## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

#### FORM 6-K

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

> For the month of January 2024 Commission File Number: 001-40010

### Pharvaris N.V.

(Translation of registrant's name into English)

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  $\boxtimes$  Form 40-F  $\square$ 

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):  $\Box$ 

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.

#### PHARVARIS N.V.

On January 5, 2024, Pharvaris N.V. (the "Company") issued a press release. The press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein. On January 8, 2024, the Company made available an investor presentation on its website. A copy of the investor presentation is attached hereto as Exhibit 99.2.

Exhibit 99.1 to this Report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-263198 and 333-273757) and Form S-8 (Registration Number 333-252897). Exhibit 99.2 to this Report on Form 6-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act.

#### **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: January 8, 2024 By: /s/ Berndt Modig

Name: Berndt Modig

Title: Chief Executive Officer

#### EXHIBIT INDEX

No. Description

 99.1
 Press release, dated January 5, 2024.

 99.2
 Investor Presentation, dated January 8, 2024.

### **PHARVARIS**

### **Corporate Presentation**

January 2024

Pioneering science for patient choice



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#### **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 deucrictibant 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, deucrictibant immediate-release capsules (PHVS416) and deucrictibant extended-release tablets (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.

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# Focused on unmet need in the treatment of hereditary angioedema (HAE) and other bradykinin-mediated diseases



#### **Competitive product profile**

- Deep expertise in bradykinin/BR2 biology and chemistry
- Orally available, small molecule targeting the validated bradykinin B2 receptor pathway
- Positive top-line Phase 2 data in HAE:
  - RAPIDe-1 study for on-demand treatment meets all primary and key secondary endpoints
    - RAPIDe-3 Phase 3 study to initiate within 1H24
  - CHAPTER-1 study in prophylaxis\* meets primary endpoint and showed clinically meaningful improvements for secondary endpoints
    - Preparing for initiation of CHAPTER-3 Phase 3 study



#### Large market opportunity

- Large global HAE market:\$2 billion with predicted 15% CAGR
- Potential portfolio expansion into other BK-mediated angioedema and diseases through B2-receptor pathway expertise



#### **Strong fundamentals**

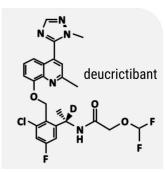
- World-wide operations: the Netherlands, U.S., and Switzerland (headquarters)
- Strong financial position, cash runway at least two years:
  - €140M cash as of Nov 30, 2023
  - \$300M underwritten offering in Dec 2023
- Experienced management team with successful track record in HAE drug design and development
- Strong IP on novel lead and backup series
  - Primary CoM granted in multiple territories, initial term to 2038
- FDA orphan drug designation

\*The FDA has placed a hold on clinical trials of deucrictibant for long-term prophylaxis of HAE in the U.S.; see slide 9 for an update on our clinical program

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# Deucrictibant: A novel, orally bioavailable bradykinin B2 receptor antagonist for bradykinin-mediated angioedema

- Entering late-state development for hereditary angioedema
- Potent inhibition of the bradykinin B2 receptor to compete with bradykinin, the ultimate driver of swelling attacks
- Results from Phase 1 and Phase 2 studies demonstrate rapid absorption, exposure, efficacy in treating and preventing HAE attacks, and good tolerability
- Dose and exposure threshold predicted from human surrogate endpoint for both on-demand and prophylaxis



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/33217945-6893-4f49-8a93-c80ea6fb2a31; https://doi.org/10.1016/j.jaci.2019.12.094

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## Excess levels of bradykinin lead to swelling characteristic of angioedema attacks

					FXIIa
1		HAE due to	Type I HAE	_	KNG1
		C1INH deficiency	Type II HAE		$( \downarrow )$
		HAE with normal C1INH	HAE-FXII	_	: HMWK
	Hereditary		HAE-PLG	_	prekallikrein plasma
	誤		HAE-HS3ST6		kallikrein
	<b>Pa</b>		HAE-KNG		: / \
	ē		HAE-unknown		C1-INH
	Ī		HAE-ANGPT		\ /
			HAE-MYOF		<b>*</b> /
			HAE-HSST	_	cHMWK + bradykinin
			HAE-SCLS		kinina
		C1INH deficiency (AAE C1-INH)	Lymphoproliferative		
			disorders, B-cell		deucrictibant
			malignancies	_	dedoriotibalit
	Acquired		Autoimmune disorders	_	<b>&gt; ♦</b>
			Other disorders	_	Bradykinin B2 Receptor
	듓		Idiopathic	_	Bradykimin B2 Neoceptor
	Ă	Drug-induced	ACE-inhibitor	_	
			Other		
		Idiopathic	Histamine independent	<b>bold</b> = known or potential role for bradykinin involvement in disease	Angioedema
			Histamine denendent	brady kinin hivory ciricin in discuse	

Source: Busse 2020 J Allergy Clin Immunol Pract; Bork et al 2021 J Allergy Clin Immunol; 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 (<a href="https://2023.haenetworkshop.hu/program/index.php">https://www.linkedin.com/feed/update/urm/iractivity/7060638305842778112/</a>); Shi et al 2021 Clin Immunol. 230 (doi.org/10.1016/j.clim.2021.108819)

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; FXII: gene encoding FXII; ANGPT: gene encoding angiopoietin; MYOF: gene encoding myoferlin; HSST: gene encoding heparan sulfate sulfotransferase; SCLS: systemic capillary leak syndrome

