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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13A-16 OR 15D-16 UNDER  
THE SECURITIES EXCHANGE ACT OF 1934**

**For the month of December 2023  
Commission File Number: 001-40010**

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**Pharvaris N.V.**

(Translation of registrant's name into English)

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Emmy Noetherweg 2  
2333 BK Leiden  
The Netherlands

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.  
Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

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## PHARVARIS N.V.

In connection with an investor event on December 6, 2023, Pharvaris N.V. (the “Company”) provided a corporate update included in a corporate presentation on its website, provided a presentation to be used in their Key Opinion Leader call and issued a press release, which, among other things, provide an update with respect to the Company’s clinical programs, including top-line Phase 2 data from the CHAPTER-1 study of deucricitibant for the prophylactic treatment of HAE attacks and that it has completed the 26-week rodent toxicology study requested by the FDA. A copy of the corporate presentation is attached hereto as Exhibit 99.1. A copy of the presentation from the Key Opinion leader call is attached hereto as Exhibit 99.2. A copy of the press release is attached hereto as Exhibit 99.3.

In addition, the Company is filing this Report on Form 6-K for the purpose of updating and supplementing its disclosure regarding the enforceability of judgments against the Company and/or its directors and officers. The updated disclosure, which is attached hereto as Exhibit 99.4 and incorporated herein by reference, updates and supplements the Company’s prior disclosures, including those discussed under the headings “Item 3. Key Information—D. Risk factors.” and “Enforceability of Judgments” in the Company’s Annual Report on Form 20-F for the year ended December 31, 2022 filed with the Securities and Exchange Commission on April 5, 2023.

This Report on Form 6-K (excluding Exhibit 99.1, including Exhibit 99.2, Exhibit 99.3 and Exhibit 99.4) shall be deemed to be incorporated by reference into the Company’s Registration Statement on Form F-3 (File No. 333-263198), the Company’s Registration Statement on Form F-3 (File No. 333-273757) and the Company’s Registration Statement on Form S-8 (File No. 333-252897).

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### PHARVARIS N.V.

Date: December 6, 2023

By: /s/ Berndt Modig  
Name: Berndt Modig  
Title: Chief Executive Officer

## EXHIB INDEX

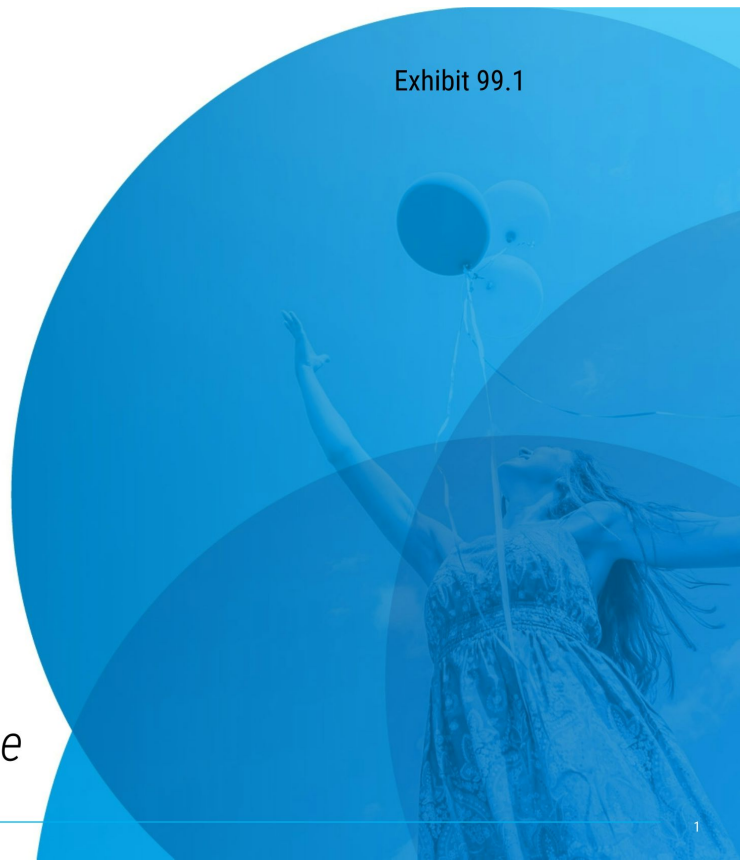
| <b>Exhibit No.</b>   | <b>Description</b>  |
|----------------------|---|
| <a href="#">99.1</a> | <a href="#">Corporate Presentation, dated December 6, 2023.</a>               |
| <a href="#">99.2</a> | <a href="#">Key Opinion Leader Call Presentation, dated December 6, 2023.</a> |
| <a href="#">99.3</a> | <a href="#">Press Release, dated December 6, 2023.</a>                        |
| <a href="#">99.4</a> | <a href="#">Enforceability of Judgments and Select Updated Risk Factor.</a>   |

**PHARVARIS**

## **Corporate Presentation**

December 2023

*Pioneering science for patient choice*



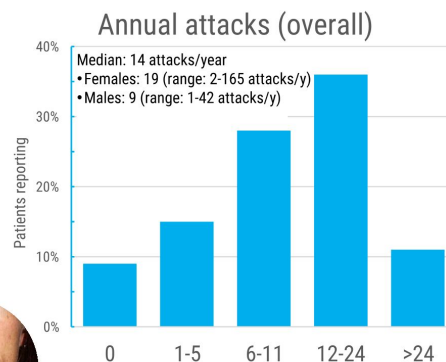


## Disclaimer

- This Presentation contains certain “forward-looking statements” within the meaning of the federal securities laws that involve substantial risks and uncertainties. All statements contained in this Presentation 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. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Such forward-looking statements involve unknown risks, uncertainties and other factors which may cause our actual results, financial condition, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that might cause such a difference include, but are not limited to, uncertainty in the outcome of our interactions with regulatory authorities, including the FDA with respect to the clinical hold on deucricitab clinical trials in the U.S., the expected timing, progress, or success of our clinical development programs especially for PHVS416 and PHVS719 which are in mid-stage clinical trials and are currently on hold in the U.S. as a result of the FDA clinical hold, our ability to replicate the efficacy and safety demonstrated in the CHAPTER-1 Phase 2 study in ongoing and future nonclinical studies and 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, including with respect to existing therapies, emerging potentially competitive therapies and with competitive generic products, 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 in general market, political and economic conditions, including as a result of the current conflict between Russia and Ukraine, the Israel-Hamas 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 Securities and Exchange Commission. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.
- Certain information contained in this Presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company’s own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this Presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

# HAE: A rare, life-long genetic condition with significant burden from unpredictable, debilitating, and potentially lethal attacks of swelling

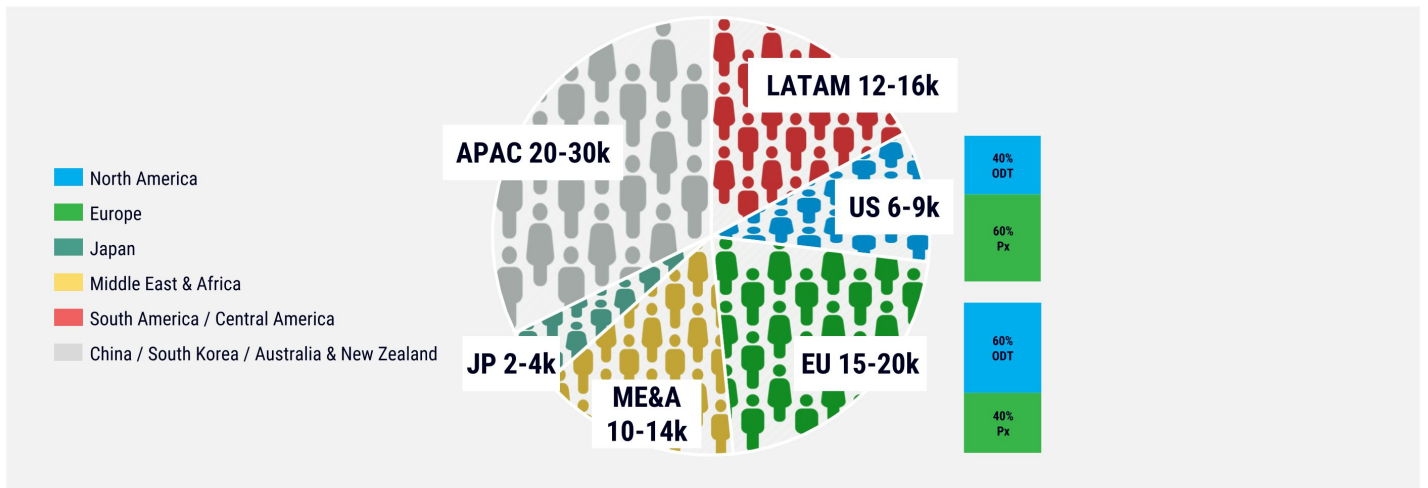
- Unpredictable frequency, location, timing, and severity
  - Multiple types of triggers
  - If untreated, attacks last multiple days
- Attacks are commonly painful, leading to hospitalization or multiple sick days
  - Half of people living with HAE experience a potentially life-threatening laryngeal attack at least once in their lifetime
- 1:10,000 to 1:50,000 Individuals affected by HAE globally
  - At least 6,600 people living with HAE in the U.S.
  - At least 8,900 people living with HAE in Europe
  - Globally, under-diagnosed/treated



Source: Nordenfelt et al, Acta Derm. Venereol 2016; 96: 540-545; Busse 2020 J Allergy Clin Immunol Pract; Bork et al 2021 J Allergy Clin Immunol



# Significant global unmet need affecting potentially up to 100,000 people living with HAE



Source: Proprietary company research 2022; Maurer et al. Consensus on diagnosis and management of Hereditary Angioedema in the Middle East: A Delphi initiative. World Allergy Organization Journal (2023);16:1-2; Zuraw et al. NEJM 2008;359:1027-1036; HAEI (haei.org), The State of Management of HAE in Latin America (2015); <https://haei.org/potentially-28000-hae-patients-in-china/dj>; Ann Allergy Asthma Immunol 2015;114(6), 492-498; Allergol Int. (2020) Nov 6;S1323-8930(20)30135-0

# People living with HAE actively switch products, seeking improvement in efficacy, safety/tolerability, and convenience



**Efficacy** is patients' prime concern ...



... but **safety & tolerability** are pushing patients to explore alternatives ...



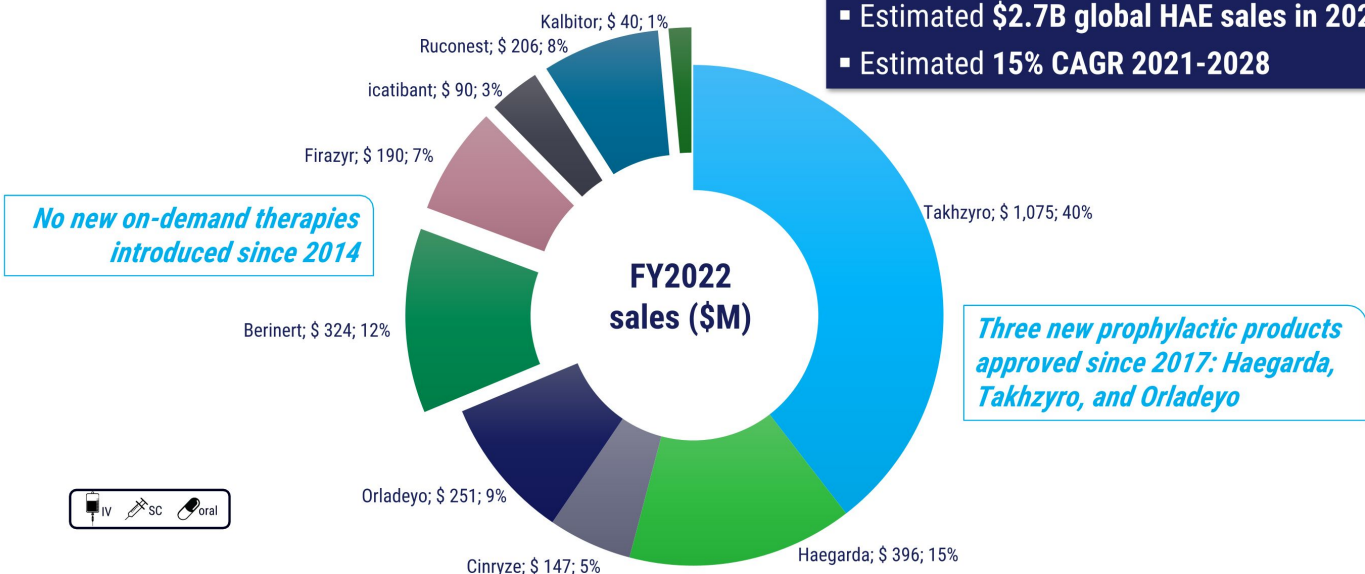
... while **convenience** has become a key driver for patient preference

**People living with HAE should not have to compromise**

Source: Proprietary company research 2022

# People living with HAE use approved therapeutics for treatment ('on demand') or prevention of attacks ('prophylaxis')

- Estimated \$2.7B global HAE sales in 2022
- Estimated 15% CAGR 2021-2028

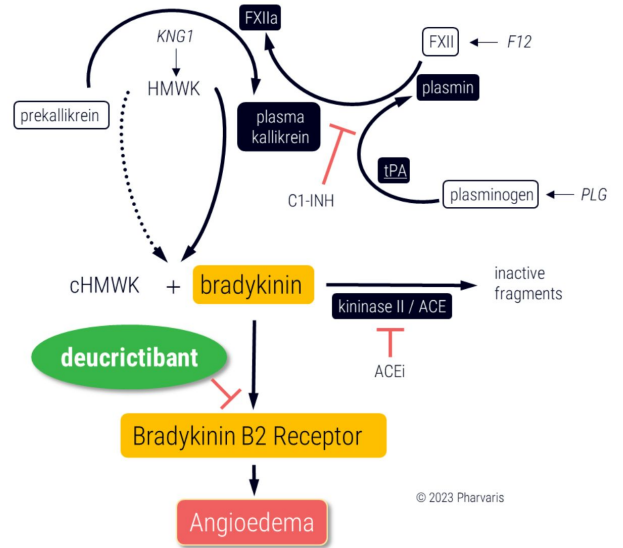
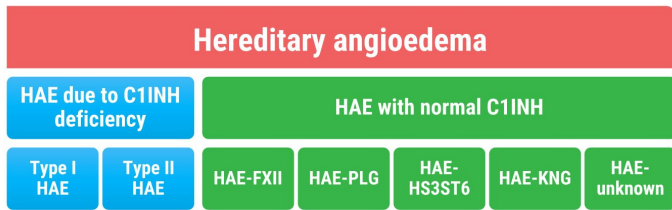


