), the global umbrella organization for the world's HAE patient groups, HAE affects from 1:50,000 to 1:10,000 individuals globally, or at least 6,600 patients in the U.S. and at least 8,900 patients in the EU.

About Pharvaris
Pharvaris is a clinical-stage biopharmaceutical 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/.

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