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FXII ← F12

plasminogen ← PLG

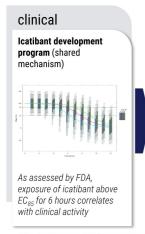
inactive fragments

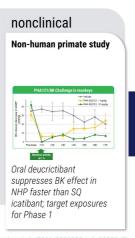
ACEi

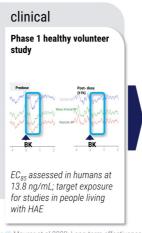
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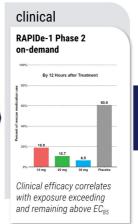
# Clinical dosing is guided by prediction from a validated *in vivo* surrogate-marker model, the bradykinin challenge

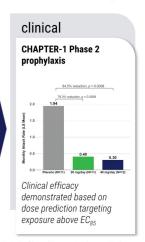
Bradykinin, injected /V in healthy volunteers, induces a transient, limited change in cardiac parameters (heart rate  $\uparrow$ , blood pressure  $\downarrow$ ) which can be blocked by pre-injection of a bradykinin B2 receptor antagonist (e.g., icatibant or deucrictibant)











https://www.accessdata.fda.gov/drugsatfda.docs/nda/2011/0221500rig1s000ClinPharmR.pdf; Maurer et al 2020: Long-term effectiveness and safety of icatibant for the on-demand treatment of hereditary angioedema attacks: 10 years of the icatibant outcome survey (EAACI Poster #1118, June 6-8, 2020): https://clinicaltrials.gov/ct2/show/NCT01034969; https://ir.pharvaris.com/static-files/33217945-6893-4f49-8a93-c80ea6fb2a31; https://doi.org/10.1016/j.jaci.2019.12.094; BK: bradykinin; NHP: non-human primates; SQ: sub-cutaneous; EC<sub>85</sub>: effective concentration achieving 85% inhibition of bradykinin effect

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

#### deucrictibant (PHVS719) deucrictibant (PHVS416) Immediate-release capsule **Extended-release tablet** rapid absorption sustained absorption deucrictibar

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

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

target plasma level

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

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## Wholly-owned pipeline focused on bradykinin B2 receptor mechanism



<sup>\*</sup> The FDA has placed a hold on clinical trials of deucrictibant for long-term prophylaxis in the U.S.; see slide 9 for an update on our clinical program

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### **Regulatory update**

#### **U.S.** clinical hold

- In August 2022, the U.S. Food & Drug Administration (FDA) placed a hold on clinical trials of deucrictibant 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, and submitted to the FDA

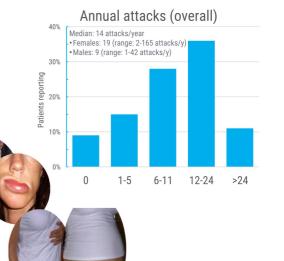
#### **Trial status**

- In June 2023, FDA removed the clinical hold on ondemand trials
  - Eligible participants in the U.S. may join RAPIDe-2, a long-term 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 deucrictibant immediate-release capsules for the on-demand treatment of HAE
- Clinical studies of deucrictibant for the long-term prophylaxis of HAE remain on hold in the U.S.
- Outside the U.S., on-demand and prophylactic clinical studies continue
  - Pharvaris notified country-specific regulatory authorities in Canada, Europe, Israel, and the UK of the U.S. clinical holds

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## 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 lifethreatening 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

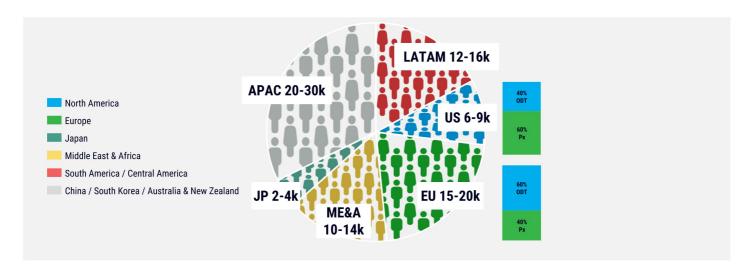


Source: Nordenfelt et al, Acta Derm. Venereol 2016: 96: 540-545; Busse 2020 J Allergy Clin Immunol Pract; Bork et al 2021 J Allergy Clin Immunol

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# 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); <a href="https://haei.org/potentially-28000-hae-patients-in-china">https://haei.org/potentially-28000-hae-patients-in-china</a>; Ann Allergy Asthma Immunol 2015:114(6), 492-498; Allergol Int. (2020) Nov 6;S1323-8930(20)30135-0

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



Efficacy is a prime concern ...



... but safety and tolerability drive exploration of alternatives ...



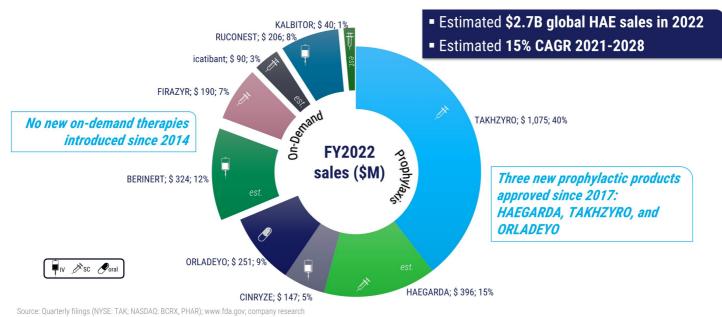
... while convenience has become a key driver for overall preference

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

Source: Proprietary company research 2022

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

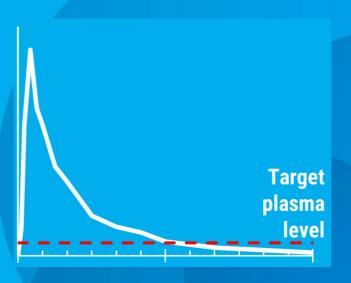


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### On-Demand

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



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## 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 ...