Source: Quarterly filings (NYSE: TAK; NASDAQ: BCRX, PHAR); www.fda.gov; company research



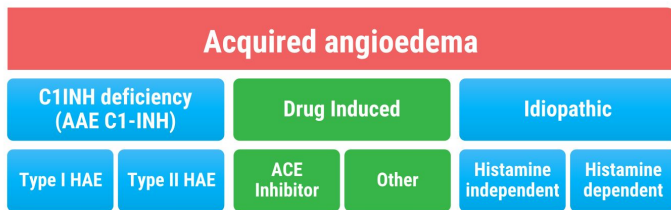
# The swelling of an HAE attack is caused by excess levels of bradykinin

Genetic causes lead to elevated levels of bradykinin



Source: Busse 2020 J Allergy Clin Immunol Pract; Bork et al 2021 J Allergy Clin Immunol; Notes: HMWK: high-molecular-weight kininogen; cHMWK: cleaved high-molecular-weight kininogen; FXII(a): Factor XII(a); ACE(i): angiotensin-converting enzyme (inhibitor); tPA: tissue plasminogen activator; KNG1: gene encoding HMWK; PLG: gene encoding plasminogen; F12: gene encoding FXII

# Bradykinin-mediated disease also includes acquired angioedema beyond HAE

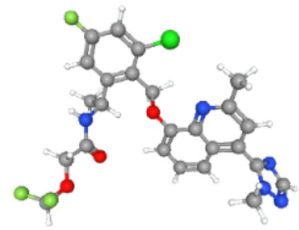


- No products approved for treatment of bradykinin-dependent acquired angioedema
- Therapies approved broadly for HAE are used for treatment
- An independent investigator-initiated trial (IIT) in AAE-C1-INH with PHVS416 has been conducted

Source: Zanichelli et al 2012 Allergy; Longhurst et al 2016 Clin. Exp. Immunol.; Otani, Banerji 2017 Immunol. Allergy Clin. N. Am.; Bova et al 2018 Int. Arch. Allergy Immunol.; Petersen, "Prophylaxis of angioedema attacks due to acquired C1-inhibitor deficiency with PHA121, a novel oral bradykinin B2 receptor antagonist" C1-Inhibitor Workshop 2023 (<https://2023.haenetworkshop.hu/program/index.php>, <https://www.linkedin.com/feed/update/urn:li:activity:7060638305842778112/>)

# Pharvaris has discovered the first orally bioavailable bradykinin B2 receptor antagonist

- New molecular entity, orally administered
- Potent inhibition of the bradykinin B2 receptor to compete with bradykinin, the ultimate driver of swelling attacks
- Results from Phase 1 healthy volunteer studies demonstrate rapid absorption, exposure, and tolerability
- Dose and exposure threshold predicted from human surrogate endpoint for both on-demand and prophylaxis
  - Bradykinin challenge in healthy volunteers



**Deucricitibant**

We aspire to develop **novel, oral alternatives** that **improve the standard of care** for people living with HAE and other bradykinin-mediated diseases

Source: Lesage et al, *Frontiers in Pharmacology* 2020, doi: 10.3389/fphar.2020.00916; ; Lesage et al, *Int. Immunopharmacology* 2022, doi.org/10.1016/j.intimp.2022.108523; <https://ir.pharvaris.com/static-files/0361cd85-6000-490b-932b-d305e1f3ca1b>; <https://ir.pharvaris.com/static-files/81a9499d-0769-4b89-8ecd-8ace5ca521d3>; <https://ir.pharvaris.com/static-files/33217945-6893-4f49-8a93-c80ea6fb2a31>; <https://doi.org/10.1016/j.jaci.2019.12.094>

# Product Strategy

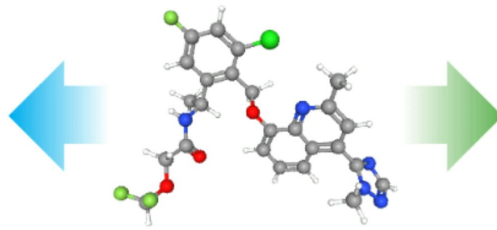
# Our strategy: Managing HAE with two oral products with the same active ingredient for on-demand and prophylactic treatment

## Deucricitabant (PHVS416)

Immediate-release capsule

rapid absorption

Aim to provide rapid and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form\*



## Deucricitabant

## Deucricitabant (PHVS719)

Extended-release tablet

sustained absorption

Aim to provide sustained exposure of attack-preventing medicine in a convenient, small oral dosage form\*

**Deucricitabant has the potential to become the preferred therapy for people living with HAE to manage their condition**

\*Aspirational; to be confirmed with clinical data

PHARVARIS

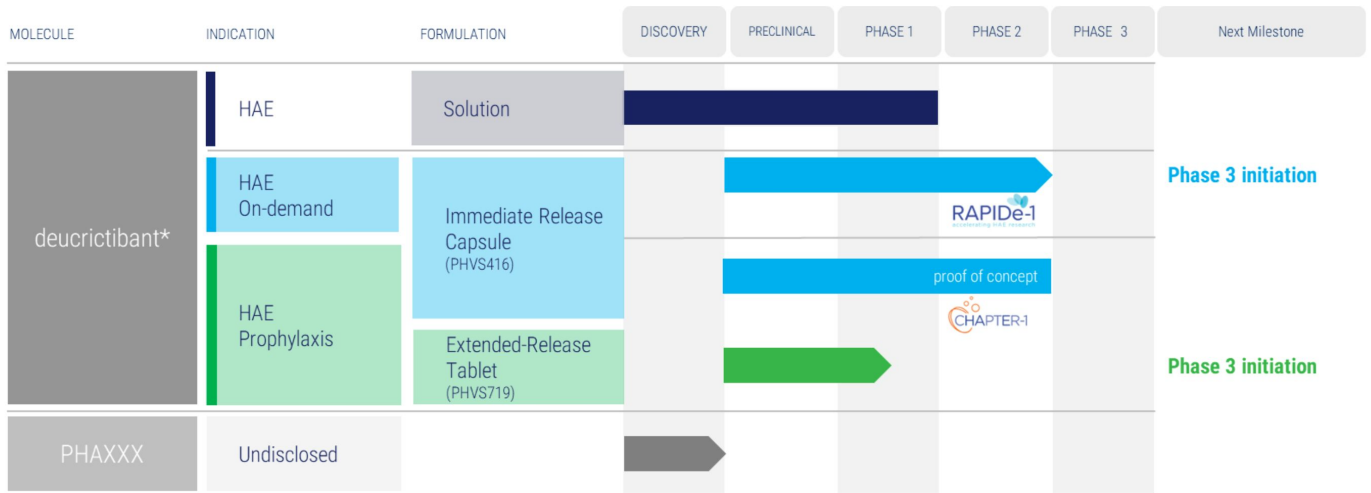
©2023



## Regulatory update

- In August 2022, the U.S. Food & Drug Administration (FDA) placed a hold on clinical trials of deucricitibant in the U.S. based on its review of nonclinical data
  - The agency requested that Pharvaris conduct an additional long-term rodent toxicology study and update the Investigator's Brochure
  - Pharvaris participated in a Type A meeting with the FDA to discuss paths to address the on-demand and prophylactic holds
- A 26-week rodent toxicology study has been completed using FDA-reviewed protocol
  - Preparing to submit the study results to the FDA by YE23
- In June 2023, FDA removed the clinical hold on on-demand trials
  - Eligible participants in the U.S. may join RAPIDe-2, a long-term extension on-demand extension study
  - An end-of-Phase 2 meeting with the agency occurred to align on key elements of RAPIDe-3 global Phase 3 study of PHVS416 for the on-demand treatment of HAE
- Clinical studies of deucricitibant for the long-term prophylaxis of HAE remain on hold in the U.S.
- Outside the U.S., CHAPTER-1 and other studies continue, including long-term extension RAPIDe-2 study
  - Pharvaris notified country-specific regulatory authorities in Canada, Europe, Israel, and the UK of the U.S. clinical holds
  - All active sites outside of the U.S. continue

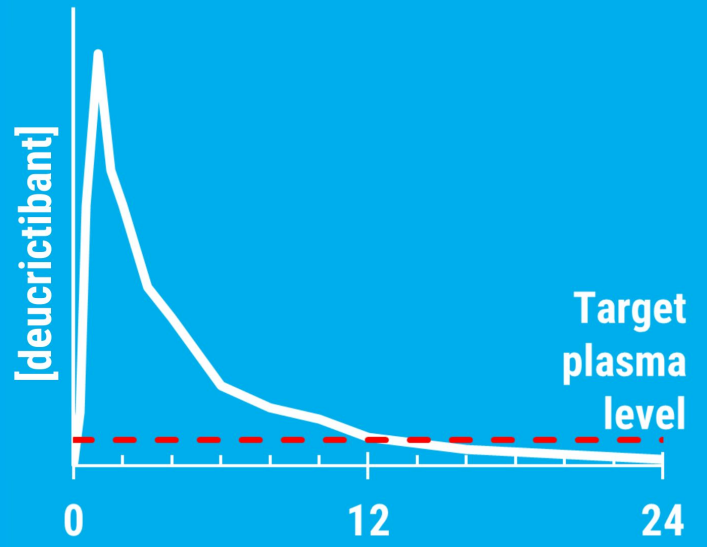
# Wholly-owned pipeline focused on bradykinin B2 receptor mechanism



\* The FDA has placed a hold on clinical trials of deucricitibant for long-term prophylaxis in the U.S.; see slide 12 for an update on our clinical program

*On-Demand*

**Deucrictibant immediate-release capsules (PHVS416)**





# Only injectable options: Significant unmet need in the on-demand treatment of HAE attacks



Treatment today means **painful** injections ...



... and often **one dose does not suffice** ...

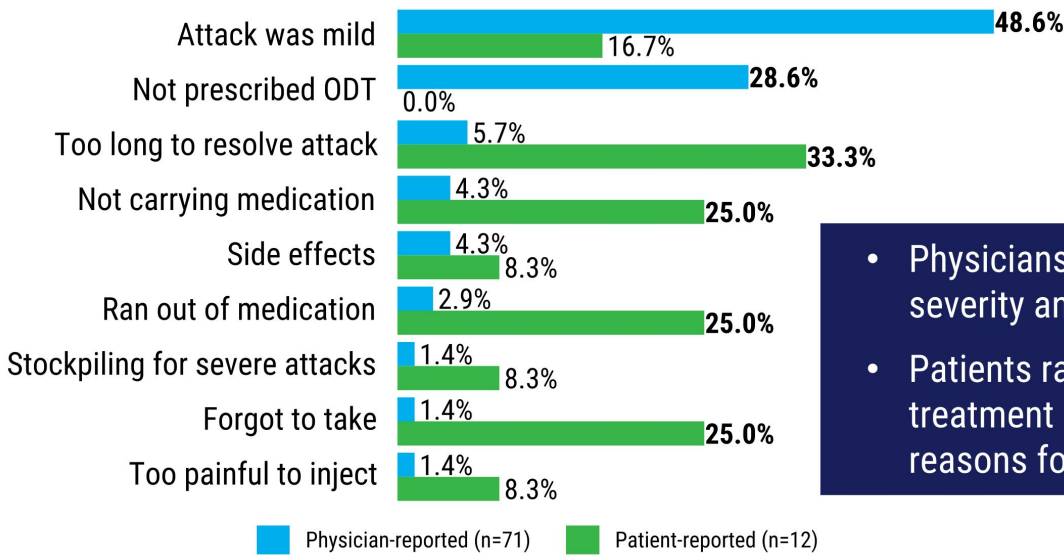


... while finding a place to administer the drug causes an **extra burden**

As a result, people living with HAE often **delay or even avoid therapy** against clinical guideline recommendations

Source: Proprietary Pharvaris research, 2022 (representative sample of patients, n = 103, and doctors, n = 100)

# Not all attacks are treated: Physicians and patients report reasons for not treating most recent attack



- Physicians focus on attack severity and lack of a prescription
- Patients raise logistics and treatment dissatisfaction as key reasons for not treating an attack

Source: Mendivil et al., ACAAI 2023; <https://ir.pharvaris.com/static-files/1b7e2270-34fd-411c-8f64-a0da8b2a65ec>

# People living with HAE are hoping for better on-demand therapies that offer rapid symptom relief with one single, oral dose



1



Patients want **rapid onset of symptom relief** ...

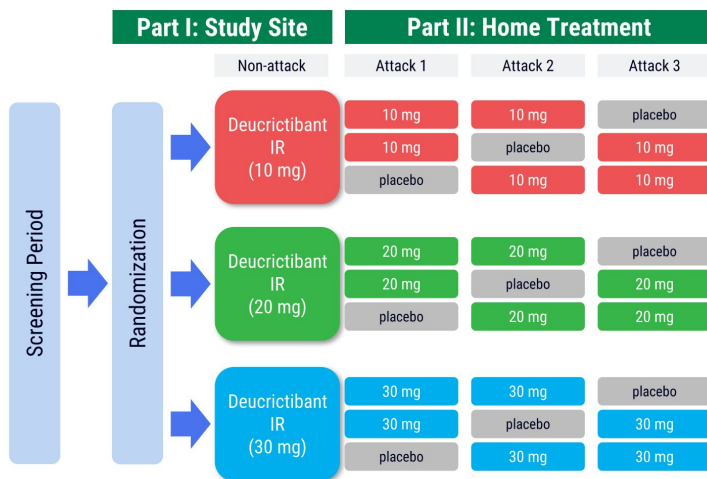
... with **single dose durability** ...