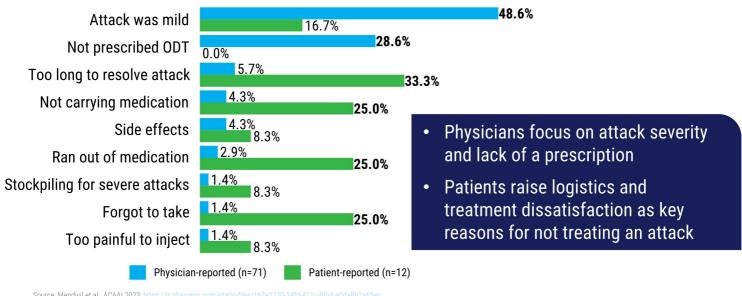
... while finding a place to administer the drug causes an **extra burden** 

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)

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



Source: Mendivil et al., ACAAI 2023; ht

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







Patients want rapid onset of symptom relief ...

... with single dose durability ...

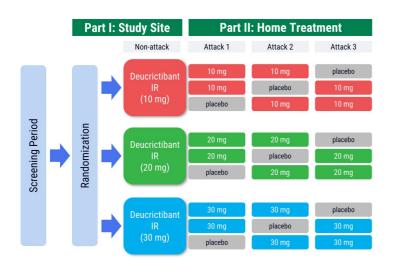
... in an oral pill

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)

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## HAE RAPIDe-1 study: Phase 2 study of on-demand treatment of angioedema attacks in patients with HAE-1/2



- Primary objective: to evaluate angioedema symptom relief within four hours in acute attacks of patients with HAE-1/2
- Study design: Placebo-controlled, three dose levels
  - Part I: patients randomized and received a single dose of deucrictibant in clinic for PK and safety assessment
  - Part II: patients treated three attacks with two deucrictibant 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; https://clinicaltrials.gov/ct2/show/NCT04618211; https://hae-rapide.us/; https://www.clinicaltrialsregister.eu/ctr-search/search

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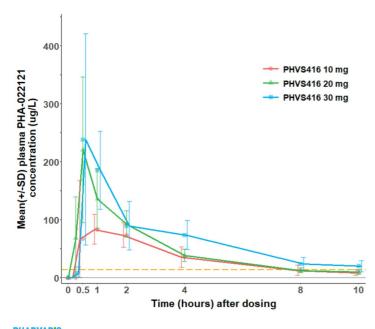
## Positive top-line Phase 2 data from RAPIDe-1 study of PHVS416 for the on-demand treatment of HAE attacks

- 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
- Deucrictibant IR showed rapid onset of action, symptom relief, and resolution of HAE attacks
- Deucrictibant IR substantially reduced the use of rescue medications
- Deucrictibant 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

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



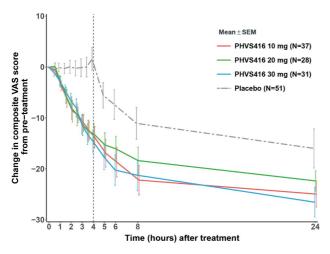
- Rapid absorption with mean plasma levels exceeding EC<sub>85</sub> (13.8 ng/mL) within 30 min
- Mean plasma levels maintained >EC<sub>85</sub> for approximately
  - 8 h at 10 mg or 20 mg
  - >10 h at 30 mg dose
- EC<sub>85</sub> levels established using bradykinin challenge, a human surrogate endpoint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

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# Primary endpoint: Deucrictibant IR significantly reduced 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 DHVS/116	-16 09 (-10 97 -12 20)	

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

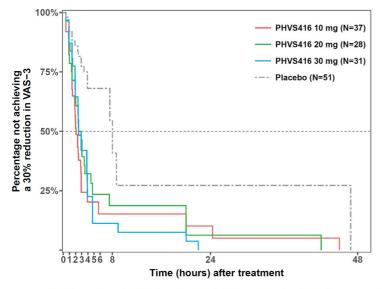
†Nominal p-value; VAS assessed every 30 minutes up to 4 hours post-treatment, then at 5, 6, 8, 24, 48 hours; N = The number of attacks in the mITT Analysis Set. Attacks in mITT Analysis Set refer to attacks treated with blinded study drug that had non-missing VAS result at pre-treatment and at least 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, Cls, 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

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# Deucrictibant 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

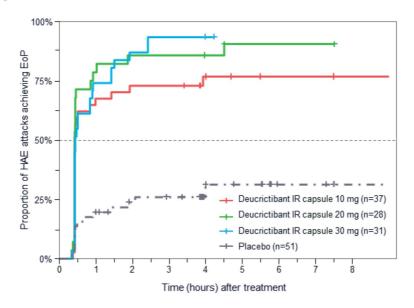
Nominal p-value; N = The number of attacks in the mITT Analysis Set. Median time based on Kaplan-Meier estimates, p-values based on a marginal Cox proportional hazards model. The combined PHVS416 results are based on post-hoc analyses to provide a reference of the result by pooling all three active doses.