... in an **oral pill**

Effectively targeting the **bradykinin receptor** with a **small molecule** has the potential to deliver on their hopes

Source: Proprietary Pharvaris research, 2022 (representative sample of patients, n = 103, and doctors, n = 100)

# HAE RAPIDE-1 study: Phase 2 study of on-demand treatment of angioedema attacks in patients with Type I or II HAE



- **Primary objective:** to evaluate angioedema symptom relief within four hours in acute attacks of patients with HAE type 1 or 2
- **Study design:** Placebo-controlled, three dose levels
  - Part I: patients randomized and received a single dose of deucricitabant in clinic for PK and safety assessment
  - Part II: patients treated three attacks with two deucricitabant vs. one placebo
  - Before an attack was treated, one of the VAS-3 elements had to be at least hit a score of 30 and it had to be qualified by the clinician
- 74 HAE patients enrolled from ~30 sites in US, Canada, Europe, Israel, and UK

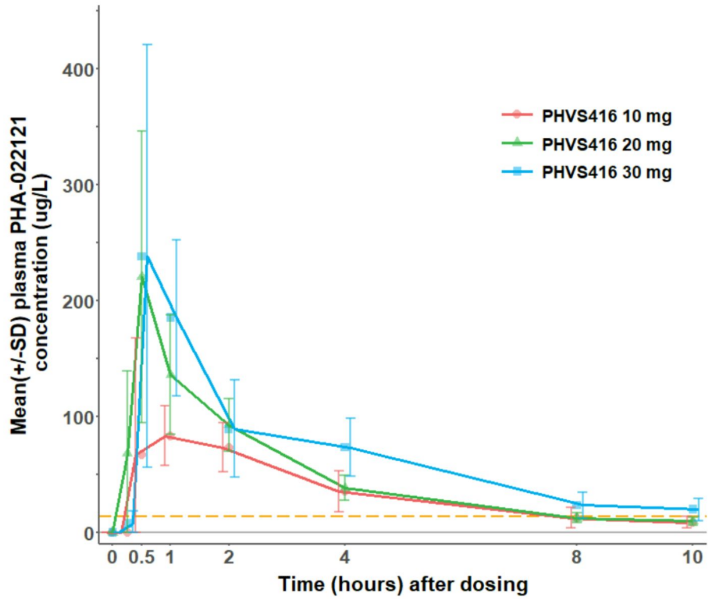
Source: [www.hae-rapide.com](http://www.hae-rapide.com); <https://clinicaltrials.gov/ct2/show/NCT04618211>; <https://hae-rapide.us/>; <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2020-003445-11>

## Positive top-line Phase 2 data from RAPIDe-1 study of PHVS416 for the on-demand treatment of HAE attacks

- A total of 74 patients from 13 countries were enrolled to the study, 62 of them had 147 attacks that were treated with blinded study drug and included in efficacy evaluation
- The **primary endpoint** and all **key secondary endpoints** were **met**
- Deucricitabant IR showed **rapid onset of action, symptom relief, and resolution** of HAE attacks
- Deucricitabant IR **substantially reduced** the use of **rescue medications**
- Deucricitabant IR was **well tolerated** at all dose levels
  - There were no treatment-related SAEs, no treatment-related AEs of severe severity, and no AEs leading to treatment discontinuation

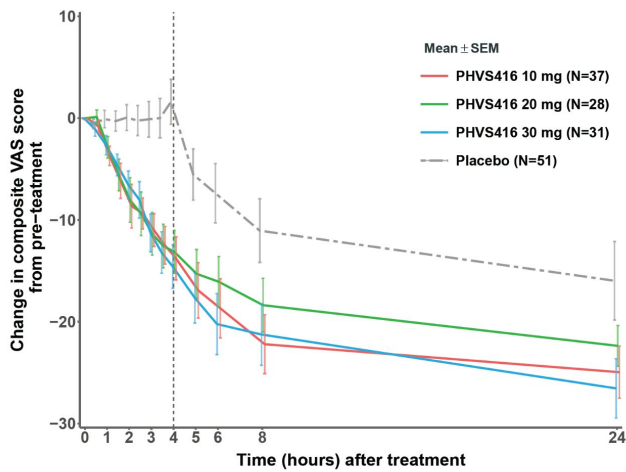
**Consistent outcomes** observed  
across all endpoints and types of measurements

## PK analysis in HAE patients confirmed rapid absorption on oral dosing, consistent with Phase 1 healthy volunteer studies



- **Rapid absorption** with mean plasma levels exceeding  $EC_{85}$  (13.8 ng/mL) within 30 min
- Mean **plasma levels maintained**  $>EC_{85}$  for approximately
  - 8 h at 10 mg or 20 mg
  - $>10$  h at 30 mg dose
- **$EC_{85}$  levels established using bradykinin challenge**, a human surrogate endpoint study in healthy volunteers

# Primary endpoint: Deucrichtibant IR significantly reduces attack symptoms by VAS-3 at 4h



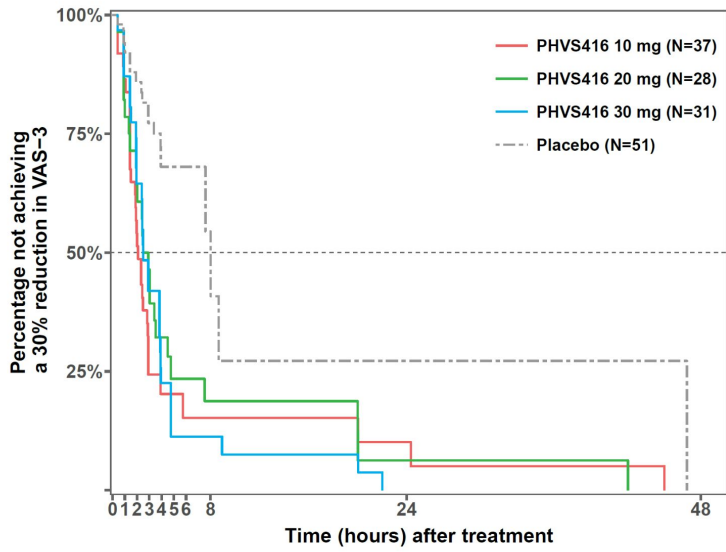
## Difference from placebo in change from pre-treatment to 4 h post-treatment, least-squares mean (95% CI)

|                  |                         |                         |
|------------------|-------------------------|-------------------------|
| PHVS416 10 mg    | -16.75 (-21.52, -11.97) | p < 0.0001 <sup>†</sup> |
| PHVS416 20 mg    | -15.02 (-20.22, -9.81)  | p < 0.0001              |
| PHVS416 30 mg    | -16.28 (-21.27, -11.29) | p < 0.0001              |
| Combined PHVS416 | -16.08 (-19.87, -12.29) |                         |

Median VAS-3 at pre-treatment ranges from 24.33-27.00 across different dose levels

<sup>†</sup>Nominal p-value; VAS assessed every 30 minutes up to 4 hours post-treatment, then at 5, 6, 8, 24, 48 hours; N = The number of attacks in the mITT Analysis Set. Attacks in mITT Analysis Set refer to attacks treated with blinded study drug that had non-missing VAS result at pre-treatment and at least one non-missing VAS result post-treatment. VAS-3 = electronically captured, numerically assisted visual analogue scale. Figure is based on descriptive summary of mean and SEM (standard error of the mean). Least-squares mean differences, CIs, and p-values come from a mixed-effects model with repeated measures (MMRM). Data after rescue medication use is not included. The combined PHVS416 result is based on post-hoc analysis using a similar MMRM with all three active doses combined vs placebo

# Deucrichtibant IR significantly shortened time to onset of symptom relief (30% reduction in VAS-3)



## Median time in hours (95% CI)

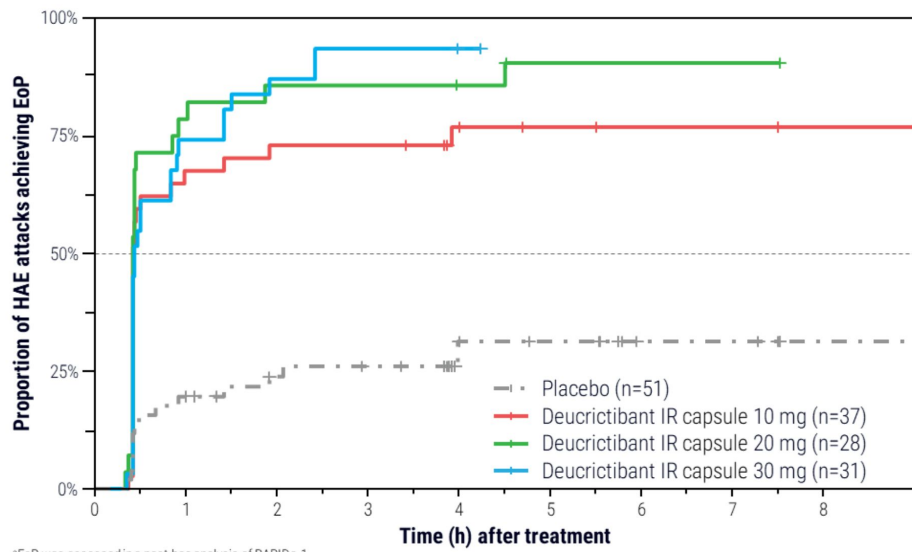
|                  |                 |                         |
|------------------|-----------------|-------------------------|
| Placebo          | 8.0 (7.6, 46.9) |                         |
| PHVS416 10 mg    | 2.1 (1.5, 2.9)  | p < 0.0001 <sup>†</sup> |
| PHVS416 20 mg    | 2.7 (1.9, 3.5)  | p = 0.0021              |
| PHVS416 30 mg    | 2.5 (1.9, 3.8)  | p < 0.0001              |
| Combined PHVS416 | 2.4 (2.0, 2.9)  |                         |

VAS assessed every 30 minutes up to 4 hours post-treatment, then at 5, 6, 8, 24, 48 hours

Nominal p-value; N = The number of attacks in the mITT Analysis Set. Median time based on Kaplan-Meier estimates. p-values based on a marginal Cox proportional hazards model. The combined PHVS416 results are based on post-hoc analyses to provide a reference of the result by pooling all three active doses.



# In a post-hoc analysis, patients on deucricitbant achieved end of progression by VAS-3 within 25 to 26 min versus 20 h for placebo



\*EoP was assessed in a post-hoc analysis of RAPIDE-1.

Source: Maurer et al., ACAAI 2023; <https://ir.pharvaris.com/static-files/0bae214b-7ff8-49ec-8340-1bb60a5935b9>

# TOS Patient Reported Outcome (PRO)

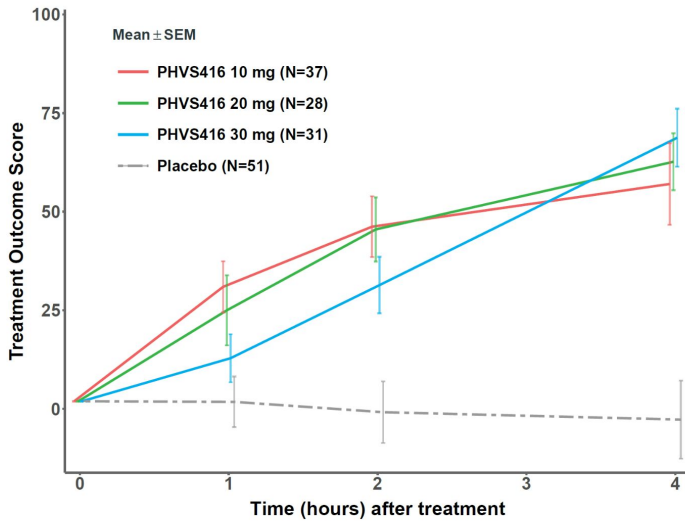
- TOS PRO captures change in five symptom complexes of HAE attacks

|                    |            |                  |                    |           |
|--------------------|------------|------------------|--------------------|-----------|
| Internal head/neck | Stomach/GI | Genital/buttocks | External head/neck | Cutaneous |
|--------------------|------------|------------------|--------------------|-----------|

- At each timepoint, the change in attack symptom from pre-treatment is reported by patient  
**PRO** – how do you feel now compared to before receiving study drug?

|                          |                 |      |                |             |
|--------------------------|-----------------|------|----------------|-------------|
| A lot better or resolved | A little better | Same | A little worse | A lot worse |
|--------------------------|-----------------|------|----------------|-------------|

# TOS endpoint shows early response to treatment: Significant at 4h



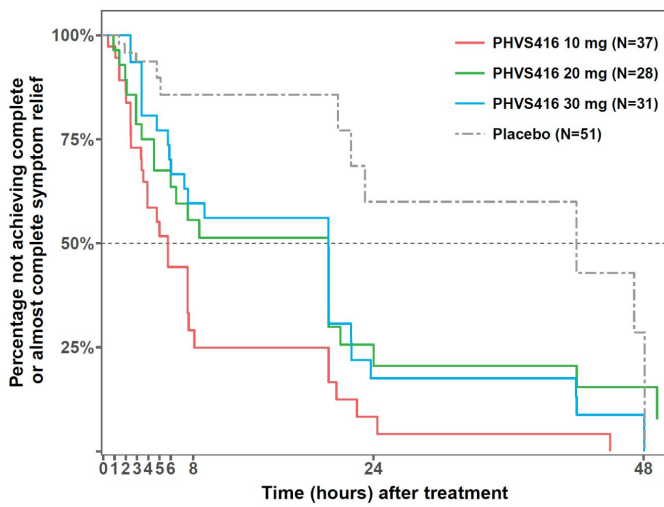
## Difference from placebo in 4 h post-treatment least-squares mean (95% CI)

|                  |                      |                         |
|------------------|----------------------|-------------------------|
| PHVS416 10 mg    | 64.13 (40.35, 87.91) | p < 0.0001 <sup>†</sup> |
| PHVS416 20 mg    | 62.69 (36.71, 88.67) | p < 0.0001              |
| PHVS416 30 mg    | 71.06 (46.09, 96.03) | p < 0.0001              |
| Combined PHVS416 | 66.05 (47.42, 84.69) |                         |

Minimally Important Difference (MID) for TOS is 30

Source: Vernon M, Rentz AM, Wyrwich KW, et al. Qual Life Res.2009; <sup>†</sup> Nominal p-value; N = The number of attacks in the mITT Analysis Set. TOS = Treatment Outcome Score. Figure is based on descriptive summary of mean and SEM. The least-squares mean differences, CIs, and p-values come from an MMRM. The data after rescue medication use is not included. The combined PHVS416 result is based on post-hoc analysis using a similar MMRM with all three active doses combined vs placebo