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### In a post-hoc analysis, patients on deucrictibant achieved end of progression by VAS-3 within 25 to 26 min

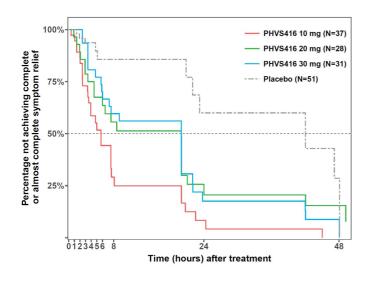


Source: Riedl et al., ACAAI 2023; https://doi.org/10.1016/j.jps.

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# Deucrictibant IR significantly reduced 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)				
Deucrictibant IR 10 mg	5.8 (3.6, 7.5)	p < 0.0001 <sup>†</sup>			
Deucrictibant IR 20 mg	20.0 (4.5, 20.0)	p = 0.0127			
Deucrictibant IR 30 mg	20.0 (6.0, 20.1)	p = 0.0001			
Combined Deucrictibant 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

†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.

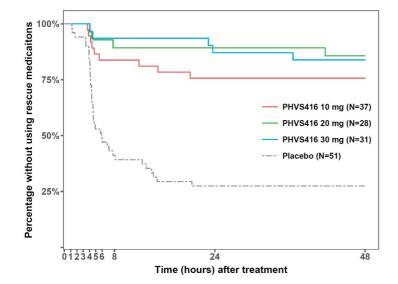
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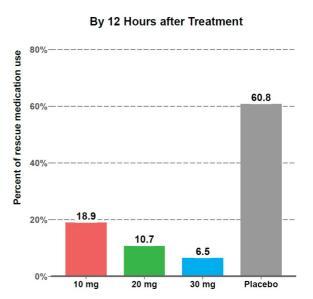
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### Patients treating with deucrictibant IR used substantially less 100%

rescue medication





N = The number of attacks in the mITT Analysis Set

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### **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 N=23	20 mg N=24	30 mg N=25	Placebo N=53	10 mg N=38	20 mg N=29	30 mg N=36
Subjects (Part I) or Attacks (Part II) with any treatment related AEs	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%)	-	-	=

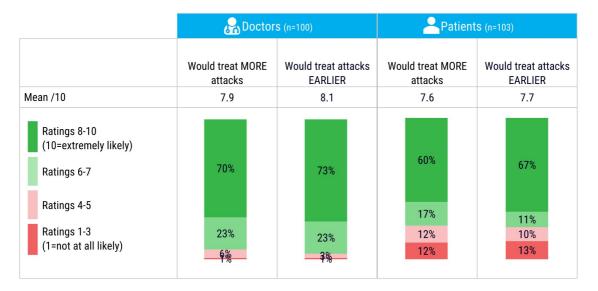
N= The number of subjects (Part I) and number of attacks (Part II) in the Safety Analysis Set. The Safety Analysis Set includes all randomized patients who received any dose of study drug. Treatment-related AEs within 48 h post-treatment are included

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### 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)

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### We have renamed VAS to AMRA, reflecting its evolution from a paper-based to electronic attack assessment

#### What is a Visual Analogue Scale (VAS)?

- · Simple, reproducible, paper-based tool to allow patient self-assessment of symptom
- Analog scale with an 'X' hand-marked to reflect severity of attack

2008-2011 Jerini-Shire



#### Why do we need change?

- · Addressing user experience to leverage technology and accuracy of data collection1
- HAE ODT trials require frequent assessments to be recorded by participants; a digital tool is an accessible method for timely data input



#### How has Pharvaris evolved the VAS to a contemporary electronic standard?

- · Electronic Clinical Outcome Assessment (eCOA)
- Presents the numeric scale vertically (e.g from 'Worst possible' = 100 to 'No symptom' = 0)
- Participants can see in real time the exact score (between 0 and 100) selected
- Performed at home

2023 **Pharvaris** 



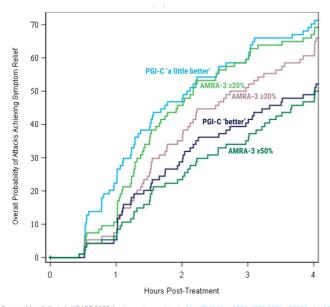
A numeric rating scale requires a self- explanatory name

Angioedema symptom Rating scAle (AMRA)

1 CDER. Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for Purpose Clinical Outcome Assessments. FDA. June 2022. Accessed December 18, 2023. https://doi.org/10.1006/j.jcg/

**PHARVARIS** 

# In a real-world study using standard-of-care therapy, similar median time to symptom relief for AMRA-3 ≥20% and PGI-C 'a little better'



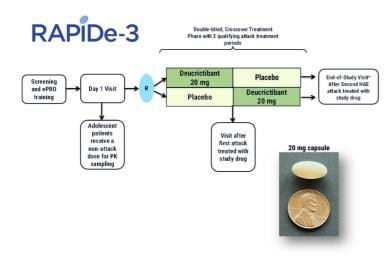
PRO instrument	Events (n)	Median time to, h (95% CI)
PGI-C "a little better"	90	<b>2.147</b> (1.518, 3.017)
AMRA-3 20% reduction from pre-treatment	89	<b>2.191</b> (1.655, 3.035)
AMRA-3 30% reduction from pre-treatment	89	<b>2.990</b> (2.123, 4.011)
PGI-C "better"	92	<b>3.925</b> (2.969, 5.055)
PGI-S 1-level reduction	91	<b>4.012</b> (3.015, 5.026)
AMRA-3 50% reduction from pre-treatment	88	<b>4.354</b> (3.256, 6.093)