# Deucricitabant IR significantly reduces time to almost complete or complete symptom relief (all individual VAS ≤10)



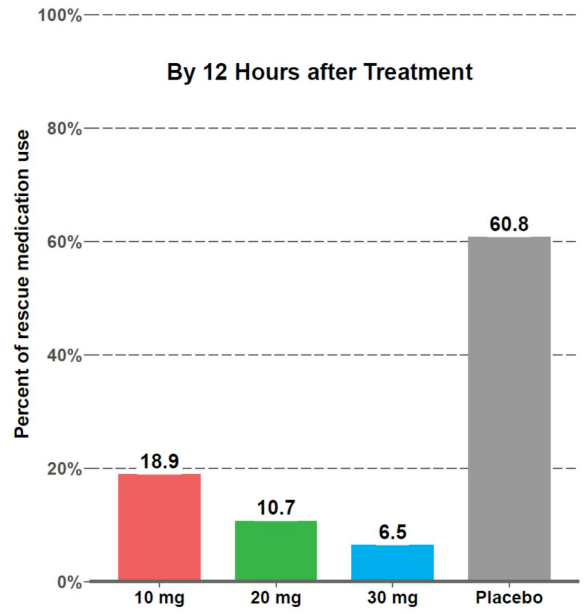
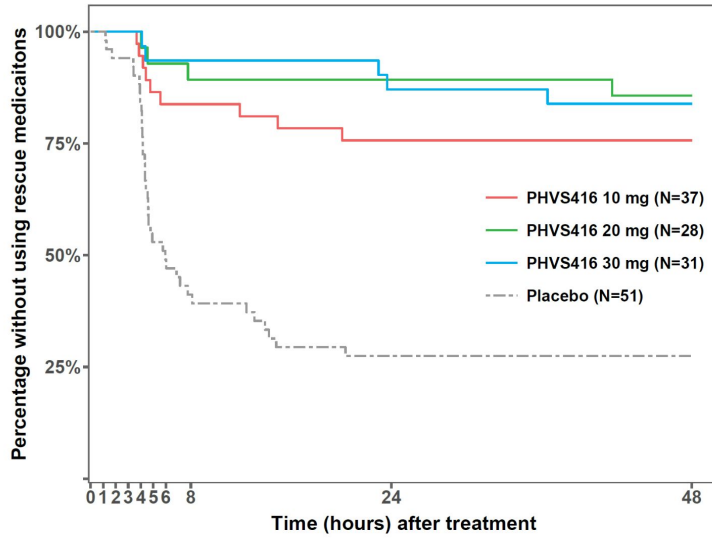
## Median time in hours (95% CI)

|                            |                   |                         |
|----------------------------|-------------------|-------------------------|
| Placebo                    | 42.0 (22.0, 48.1) |                         |
| Deucricitabant IR 10 mg    | 5.8 (3.6, 7.5)    | p < 0.0001 <sup>†</sup> |
| Deucricitabant IR 20 mg    | 20.0 (4.5, 20.0)  | p = 0.0127              |
| Deucricitabant IR 30 mg    | 20.0 (6.0, 20.1)  | p = 0.0001              |
| Combined Deucricitabant IR | 7.5 (5.9, 20.0)   |                         |

VAS assessed every 30 minutes up to 4 hours post-treatment, then at 5, 6, 8, 24, 48 hours

<sup>†</sup>Nominal p-value; N = The number of attacks in the mITT Analysis Set. Median time based on Kaplan-Meier estimates. p-values based on a marginal Cox proportional hazards model. The combined PHVS416 results are based on post-hoc analyses to provide a reference of the result by pooling all three active doses.

# Patients treating with deucricitbant IR used substantially less rescue medication



N = The number of attacks in the mITT Analysis Set

## Deucrictibant IR was well tolerated at all doses

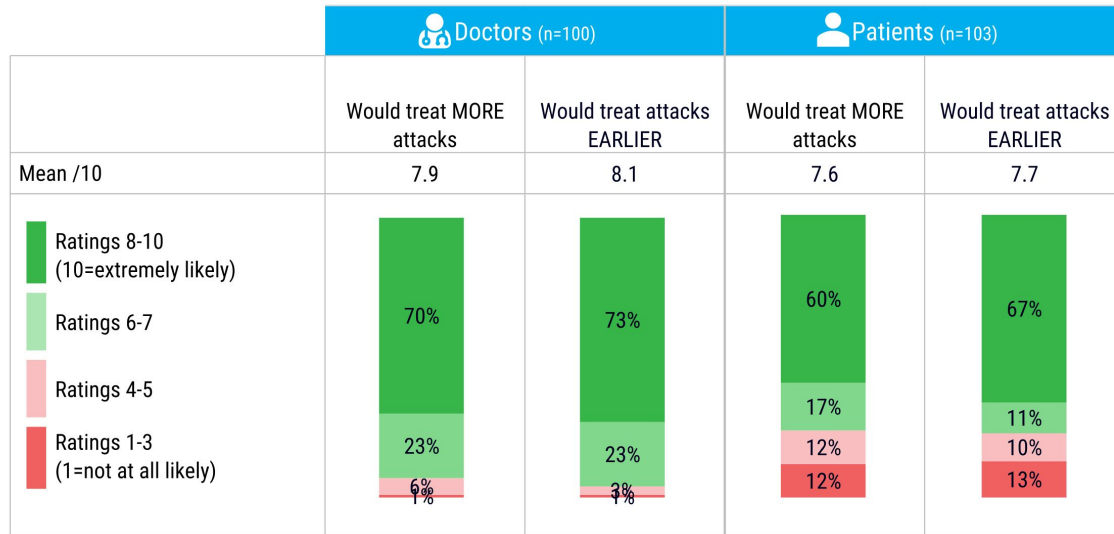
- No treatment-related SAEs or AEs of severe severity
- No AEs leading to treatment discontinuation
- No treatment-related AEs of laboratory parameters, vital signs, or ECG parameters
- Few treatment-related AEs reported within 48 h after administration of study drug

|  | Part I (Non-Attack) |               |               | Part II (Attack 1,2,3) |               |               |               |
|--|---------------------|---------------|---------------|------------------------|---------------|---------------|---------------|
|  | 10 mg<br>N=23       | 20 mg<br>N=24 | 30 mg<br>N=25 | Placebo<br>N=53        | 10 mg<br>N=38 | 20 mg<br>N=29 | 30 mg<br>N=36 |
| <b>Subjects (Part I) or Attacks (Part II) with any treatment related AEs</b> | 1 (4.3%)            | 1 (4.2%)      | -             | 1 (1.9%)               | -             | -             | 1 (2.8%)      |
| Headache   | -                   | 1 (4.2%)      | -             | -                      | -             | -             | -             |
| Nausea   | 1 (4.3%)            | -             | -             | -                      | -             | -             | 1 (2.8%)      |
| Vomiting   | -                   | -             | -             | -                      | -             | -             | 1 (2.8%)      |
| Fatigue  | -                   | -             | -             | -                      | -             | -             | 1 (2.8%)      |
| Blister  | -                   | -             | -             | 1 (1.9%)               | -             | -             | -             |

N= The number of subjects (Part I) and number of attacks (Part II) in the Safety Analysis Set. The Safety Analysis Set includes all randomized patients who received any dose of study drug. Treatment-related AEs within 48 h post-treatment are included



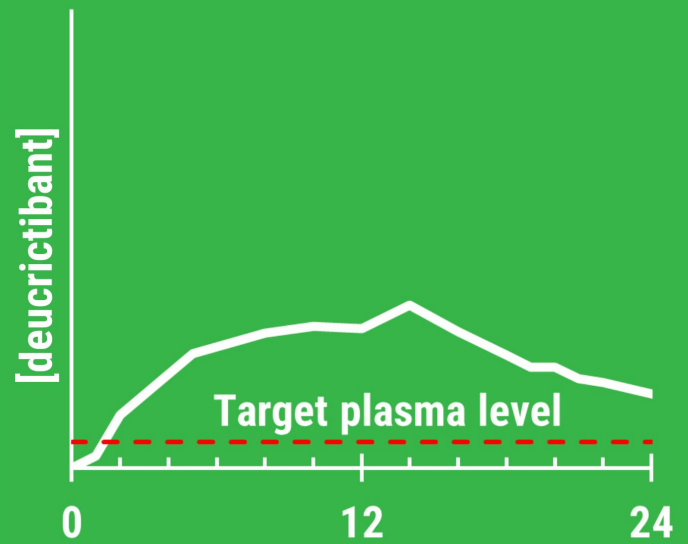
# Both doctors and patients consider an oral acute therapy would increase likelihood that patients would treat more attacks, earlier



Source: Proprietary Pharvaris research, 2022 (representative sample of patients, n = 103, and doctors, n = 100)

## *Long Term Prophylaxis*

### Deucrictibant extended-release tablets (PHVS719)





# People living with HAE are seeking highly effective, well-tolerated, and less burdensome prophylactic therapies



Injectable-like  
**efficacy**



**Well-tolerated**



**Easy, painless**  
administration

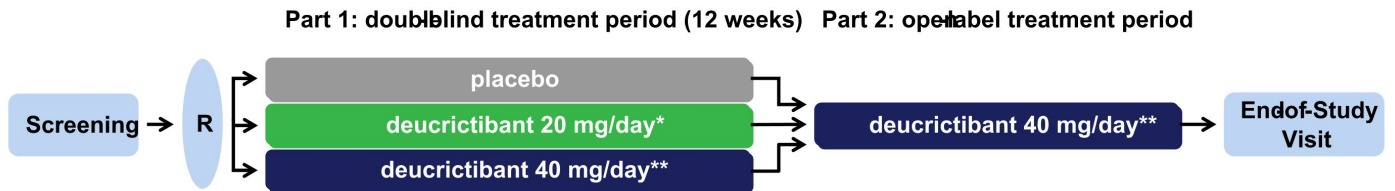
Effectively targeting the **bradykinin receptor** with a **small molecule** has the potential to deliver on their hopes

Source: Proprietary Pharvaris research, 2022 (representative sample of patients, n = 103, and doctors, n = 100)

# HAE CHAPTER-1 study has completed: Study design

Double-blind, placebo-controlled Phase 2 study assessing safety and efficacy of deucricitabant in preventing HAE attacks in patients with HAE type 1 or type 2

- 34 participants enrolled in North America and Europe

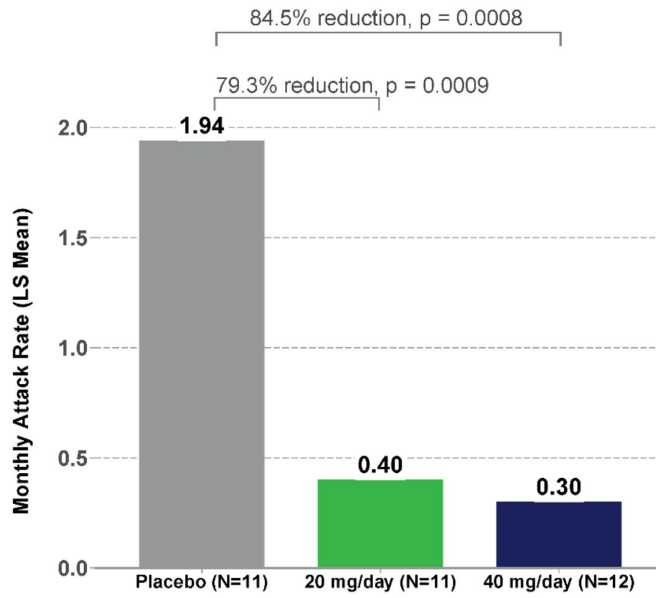


R = randomization;

\*deucricitabant 20 mg/day = deucricitabant immediate-release capsules (PHVS416) 10 mg twice daily

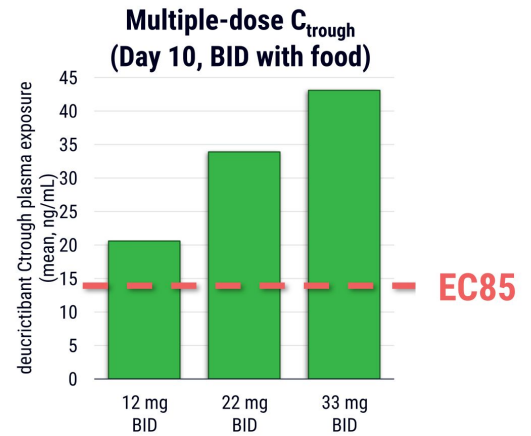
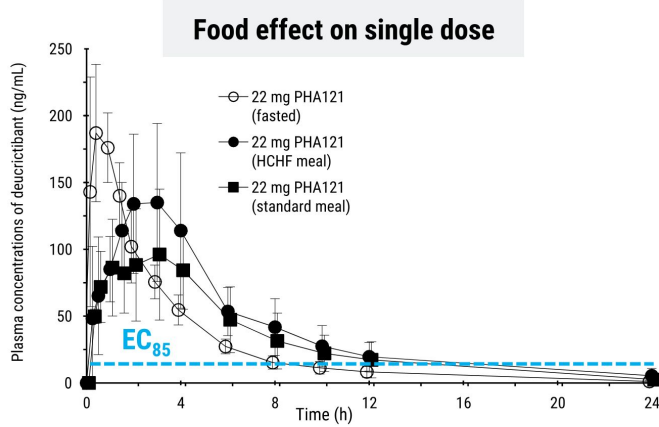
\*\*deucricitabant 40 mg/day = deucricitabant immediate-release capsules (PHVS416) 20 mg twice daily

# Positive top-line Phase 2 data from the CHAPTER-1 study of deucricitibant for the prophylactic treatment of HAE attacks



LS Mean = least squares mean. Results based on a Poisson regression model adjusted for baseline attack rate and time on treatment.

# Phase 1 pharmacokinetics offered options to use deucricitbant IR as proof-of-concept in prophylactic development

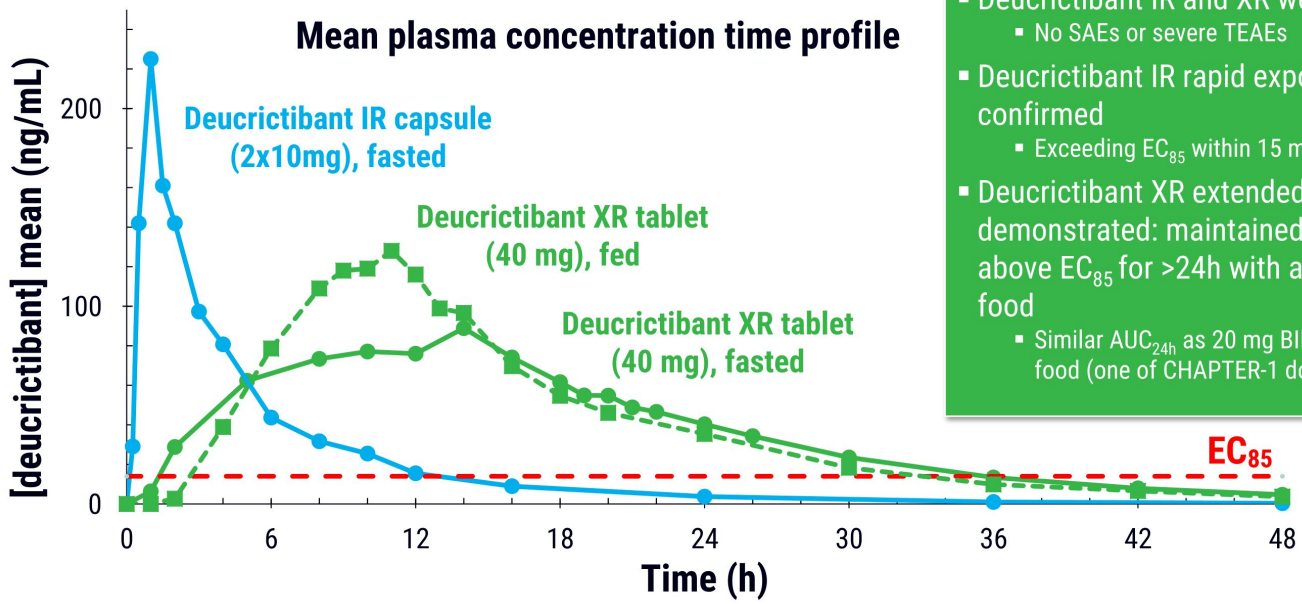


When dosed BID with food, exposure maintained above target levels, steady state reached within 72 hours

Source: <https://ir.pharvaris.com/static-files/0361cd85-6000-490b-932b-d305e1f3ca1b>; <https://ir.pharvaris.com/static-files/81a9499d-0769-4b89-8ecd-8ace5ca521d3>

# Deucricitbant XR single-dose PK study demonstrates QD potential; target for Phase 3 dosage form

## Mean plasma concentration time profile



- Deucricitbant IR and XR well tolerated
  - No SAEs or severe TEAEs
- Deucricitbant IR rapid exposure confirmed
  - Exceeding EC<sub>85</sub> within 15 minutes
- Deucricitbant XR extended release demonstrated: maintained exposure above EC<sub>85</sub> for >24h with and without food
  - Similar AUC<sub>24h</sub> as 20 mg BID PHVS416 with food (one of CHAPTER-1 doses)

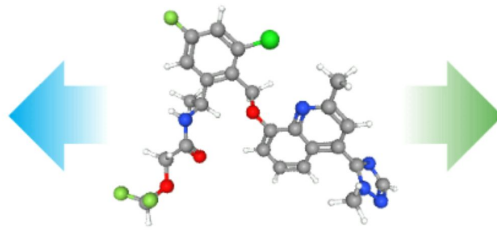
# Our strategy: Managing HAE with two oral products with the same active ingredient for on-demand and prophylactic treatment

## Deucricitabant (PHVS416)

Immediate-release capsule

rapid absorption

Aim to provide rapid and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form\*



## Deucricitabant

## Deucricitabant (PHVS719)

Extended-release tablet

sustained absorption

Aim to provide sustained exposure of attack-preventing medicine in a convenient, small oral dosage form\*

**Based on the results in RAPIDe-1 and CHAPTER-1, deucricitabant has the potential to become the preferred option to treat and prevent HAE attacks**

\*Aspirational; to be confirmed with clinical data

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## Corporate summary and milestones

|  | HAE On-Demand<br>(type 1 and type 2)  | HAE Prophylaxis<br>(type 1 and type 2)  |
|--|---|---|
| PHVS416<br>deucricitibant<br>immediate-release capsule | <ul style="list-style-type: none"><li>✓ RAPIDe-1 Ph2 top-line data <b>meets all primary and key secondary endpoints</b><ul style="list-style-type: none"><li>▪ Phase 3 initiation</li></ul></li></ul> | <ul style="list-style-type: none"><li>✓ CHAPTER-1 Ph2 top-line data <b>meets the primary endpoint</b><ul style="list-style-type: none"><li>▪ Phase 3 initiation</li></ul></li></ul> |
| PHVS719<br>deucricitibant<br>extended-release tablet   | --  | <ul style="list-style-type: none"><li>✓ Ph1 SD PK demonstrates once-daily potential<ul style="list-style-type: none"><li>▪ Phase 3 readiness</li></ul></li></ul>                    |

Financially strong: approximately €140M cash as of November 30, 2023

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[www.pharvaris.com](http://www.pharvaris.com)

*Aspiring to free people from HAE or other bradykinin-mediated diseases*

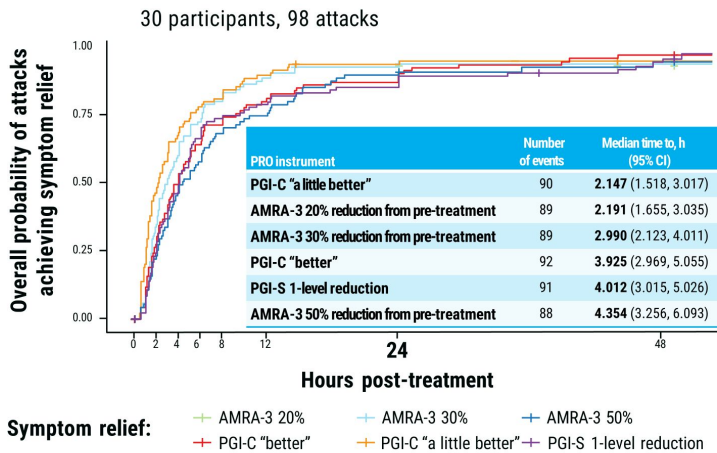






# The relationship between alternative endpoints to measure symptom relief in an HAE attack was assessed in a mixed-methods study

Kaplan-Meier plot on non-laryngeal attacks achieving symptom relief



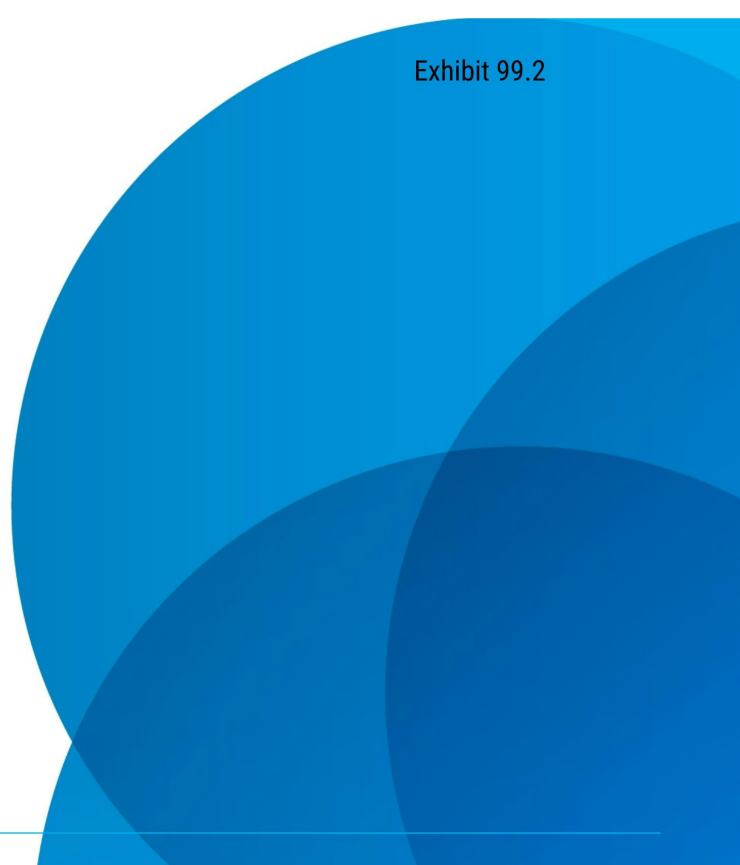
- Median time to symptom relief using **AMRA-3 20% reduction** from pre-treatment and **PGI-C "a little better"** on 2 consecutive timepoints are **comparable**
- AMRA-3 50% reduction from pre-treatment, PGI-C "better," and PGI-S 1-level improvement take longer and are within the same range

Source: Mendivil et al., UCARE 2023

**PHARVARIS**

**CHAPTER-1 Phase 2  
Top-line Data**

December 6, 2023





# Disclaimer

This Presentation contains certain “forward-looking statements” within the meaning of the federal securities laws that involve substantial risks and uncertainties. All statements contained in this Presentation 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. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Such forward-looking statements involve unknown risks, uncertainties and other factors which may cause our actual results, financial condition, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that might cause such a difference include, but are not limited to, uncertainty in the outcome of our interactions with regulatory authorities, including the FDA with respect to the clinical hold on deucricitabnt clinical trials in the U.S., the expected timing, progress, or success of our clinical development programs especially for PHVS416 and PHVS719 which are in mid-stage clinical trials and are currently on hold in the U.S. as a result of the FDA clinical hold, our ability to replicate the efficacy and safety demonstrated in the CHAPTER-1 Phase 2 study in ongoing and future nonclinical studies and 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, 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 in general market, political and economic conditions, including as a result of the current conflict between Russia and Ukraine, the Israel-Hamas 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 Securities and Exchange Commission. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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# Agenda



## Introduction

**Berndt Modig**, CEO Pharvaris



## Review of CHAPTER-1 top-line Phase 2 data

**Peng Lu**, M.D. PhD, CMO Pharvaris



## KOL perspective

**Marc A. Riedl**, M.D., M.S., Professor of Medicine, Clinical Director of the U.S. Hereditary Angioedema Association (HAEA) Angioedema Center at the University of California San Diego (UCSD), Clinical Service Chief for Allergy/Immunology at UCSD; principal investigator in the CHAPTER-1 study



## Closing Remarks, Q&A

# Agenda



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## Closing Remarks, Q&A

# People living with HAE are seeking highly effective, well-tolerated and less burdensome prophylactic therapies



**Injectable-like  
efficacy**



**Well-tolerated**



**Easy, painless  
administration**

**An effective oral bradykinin B2 receptor antagonist has  
the potential to deliver on their hopes**

Proprietary Pharvaris research, 2022 (representative sample of patients, n = 103, and doctors, n = 100)

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## Closing Remarks, Q&A



# CHAPTER-1, a Phase 2 prophylactic study of deucricitibant in HAE

**Primary endpoint met: 84.5% (p=0.0008) reduction in monthly attack rate versus placebo\***

- 92.3% reduction in occurrence of moderate and severe attacks\*
- 92.6% reduction in occurrence of attacks treated with on-demand medication\*
- Clinically meaningful results across primary, secondary, and health-related quality of life endpoints
- Deucricitibant well-tolerated at both doses

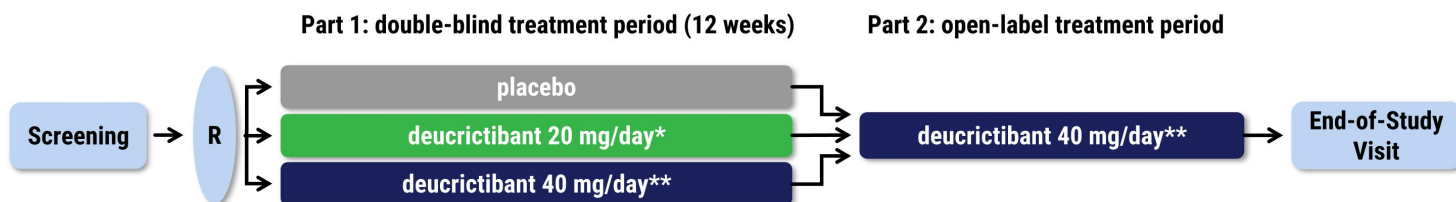
\*40 mg/day deucricitibant treatment group; %reduction in monthly attack rate is based on a Poisson regression model

Note: all attacks reported herein are investigator-confirmed; attack rate is number of attacks per month of exposure, also referred to as time-normalized number of attacks; all statistical analyses comparing deucricitibant and placebo are made without adjustment for multiplicity.