Similar median time to symptom relief using AMRA-3 ≥20% reduction from pre-treatment and PGI-C "a little better" on two consecutive timepoints

Source: Mendivil et al., UCARE 2023 (ir.pharvaris.com/static-files/f2d3d4ea-2526-4885-9951-a90015add462)

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## HAE RAPIDe-3 study: A global Phase 3 study of on-demand treatment of angioedema attacks in patients with HAE-1/2

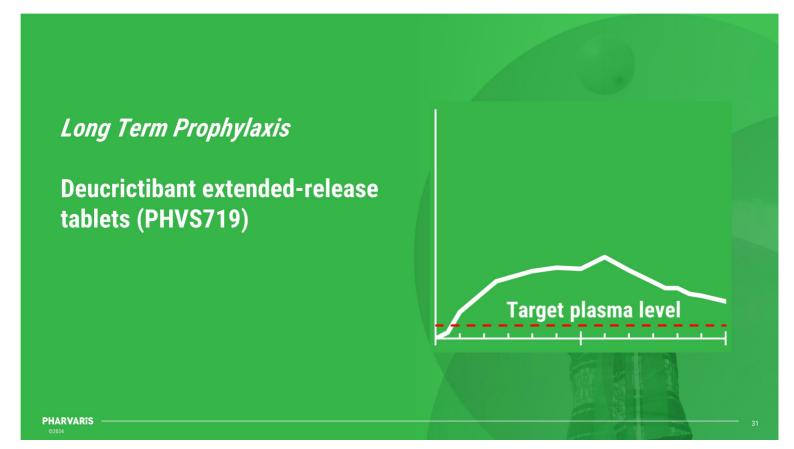


#### Endpoints

- Onset of symptom relief
  - Patient Global Impression of Change (PGI-C) rating of at least "a little better" for two consecutive timepoints within 12 hours post-treatment
- Secondary
  - Time to end of progression of attack symptoms, substantial symptom relief, and symptom resolution
    - PGI-C, Patient Global Impression of Severity (PGI-S), Angioedema syMptom Rating scAle (AMRA)
  - Use of rescue medication
- Incidence of treatment-emergent adverse events
- Rollover to open-label extension

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









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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### CHAPTER-1, a Phase 2 prophylactic study of deucrictibant 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
- Deucrictibant well-tolerated at both doses

\*40 mg/day deucrictibant 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 deucrictibant and placebo are made without adjustment for multiplicity.

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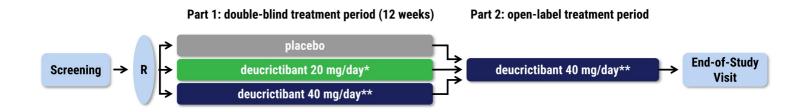
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### **CHAPTER-1 study design**

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

34 participants enrolled in North America and Europe



R = randomization

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

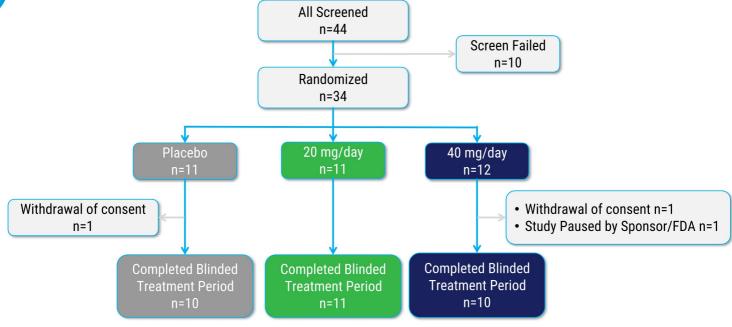
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<sup>\*</sup>deucrictibant 20 mg/day = deucrictibant immediate-release capsules (PHVS416) 10 mg twice daily

## **Participant disposition**



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

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## **Balanced demographics and baseline characteristics**

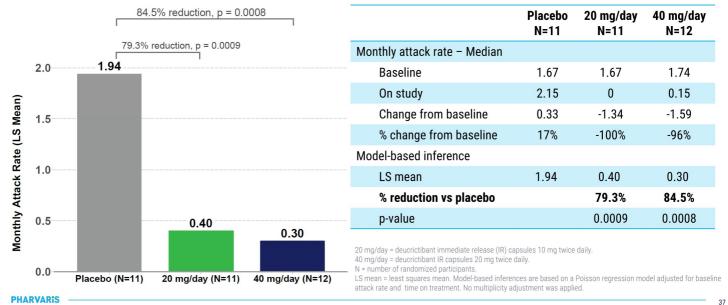
	Placebo N=11	20 mg/day N=11	40 mg/day N=12	All N=34
Age in years – Mean	41.4	38.4	40.8	40.2
Sex: M/F - n	3/8	6/5	4/8	13/21
Race: White - n (%)	11 (100)	11 (100)	12 (100)	34 (100)
BMI (kg/m2) - Mean	26.7	29.5	25.4	27.1
HAE Type – n				
Type 1	10	9	12	31
Type 2	1	2	0	3
Baseline HAE attack rate per month				
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)

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

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### Primary endpoint met: deucrictibant significantly reduced attack rate