# CHAPTER-1 study design

Double-blind, placebo-controlled Phase 2 study evaluating deucricitibant for long-term prophylaxis in HAE-1/2

- 34 participants enrolled in North America and Europe

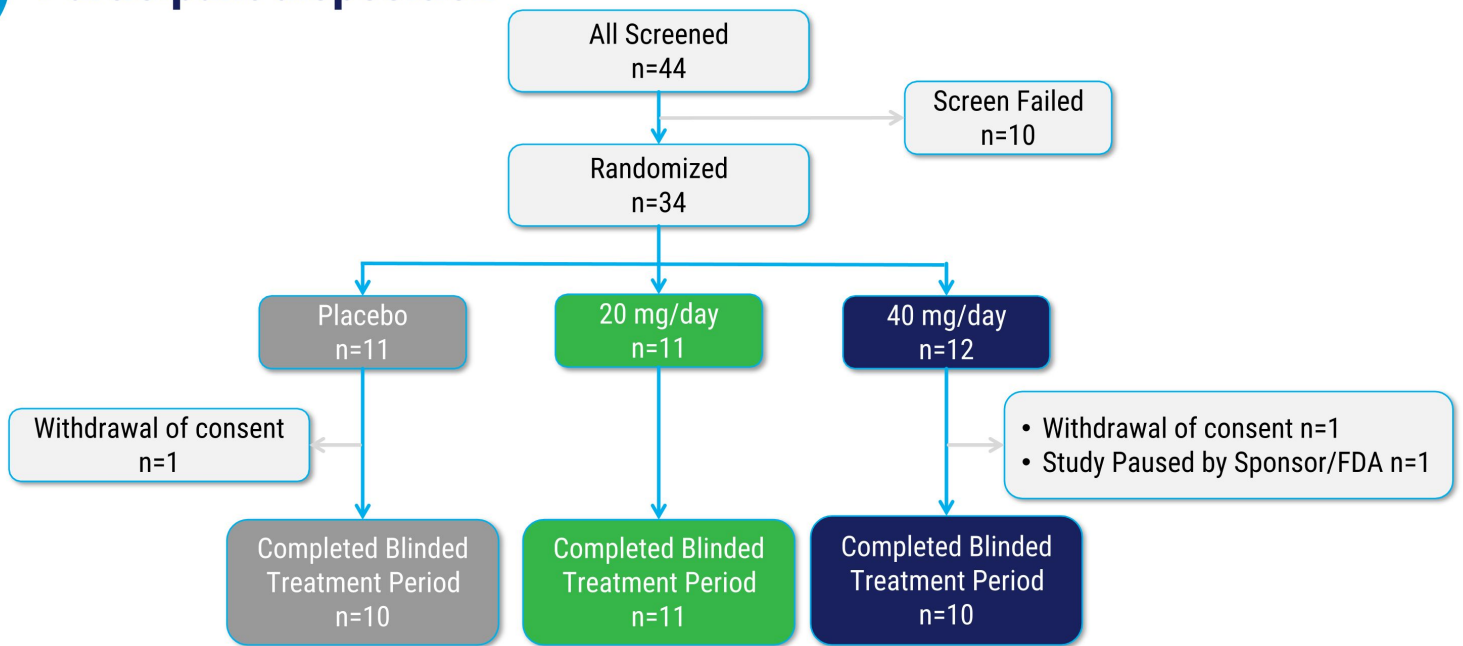


R = randomization;

\*deucricitibant 20 mg/day = deucricitibant immediate-release capsules (PHVS416) 10 mg twice daily

\*\*deucricitibant 40 mg/day = deucricitibant immediate-release capsules (PHVS416) 20 mg twice daily

# Participant disposition



20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily; 40 mg/day = deucricitabant IR capsules 20 mg twice daily; n = number of participants.

## Balanced demographics and baseline characteristics

|  | Placebo<br>N=11 | 20 mg/day<br>N=11 | 40 mg/day<br>N=12 | All<br>N=34   |
|--|-----------------|-------------------|-------------------|---------------|
| Age in years – Mean                                    | 41.4            | 38.4              | 40.8              | 40.2          |
| Sex: M/F – n   | 3/8             | 6/5               | 4/8               | 13/21         |
| Race: White – n (%)                                    | 11 (100)        | 11 (100)          | 12 (100)          | 34 (100)      |
| BMI (kg/m <sup>2</sup> ) – Mean                        | 26.7            | 29.5              | 25.4              | 27.1          |
| HAE Type – n   |                 |                   |                   |               |
| Type 1   | 10              | 9                 | 12                | 31            |
| Type 2   | 1               | 2                 | 0                 | 3             |
| Baseline HAE attack rate per month                     |                 |                   |                   |               |
| Mean   | 1.9             | 2.1               | 2.5               | 2.2           |
| Median (Min, Max)                                      | 1.7 (0.7, 3.7)  | 1.7 (1.0, 5.3)    | 1.7 (1.0, 6.7)    | 1.7(0.7, 6.7) |
| Randomized baseline HAE attack rate categories – n (%) |                 |                   |                   |               |
| 1 to < 2 attacks per 4 weeks                           | 6 (54.5)        | 7 (63.6)          | 7 (58.3)          | 20 (58.8)     |
| 2 to < 3 attacks per 4 weeks                           | 3 (27.3)        | 1 (9.1)           | 1 (8.3)           | 5 (14.7)      |
| ≥ 3 attacks per 4 weeks                                | 2 (18.2)        | 3 (27.3)          | 4 (33.3)          | 9 (26.5)      |

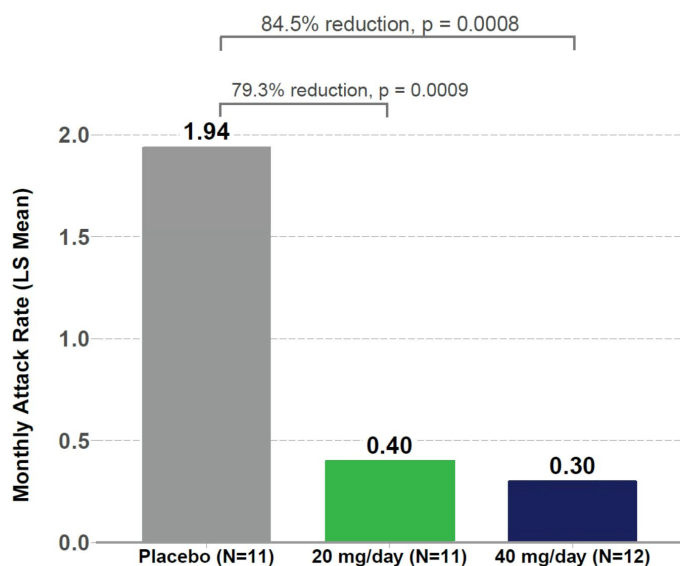
20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily.

40 mg/day = deucricitabant IR capsules 20 mg twice daily.

N = number of randomized participants.

# Primary endpoint met: deucricitbant significantly reduced attack rate

Monthly attack rate measured as time-normalized number of investigator confirmed HAE attacks



|                                     | Placebo<br>N=11 | 20 mg/day<br>N=11 | 40 mg/day<br>N=12 |
|-------------------------------------|-----------------|-------------------|-------------------|
| <b>Monthly attack rate – Median</b> |                 |                   |                   |
| Baseline                            | 1.67            | 1.67              | 1.74              |
| On study                            | 2.15            | 0                 | 0.15              |
| Change from baseline                | 0.33            | -1.34             | -1.59             |
| % change from baseline              | 17%             | -100%             | -96%              |
| <b>Model-based inference</b>        |                 |                   |                   |
| LS mean                             | 1.94            | 0.40              | 0.30              |
| <b>% reduction vs placebo</b>       |                 | <b>79.3%</b>      | <b>84.5%</b>      |
| <b>p-value</b>                      |                 | <b>0.0009</b>     | <b>0.0008</b>     |

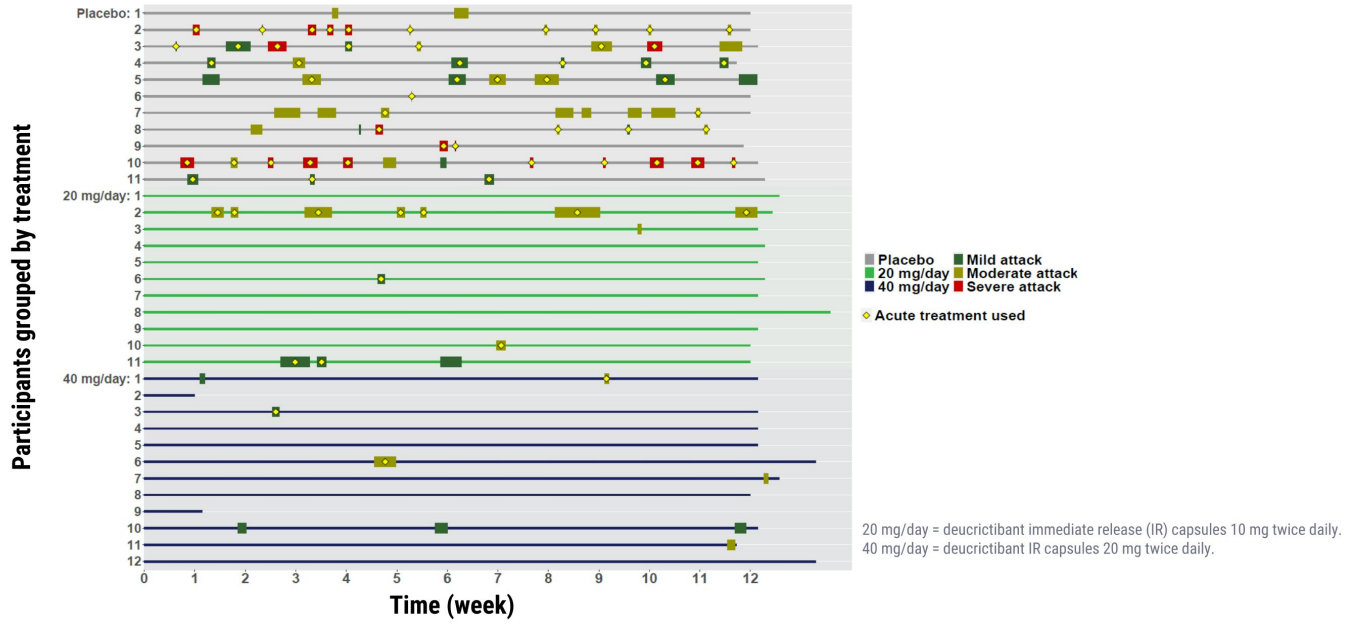
20 mg/day = deucricitbant immediate release (IR) capsules 10 mg twice daily.

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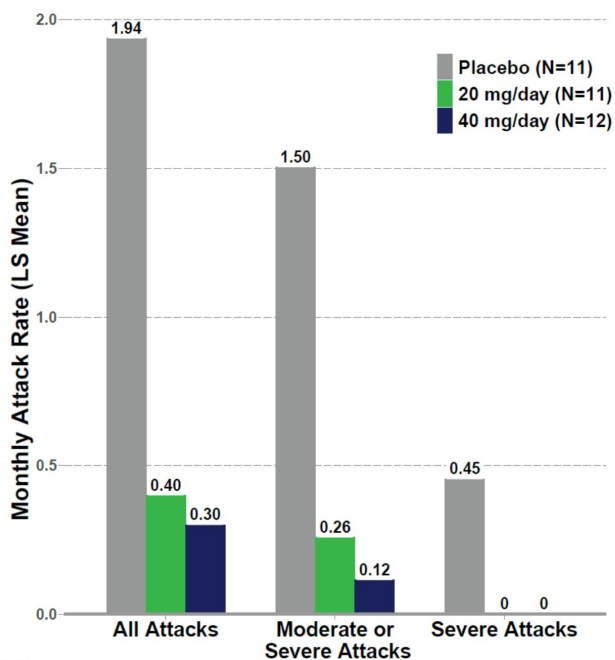
N = number of randomized participants.

LS mean = least squares mean. Model-based inferences are based on a Poisson regression model adjusted for baseline attack rate and time on treatment. No multiplicity adjustment was applied.

# Significant attack reduction and no severe attacks with deucricitbant



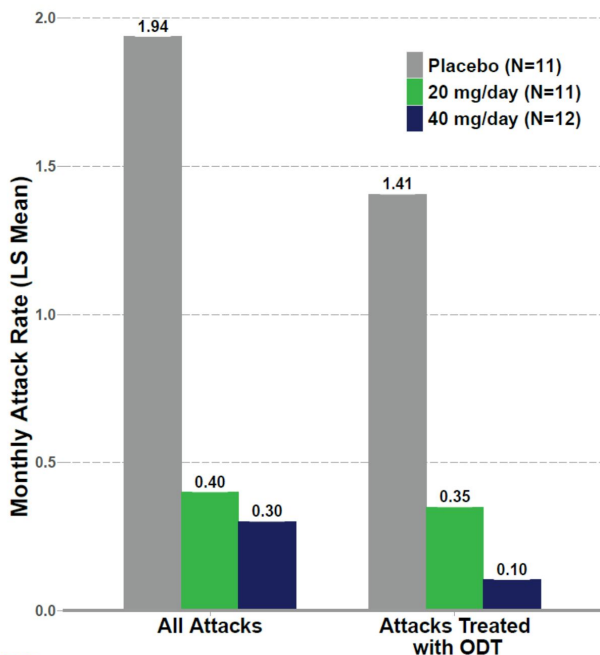
# 92.3% reduction in moderate or severe attacks at 40 mg/day dose



|  | Placebo<br>N=11 | 20 mg/day<br>N=11 | 40 mg/day<br>N=12 |
|--|-----------------|-------------------|-------------------|
| <b>Monthly attack rate of moderate or severe attacks</b> |                 |                   |                   |
| LS mean  | 1.50            | 0.26              | 0.12              |
| <b>% reduction vs placebo</b>                            |                 | <b>82.8%</b>      | <b>92.3%</b>      |
| Nominal p-value  |                 | 0.0066            | 0.0067            |

20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily.  
 40 mg/day = deucricitabant IR capsules 20 mg twice daily.  
 N = number of randomized participants.  
 LS mean = least squares mean. Monthly attack rates are based on a Poisson regression model adjusted for baseline attack rate and time on treatment. No multiplicity adjustment was applied.

# 92.6% reduction in attacks treated with ODT at 40 mg/day dose

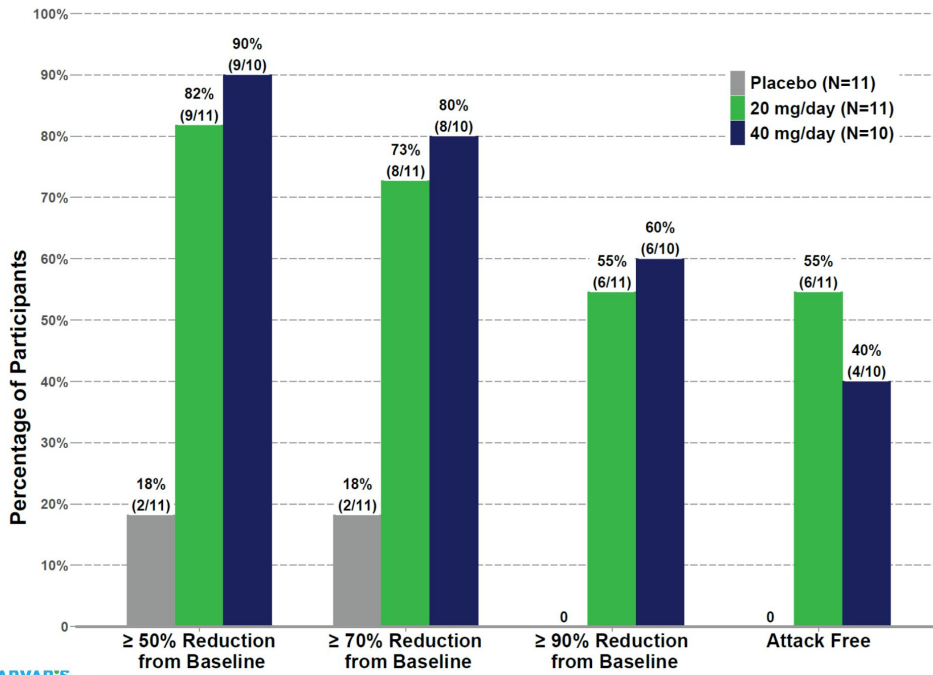


|  | Placebo<br>N=11 | 20 mg/day<br>N=11 | 40 mg/day<br>N=12 |
|--|-----------------|-------------------|-------------------|
| <b>Monthly attack rate of attacks treated with ODT</b> |                 |                   |                   |
| LS mean  | 1.41            | 0.35              | 0.10              |
| <b>% reduction vs placebo</b>                          |                 | <b>75.1%</b>      | <b>92.6%</b>      |
| Nominal p-value  |                 | 0.0074            | 0.0040            |

ODT = on-demand treatment (icatibant, C1-inhibitor (C1-INH))  
 20 mg/day = deucricitabnt immediate release (IR) capsules 10 mg twice daily;  
 40 mg/day = deucricitabnt IR capsules 20 mg twice daily.  
 N = number of randomized participants.  
 LS mean = least squares mean. Monthly attack rates are based on a Poisson regression model adjusted for baseline attack rate and time on treatment. No multiplicity adjustment was applied.

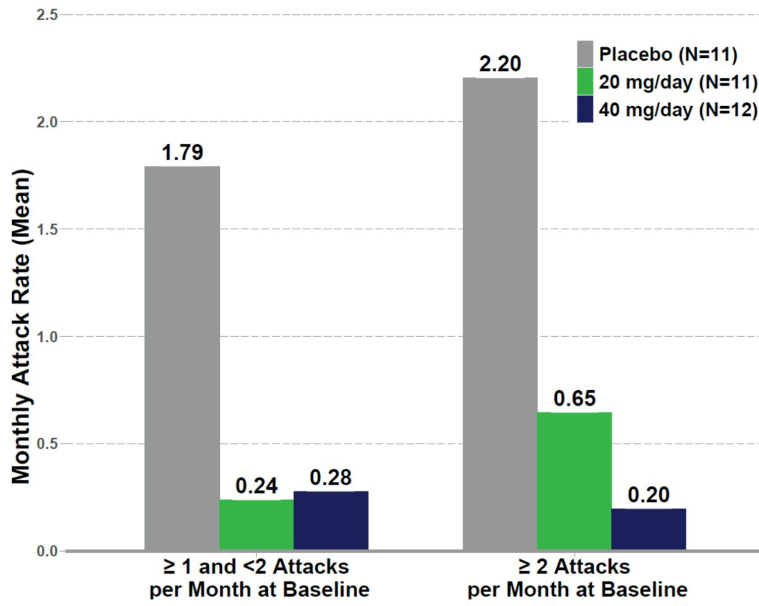


# Substantial reduction of attack rate from baseline



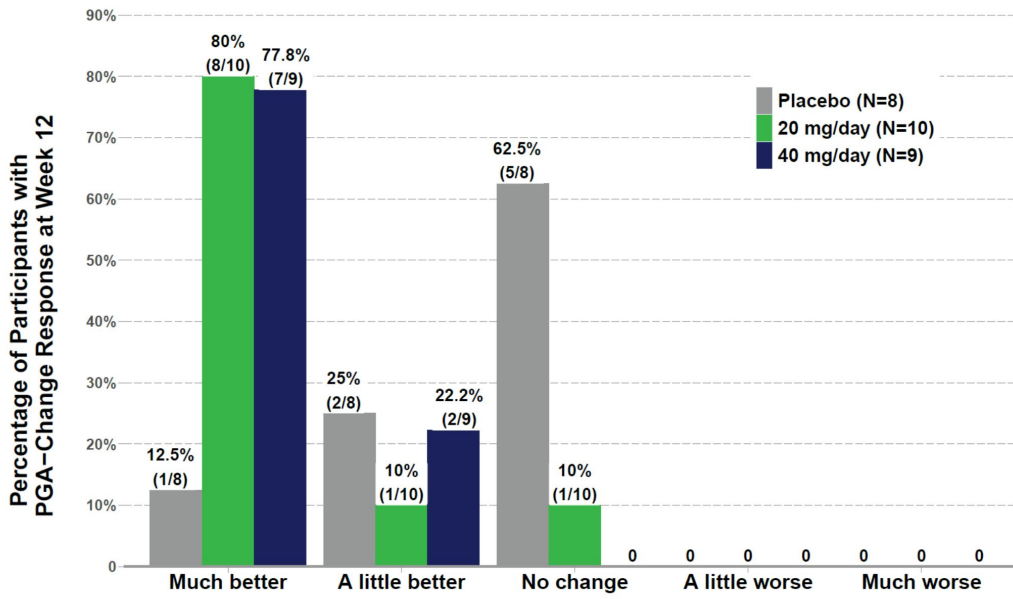
20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily.  
 40 mg/day = deucricitabant IR capsules 20 mg twice daily.  
 N = number of randomized participants.  
 Results based on participants with at least 4 weeks of treatment.

# Consistent efficacy regardless of baseline attack rate



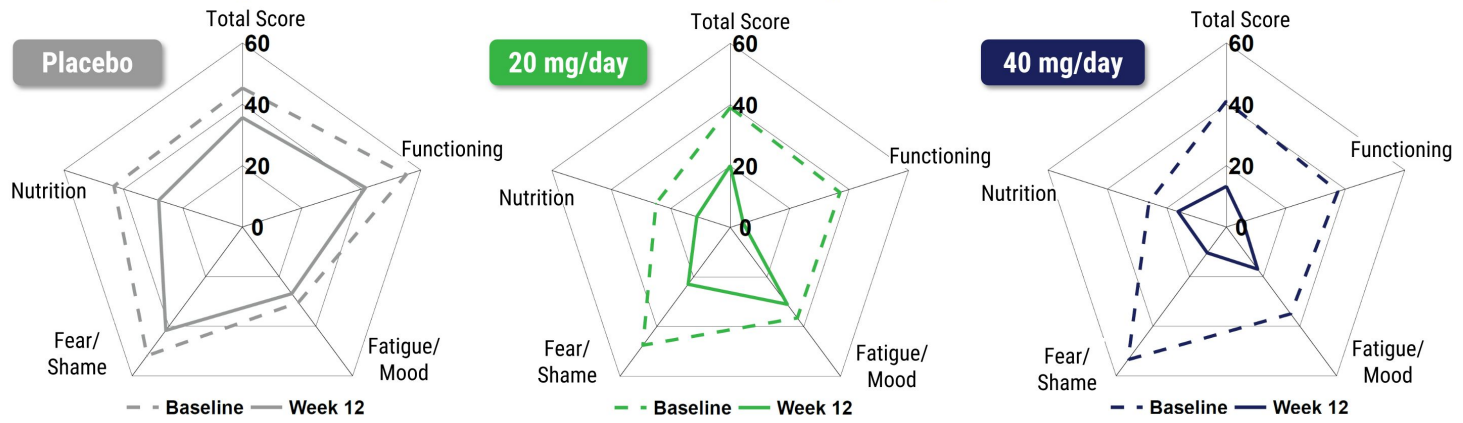
20 mg/day = deucricitbant immediate release (IR) capsules 10 mg twice daily.  
40 mg/day = deucricitbant IR capsules 20 mg twice daily.  
N = number of randomized participants.

# All 40 mg/day participants reported an improvement in PGA-Change



20 mg/day = deucricitbant immediate release (IR) capsules 10 mg twice daily. 40 mg/day = deucricitbant IR capsules 20 mg twice daily.  
PGA-Change = patient global assessment of change (question). N = number of participants with PGA-Change results at Week 12.

# AE-QoL: improvement in health-related quality of life



| AE-QoL Total Score |                 | Placebo           | 20 mg/day         | 40 mg/day         |
|--------------------|-----------------|-------------------|-------------------|-------------------|
| Baseline           | N               | 11                | 10                | 12                |
|                    | Mean            | 45.3              | 39.1              | 41.1              |
|                    | Median (Q1, Q3) | 42.6 (29.4, 57.4) | 37.5 (16.2, 55.9) | 40.4 (31.6, 49.3) |
| Week 12            | N'              | 8                 | 10                | 10                |
|                    | Mean            | 35.7              | 20.2              | 13.2              |
|                    | Median (Q1, Q3) | 37.5 (19.1, 49.3) | 18.4 (7.4, 33.8)  | 12.5 (10.3, 17.7) |

20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily. 40 mg/day = deucricitabant IR capsules 20 mg twice daily.  
 AE-QoL = angioedema quality of life (questionnaire). N = number of randomized participants. N' = number of participants with AE-QoL data at Week 12.

## Deucricitibant well-tolerated at both doses

|   | Placebo<br>(N=11) |                     | 20 mg/day<br>(N=11) |                     | 40 mg/day<br>(N=12) |                     |
|---|-------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
|   | Subjects<br>n (%) | Number<br>of events | Subjects<br>n (%)   | Number<br>of events | Subjects<br>n (%)   | Number<br>of events |
| TEAEs                                       | 7 (63.6)          | 16                  | 6 (54.5)            | 11                  | 7 (58.3)            | 12                  |
| Treatment related TEAEs                     | 1 (9.1)           | 1                   | 2 (18.2)            | 2                   | 1 (8.3)             | 1                   |
| Serious TEAEs                               | 0                 | 0                   | 0                   | 0                   | 0                   | 0                   |
| Treatment related Serious TEAEs             | 0                 | 0                   | 0                   | 0                   | 0                   | 0                   |
| TEAEs leading to study drug discontinuation | 0                 | 0                   | 0                   | 0                   | 0                   | 0                   |
| TEAEs leading to withdrawal from study      | 0                 | 0                   | 0                   | 0                   | 0                   | 0                   |
| TEAEs leading to death                      | 0                 | 0                   | 0                   | 0                   | 0                   | 0                   |

20 mg/day = deucricitibant immediate release (IR) capsules 10 mg twice daily. 40 mg/day = deucricitibant IR capsules 20 mg twice daily.  
N = number of participants randomized and dosed. n = number of participants having a treatment emergent adverse event.  
TEAE = treatment-emergent adverse event, defined as adverse events that occur after the first administration of blinded study treatment.

## All treatment-related adverse events were mild

| <b>System Organ Class</b><br>Preferred Term                  | <b>Placebo</b><br><b>(N=11)</b> | <b>20 mg/day</b><br><b>(N=11)</b> | <b>40 mg/day</b><br><b>(N=12)</b> |
|--|---------------------------------|-----------------------------------|-----------------------------------|
| <b>Participants with at least one treatment-related TEAE</b> | <b>1 (9.1%)</b>                 | <b>2 (18.2%)</b>                  | <b>1 (8.3%)</b>                   |
| <b>Gastrointestinal disorders</b>                            | <b>0</b>                        | <b>1 (9.1%)</b>                   | <b>0</b>                          |
| Nausea   | 0                               | 1 (9.1%)                          | 0                                 |
| <b>Investigations</b>  | <b>0</b>                        | <b>0</b>                          | <b>1 (8.3%)</b>                   |
| Gamma-glutamyltransferase increased                          | 0                               | 0                                 | 1 (8.3%)                          |
| <b>Nervous system disorders</b>                              | <b>1 (9.1%)</b>                 | <b>1 (9.1%)</b>                   | <b>0</b>                          |
| Dizziness postural   | 0                               | 1 (9.1%)                          | 0                                 |
| Headache   | 1 (9.1%)                        | 0                                 | 0                                 |

20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily. 40 mg/day = deucricitabant IR capsules 20 mg twice daily.

N = number of participants randomized and dosed.

TEAE = treatment-emergent adverse event, defined as adverse events that occur after the first administration of blinded study treatment.

# Main efficacy results

|  | Placebo<br>N=11          | 20 mg/day<br>N=11        | 40 mg/day<br>N=12        |
|--|--------------------------|--------------------------|--------------------------|
| Monthly attack rate – LS Mean (95% CI)*                      |                          |                          |                          |
| <b>All attacks (primary endpoint)</b>                        | <b>1.94 (1.31, 2.87)</b> | <b>0.40 (0.17, 0.92)</b> | <b>0.30 (0.11, 0.82)</b> |
| <b>% reduction vs placebo, p-value</b>                       |                          | <b>79.3%, p=0.0009</b>   | <b>84.5%, p=0.0008</b>   |
| Moderate or severe attacks                                   | 1.50 (0.91, 2.50)        | 0.26 (0.08, 0.81)        | 0.12 (0.02, 0.67)        |
| Attacks treated with on-demand medication                    | 1.41 (0.88, 2.24)        | 0.35 (0.14, 0.85)        | 0.10 (0.02, 0.57)        |
| Achieving threshold reduction of attack rate from baseline** |                          |                          |                          |
| >=50% reduction  | 2/11 (18%)               | 9/11 (82%)               | 9/10 (90%)               |
| >=70% reduction  | 2/11 (18%)               | 8/11 (73%)               | 8/10 (80%)               |
| >=90% reduction  | 0                        | 6/11 (55%)               | 6/10 (60%)               |
| Attack free during treatment period                          | 0                        | 6 /11(55%)               | 4/10 (40%)               |

20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily; 40 mg/day = deucricitabant IR capsules 20 mg twice daily. N = number of randomized participants.

LS mean = least squares mean. CI = confidence interval.

\*Results of monthly attack rates are based on Poisson regressions adjusted for baseline attack rate and time on treatment. No multiplicity adjustment was applied. Nominal p-value < 0.01 for all secondary endpoints included in this section comparing deucricitabant with placebo.

\*\*Participants with <4 weeks of treatment (2 participants on 40 mg/day) were not included in the summaries of proportions achieving threshold reduction of attack rate from baseline. Nominal p-value < 0.05 for all secondary endpoints included in this section comparing deucricitabant with placebo.