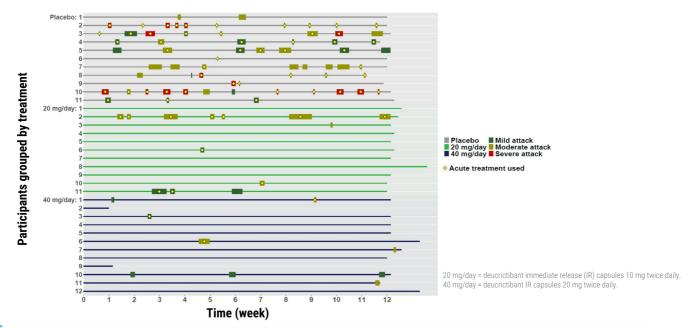
Monthly attack rate measured as time-normalized number of investigator confirmed HAE attacks



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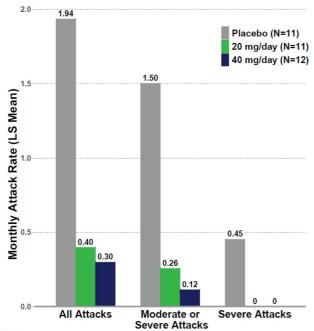
## Significant attack reduction and no severe attacks with deucrictibant



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



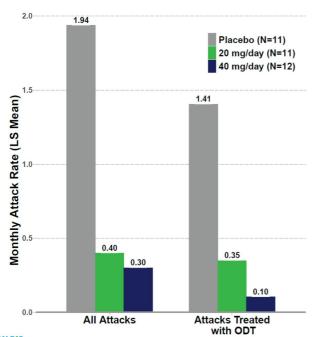
	Placebo N=11	20 mg/day N=11	40 mg/day N=12
Monthly attack rate of moder or severe attacks	rate		
LS mean	1.50	0.26	0.12
% reduction vs placebo		82.8%	92.3%
Nominal p-value		0.0066	0.0067

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<sup>20</sup> mg/day = deucrictibant immediate release (IR) capsules 10 mg twice daily.
40 mg/day = deucrictibant 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



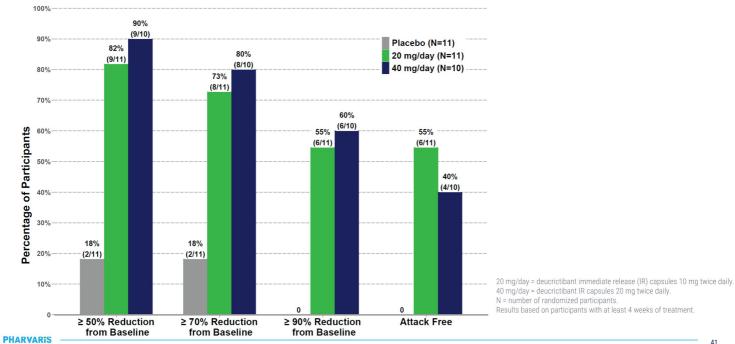
	Placebo N=11	20 mg/day N=11	40 mg/day N=12
Monthly attack rate of attacks treated with ODT			
LS mean	1.41	0.35	0.10
% reduction vs placebo		75.1%	92.6%
Nominal p-value		0.0074	0.0040

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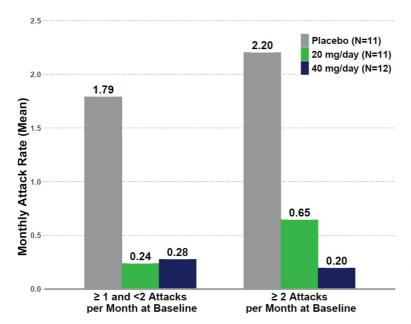
ODT = on-demand treatment (icatibant, C1-inhibitor (C1-INH))
20 mg/day = deucrictibant immediate release (IR) capsules 10 mg twice daily,
40 mg/day = deucrictibant IR capsules 20 mg twice daily.
N = number of randomized participants.
LS mean = least squares mean. Monthly attack rates are based on a Poisson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

## Substantial reduction of attack rate from baseline

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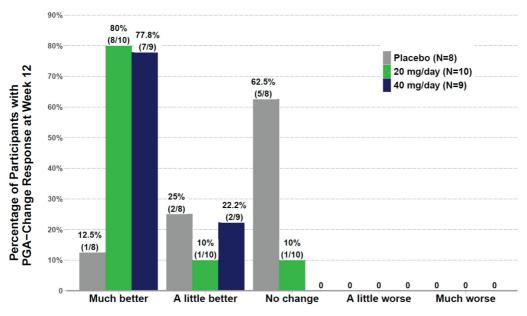
## Consistent efficacy regardless of baseline attack rate



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

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

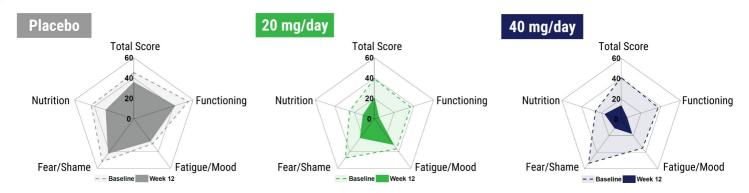


20 mg/day = deucrictibant immediate release (IR) capsules 10 mg twice daily. 40 mg/day = deucrictibant IR capsules 20 mg twice daily PGA-Change = patient global assessment of change (question). N = number of participants with PGA-Change results at Week 12.

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## 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 = deucrictibant immediate release (IR) capsules 20 mg per day. 40 mg/day = deucrictibant IR capsules 40 mg per day.

AE-QoL = angioedema quality of life (questionnaire). N = number of randomized participants with AE-QoL data at baseline. N' = number of participants with AE-QoL data at Week 12.

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### **Deucrictibant well-tolerated at both doses**

	Placebo (N=11)			g/day :11)		g/day :12)
	Subjects n (%)	Number of events	Subjects n (%)	Number of events	Subjects n (%)	Number 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 = deucrictibant immediate release (IR) capsules 10 mg twice daily. 40 mg/day = deucrictibant 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.

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## All treatment-related adverse events were mild

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

<sup>20</sup> mg/day = deucrictibant immediate release (IR) capsules 10 mg twice daily. 40 mg/day = deucrictibant 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.

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## **Main efficacy results**

	Placebo N=11	20 mg/day N=11	40 mg/day N=12
Monthly attack rate – LS Mean (95% CI)*			
All attacks (primary endpoint)	1.94 (1.31, 2.87)	0.40 (0.17, 0.92)	0.30 (0.11, 0.82)
% reduction vs placebo, p-value		79.3%, p=0.0009	84.5%, p=0.0008
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%)

<sup>20</sup> mg/day = deucrictibant immediate release (IR) capsules 10 mg twice daily, 40 mg/day = deucrictibant IR capsules 20 mg twice daily, N = number of randomized participants.

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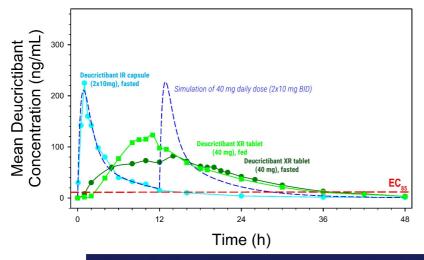
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ES mean = least squares mean. Cl = confidence interval.

\*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 deucrictibant 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 deucrictibant with placebo.

# As seen in a single-dose Phase 1 PK study, deucrictibant XR demonstrates QD potential: Phase 3 dosage form



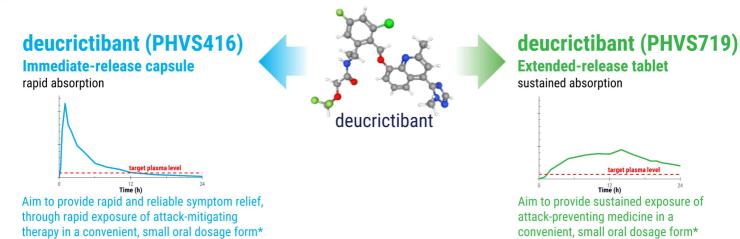
- Deucrictibant IR and XR well tolerated
  - No SAEs or severe TEAEs
- Deucrictibant XR extended-release maintained exposure above EC<sub>85</sub> for >24h with and without food
  - Similar AUC<sub>24h</sub> as 40 mg deucrictibant IR dosed with food

Deucrictibant XR anticipated to maintain higher trough exposure relative to BID deucrictibant IR

Source: Company data

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



Based on the results in RAPIDe-1 and CHAPTER-1, deucrictibant 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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# Focused on unmet need in the treatment of hereditary angioedema (HAE) and other bradykinin-mediated diseases



#### **Competitive product profile**

- Deep expertise in bradykinin/BR2 biology and chemistry
- Orally available, small molecule targeting the validated bradykinin B2 receptor pathway
- Positive top-line Phase 2 data in HAE:
  - RAPIDe-1 study for on-demand treatment meets all primary and key secondary endpoints
    - RAPIDe-3 Phase 3 study to initiate within 1H24
  - CHAPTER-1 study in prophylaxis\* meets primary endpoint and showed clinically meaningful improvements for secondary endpoints
    - Preparing for initiation of CHAPTER-3 Phase 3 study



#### Large market opportunity

- Large global HAE market:\$2 billion with predicted 15% CAGR
- Potential portfolio expansion into other BK-mediated angioedema and diseases through B2-receptor pathway expertise



#### **Strong fundamentals**

- World-wide operations: the Netherlands, U.S., and Switzerland (headquarters)
- Strong financial position, cash runway at least two years:
  - €140M cash as of Nov 30, 2023
  - \$300M underwritten offering in Dec 2023
- Experienced management team with successful track record in HAE drug design and development
- Strong IP on novel lead and backup series
  - Primary CoM granted in multiple territories, initial term to 2038
- FDA orphan drug designation

\*The FDA has placed a hold on clinical trials of deucrictibant for long-term prophylaxis of HAE in the U.S.; see slide 9 for an update on our clinical program

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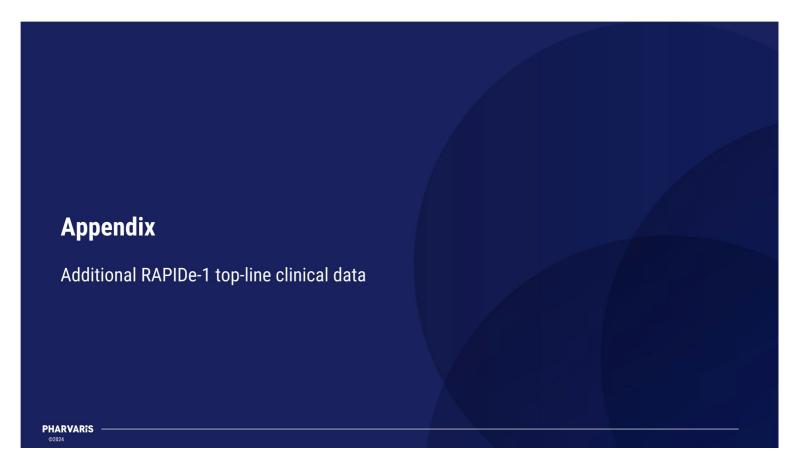
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NASDAQ: PHVS