# Agenda



## Introduction

**Berndt Modig**, CEO Pharvaris



## Review of CHAPTER-1 top-line Phase 2 data

**Peng Lu**, M.D. PhD, CMO Pharvaris



## KOL perspective

**Marc A. Riedl**, M.D., M.S., Professor of Medicine, Clinical Director of the U.S. Hereditary Angioedema Association (HAEA) Angioedema Center at the University of California San Diego (UCSD), Clinical Service Chief for Allergy/Immunology at UCSD; principal investigator in the CHAPTER-1 study



## Closing Remarks, Q&A



# Agenda



## Introduction

**Berndt Modig**, CEO Pharvaris



## Review of CHAPTER-1 top-line Phase 2 data

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## KOL perspective

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## Closing Remarks, Q&A

# Managing HAE with two oral products utilizing the same active ingredient for on-demand and prophylactic treatment

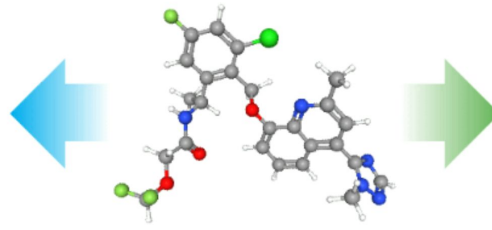
## deucricitbant

Immediate release capsule

PHVS416

rapid absorption

Aim to provide rapid and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form\*



deucricitbant

## deucricitbant

Extended-release tablet

PHVS719

sustained absorption

Aim to provide sustained exposure of attack-preventing therapy in a convenient, small oral dosage form\*

**Based on the results in RAPIDe-1 and CHAPTER-1 deucricitbant has the potential to become the preferred option to treat and prevent HAE attacks**

\*Aspirational; to be confirmed with clinical data

PHARVARIS

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This presentation includes data for an investigational product not yet approved by regulatory authorities.

# PHARVARiS

[www.pharvaris.com](http://www.pharvaris.com)

## Pharvaris Announces Positive Top-line Phase 2 Data from the CHAPTER-1 Study of Deucricitibant for the Prophylactic Treatment of HAE Attacks

- **Primary endpoint met; 40 mg/day orally administered deucricitibant significantly reduced mean monthly attack rate by 84.5% (p=0.0008) compared to placebo**
- 92.3% reduction in occurrence of moderate and severe attacks
- 92.6% fewer attacks treated with on-demand medication by participants
- Deucricitibant well-tolerated
- Pharvaris to host a conference call today at 8:00 a.m. EST

**Zug, Switzerland, December 6, 2023** – Pharvaris (Nasdaq: PHVS), a clinical-stage company developing novel, oral bradykinin B2 receptor antagonists to treat and prevent hereditary angioedema (HAE) attacks, today announced positive top-line data from the CHAPTER-1 Phase 2 clinical study meeting its primary endpoint, with deucricitibant demonstrating statistically significant and clinically meaningful results of deucricitibant as an oral preventative treatment for people living with HAE. Pharvaris plans to present data from the study at future medical meetings.

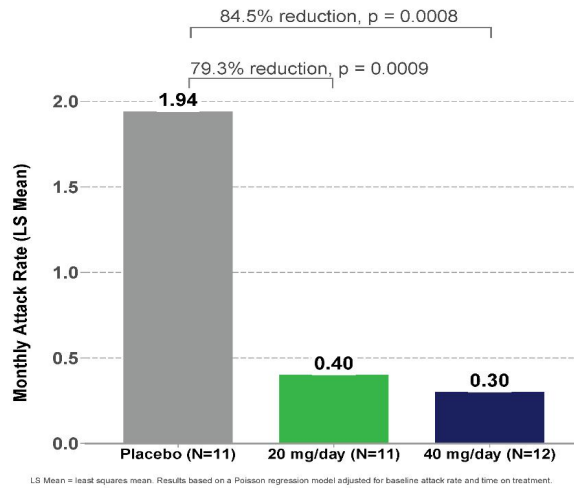
### CHAPTER-1 Clinical Study Design and Results

CHAPTER-1 (NCT05047185) is a double-blind, placebo-controlled Phase 2 study evaluating the efficacy as well as the safety and tolerability of deucricitibant for long-term prophylaxis against angioedema attacks in HAE-1/2. In the study, 34 participants were enrolled globally and randomized to receive one of two doses of deucricitibant (20 mg/day or 40 mg/day) or placebo for 12 weeks of treatment. Deucricitibant immediate-release capsule (PHVS416) was dosed twice-a-day as a proof-of-concept for the once-daily deucricitibant extended-release tablet (PHVS719), which is the intended formulation for the prophylactic treatment of HAE. The open-label portion of the CHAPTER-1 study is ongoing at the 40 mg/day dose.

The study's primary endpoint 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 deucricitibant.

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**Primary endpoint met:  
deucricitbant significantly reduced attack rate**



Marc A. Riedl, M.D., M.S., Professor of Medicine, Clinical Director of the US Hereditary Angioedema Association (HAEA) Angioedema Center at the University of California San Diego (UCSD), Clinical Service Chief for Allergy/Immunology at UCSD, and principal investigator in the CHAPTER-1 study, commented, “The HAE community is seeking highly effective, well-tolerated, and less burdensome therapies. The CHAPTER-1 data represent an important step forward in the evolution of HAE treatment. Given these encouraging results, deucricitbant has the potential to significantly improve clinical outcomes for people living with HAE.”

Peng Lu, M.D., Ph.D., Chief Medical Officer of Pharvaris, stated, “Deucricitbant is the first HAE treatment with the potential to combine injectable-like efficacy and a favorable safety profile with the convenience of an oral therapy. The study demonstrates, for the first time ever, that antagonism of the bradykinin B2 receptor can provide early and sustained protection from HAE attacks, including substantial reduction of moderate and severe attacks, with clinically meaningful improvement in health-related quality of life. We look forward to advancing the development of deucricitbant for the prevention of HAE attacks.”

Berndt Modig, Chief Executive Office of Pharvaris, added, “We sincerely thank the clinical trial participants and their caregivers, the site investigators and staff, the HAE community, and the Pharvaris team for their

contributions to the CHAPTER-1 study. These study results, together with the compelling data from our on-demand program, further strengthens our confidence that deucricitbant can become the preferred option to treat as well as prevent HAE attacks.”

In the analysis of the secondary endpoints, deucricitbant demonstrated clinically meaningful improvement in the severity of attacks and a decrease in the number of attacks treated with on-demand medication. Participants on deucricitbant treatment experienced a meaningful improvement in their quality of life. The table below lists additional study findings:

|  | Placebo<br>N=11   | 20 mg/day<br>N=11 | 40 mg/day<br>N=12 |
|--|-------------------|-------------------|-------------------|
| Monthly attack rate – LS Mean (95% CI)*                      |                   |                   |                   |
| Moderate or severe attacks                                   | 1.50 (0.91, 2.50) | 0.26 (0.08, 0.81) | 0.12 (0.02, 0.67) |
| Attacks treated with on-demand medication                    | 1.41 (0.88, 2.24) | 0.35 (0.14, 0.85) | 0.10 (0.02, 0.57) |
| Achieving threshold reduction of attack rate from baseline** |                   |                   |                   |
| >=50% reduction  | 2/11 (18%)        | 9/11 (82%)        | 9/10 (90%)        |
| >=70% reduction  | 2/11 (18%)        | 8/11 (73%)        | 8/10 (80%)        |
| >=90% reduction  | 0                 | 6/11 (55%)        | 6/10 (60%)        |
| Attack free during treatment period                          | 0                 | 6/11(55%)         | 4/10 (40%)        |

LS = least squares; CI = confidence interval.

\*Results of monthly attack rates are based on Poisson regression models adjusted for baseline attack rate and time on treatment. Nominal p-value < 0.01 for all endpoints included in this section comparing deucricitbant with placebo.

\*\*Participants with <4 weeks of treatment (two participants on 40 mg/day) were not included in the summaries of proportions achieving threshold reduction of attack rate from baseline.

Nominal p-value < 0.05 for all endpoints included in this section comparing deucricitbant with placebo.

Throughout 12 weeks of treatment in CHAPTER-1, both doses of deucricitbant were well-tolerated. There were no serious adverse events, no severe treatment-emergent adverse events, and no adverse events leading to treatment discontinuation.

In August 2022, the U.S. Food & Drug Administration (FDA) placed clinical studies of deucricitbant, including CHAPTER-1, on hold. Pharvaris notified country-specific regulatory authorities in Canada, Europe, Israel, and the UK regarding the clinical holds in the U.S., and the regulatory status of deucricitbant outside the U.S. has not been affected. In June 2023, Pharvaris announced the removal of the clinical hold of deucricitbant for the on-demand treatment of HAE in the U.S. Pharvaris has completed the 26-week rodent toxicology study requested by the FDA, which we believe met its objective. Pharvaris is preparing to submit the study results to the FDA by the end of the year. However, neither the nature nor timing of the response from FDA is certain.

### Conference Call

Pharvaris will host a live conference call and webcast to discuss the CHAPTER-1 study topline data in greater

detail at 8:00 a.m. EST today via a live webcast; presentation slides may be accessed on the “Events and Presentations” page of the Pharvaris investor relations website. Participants interested in asking a verbal question during the Q&A may do so in the live conference call. An archived replay will also be available on the website for 90 days following the event.

#### **About Deucricitibant**

Deucricitibant is a potent, selective, and orally available antagonist of the bradykinin B2 receptor. By inhibiting bradykinin signaling through the bradykinin B2 receptor, deucricitibant 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 deucricitibant 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 subtypes 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 deucricitibant in the U.S.; the expected timing, progress, or success of our clinical development programs, especially for PHVS416 (immediate-release deucricitibant capsules) and PHVS719 (extended-release deucricitibant tablets), which are in mid-stage

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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 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, 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.

**Contact**

Maggie Beller

Executive Director, Head of External and Internal Communications

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

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## ENFORCEABILITY OF JUDGMENTS

We are organized and existing under the laws of the Netherlands. As such, under Dutch private international law, the rights and obligations of our shareholders vis-à-vis the company originating from Dutch corporate law and our Articles of Association, as well as the civil liability of our officers (*functionarissen*) (including our directors and executive officers) are governed in certain respects by the laws of the Netherlands.

We are not a resident of the United States and our officers may also not all be residents of the United States. As a result, depending on the subject matter of the action brought against us and/or our officers, United States courts may not have jurisdiction. If a Dutch court has jurisdiction with respect to such action, that court will apply Dutch procedural law and Dutch private international law to determine the law applicable to that action. Depending on the subject matter of the relevant action, a competent Dutch court may apply another law than the laws of the United States.

Also, service of process against non-residents of the United States can in principle (absent, for example, a valid choice of domicile) not be effected in the United States.

Furthermore, substantially all of our assets are located outside the United States. As of the date of this filing, (i) there is no treaty in force between the United States and the Netherlands for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters and (ii) both the Hague Convention on Choice of Court Agreements (2005) and the Hague Judgments Convention (2019) have entered into force for the Netherlands, but have not entered into force for the United States. Consequently, a judgment rendered by a court in the United States will not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a judgment rendered by a court in the United States that is enforceable under the laws of the United States and files a claim with the competent Dutch court, the Dutch court will in principle give binding effect to that United States judgment if (i) the jurisdiction of the United States court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the United States court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such United States judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the United States court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a foreign court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for recognition in the Netherlands. Even if such a United States judgment is given binding effect, a claim based thereon may, however, still be rejected if the United States judgment is not or no longer formally enforceable. Moreover, if the United States judgment is not final (for instance when appeal is possible or pending) a competent Dutch court may postpone recognition until the United States judgment will have become final, refuse recognition under the understanding that recognition can be asked again once the United States judgment will have become final, or impose as a condition for recognition that security is posted.

A competent Dutch court may deny the recognition and enforcement of punitive damages or other awards. Moreover, a competent Dutch court may reduce the amount of damages granted by a United States court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Thus, United States investors may not be able, or experience difficulty, to enforce a judgment obtained in a United States court against us or our officers.

## RISK FACTORS

The following risk factors should be read in conjunction with, and amend and supplement, those included in the Annual Report on Form 20-F filed by Pharvaris N.V. (“we”, “our”, “us” or the “Company”) on April 5, 2023 (the “Form 20-F” or the “Annual Report”). Investing in the Company’s ordinary shares involves a high degree of risk. You should carefully consider the risks described below, and all other information contained in or incorporated by reference in the Form 20-F, before making an investment decision regarding the Company’s securities. Defined terms used, but not defined, in these “Risk Factors” have the meaning ascribed to them in the Form 20-F.

### **Risks Related to Our Ordinary Shares and Our Status as a Public Company**

#### **Investors may have difficulty enforcing civil liabilities against us or our directors and/or other officers.**

We are organized and existing under the laws of the Netherlands. As such, under Dutch private international law, the rights and obligations of our shareholders vis-à-vis the company originating from Dutch corporate law and our Articles of Association, as well as the civil liability of our officers (*functionarissen*) (including our directors and executive officers) are governed in certain respects by the laws of the Netherlands.

We are not a resident of the United States and our officers may also not all be residents of the United States. As a result, depending on the subject matter of the action brought against us and/or our officers, United States courts may not have jurisdiction. If a Dutch court has jurisdiction with respect to such action, that court will apply Dutch procedural law and Dutch private international law to determine the law applicable to that action. Depending on the subject matter of the relevant action, a competent Dutch court may apply another law than the laws of the United States.

Also, service of process against non-residents of the United States can in principle (absent, for example, a valid choice of domicile) not be effected in the United States.

Furthermore, substantially all of our assets are located outside the United States. On the date of this filing, (i) there is no treaty in force between the United States and the Netherlands for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters and (ii) both the Hague Convention on Choice of Court Agreements (2005) and the Hague Judgments Convention (2019) have entered into force for the Netherlands, but have not entered into force for the United States. Consequently, a judgment rendered by a court in the United States will not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a judgment rendered by a court in the United States that is enforceable under the laws of the United States and files a claim with the competent Dutch court, the Dutch court will in principle give binding effect to that United States judgment if (i) the jurisdiction of the United States court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the United States court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such United States judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the United States court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a foreign court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for recognition in the Netherlands. Even if such a United States judgment is given binding effect, a claim based thereon may, however, still be rejected if the United States judgment is not or no longer formally enforceable. Moreover, if the United States judgment is not final (for instance when appeal is possible or pending) a competent Dutch court may postpone recognition until the United States judgment will have become final, refuse recognition under the understanding that recognition can be asked again once the United States judgment will have become final, or impose as a condition for recognition that security is posted.

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