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





### RAPIDe-1: Primary, key secondary and other endpoints

#### **Primary Endpoint**

■ Change in VAS-3 score from pre-treatment to 4h post-treatment

#### **Key Secondary Endpoints**

- Time to onset of symptom relief (VAS-3; ≥30% reduction from the pre-treatment score)
- Time to a ≥50% reduction in VAS-3 score from the pre-treatment score
- Time to almost complete and complete symptom relief (VAS; all 3 items ≤10)
- Change of MSCS (mean symptom complex severity) score from pre-treatment to 4h post-treatment
- TOS (treatment outcome score) at 4h post-treatment

#### Other Endpoints Included in the top-line Outputs

- Proportion of study-drug-treated attacks requiring the use of HAE rescue medication
- Time to the first use of HAE rescue medication
- Safety and PK assessments

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## **Results summary of primary efficacy endpoint**

	Placebo N=51	PHVS416 10 mg N=37	PHVS416 20 mg N=28	PHVS416 30 mg N=31	Combined PHVS416* N=96
Mean VAS-3 at pre-treatment Change in VAS-3 at 4 hours least-squares mean	27.76	26.16	25.46	29.73	27.11
difference: PHVS416 - Placebo		-16.75	-15.02	-16.28	-16.08
p-value		<0.0001 <sup>†</sup>	<0.0001	<0.0001	

<sup>\*</sup>nominal p-value; N = The number of attacks included in the mITT Analysis Set p-values for PHVS416 20mg and PHVS416 30mg are based on statistical tests in the pre-specified multiple comparison procedure, other p-values are nominal least-squares = Least squares. The least-squares mean differences and p-values are based on mixed-effects model for repeated measures \*The combined PHVS416 results are based on post-hoc analyses to provide a reference of the result by pooling all three active doses

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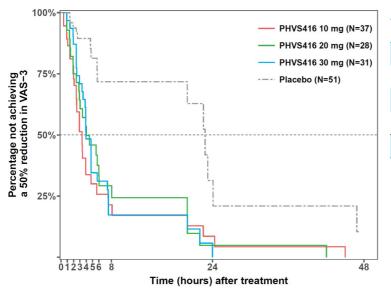
## **Results summary of key secondary efficacy endpoints**

	Placebo N=51	PHVS416 10 mg N=37	PHVS416 20 mg N=28	PHVS416 30 mg N=31	Combined PHVS416* N=96
Time to onset of symptom relief by VAS-3 30% reduction <sup>a</sup>					
Median time in hours (95% CI)	8.0 (7.6, 46.9)	2.1 (1.5, 2.9)	2.7 (1.9, 3.5)	2.5 (1.9, 3.8)	2.4 (2.0, 2.9)
Hazard ratio		3.81	3.08	3.61	
p-value		<0.0001 <sup>†</sup>	0.0021	<0.0001	
Time to VAS-3 50% reduction <sup>a</sup>					
Median time in hours (95% CI)	22.8 (20.0, 24.1)	3.3 (2.4, 3.9)	4.0 (2.9, 6.0)	4.0 (3.3, 5.8)	3.9 (3.0, 4.8)
Hazard ratio		4.55	3.65	3.87	
p-value		<0.0001 <sup>†</sup>	0.0003	<0.0001	
Time to almost complete or complete symptom relief by VAS	<b>3</b> a				
Median time in hours (95% CI)	42 (22.0, 48.1)	5.8 (3.6, 7.5)	20 (4.5, 20.0)	20 (6.0, 20.1)	7.5 (5.9, 20.0)
Hazard ratio		5.09	2.25	2.65	
p-value		<0.0001 <sup>†</sup>	0.0127	0.0001	
Change in MSCS score at 4 hours <sup>b</sup>					
least-squares mean difference: PHVS416 - Placebo		-0.79	-0.61	-0.39	-0.61
p-value p-value		<0.0001 <sup>†</sup>	0.0008	0.0291	
TOS at 4 hours <sup>b</sup>					
least-squares mean difference: PHVS416 - Placebo		64.13	62.69	71.06	66.05
p-value p-value		<0.0001 <sup>†</sup>	<0.0001	<0.0001	

#### **PHARVARIS**

<sup>\*</sup>nominal p-value; N = The number of attacks included in the mITT Analysis Set
p-values for PHVS416 20mg and PHVS416 30mg are based on statistical tests in the pre-specified multiple comparison procedure, other p-values are nominal
\*Hazard ratios and p-values are based on marginal Cox proportional hazards models
\*bp-values are based on mixed-effects models for repeated measures
\*The combined PHVS416 results are based on post-hoc analyses to provide a reference of the result by pooling all three active doses

## PHVS416 significantly reduced time to 50% reduction in VAS-3



Median time in hours (95% CI)						
22.8 (20.0, 24.1)						
3.3 (2.4, 3.9)	p < 0.0001 <sup>†</sup>					
4.0 (2.9, 6.0)	p = 0.0003					
4.0 (3.3, 5.8)	p < 0.0001					
3.9 (3.0, 4.8)						
	22.8 (20.0, 24.1) 3.3 (2.4, 3.9) 4.0 (2.9, 6.0) 4.0 (3.3, 5.8)					

†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. 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.

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### **MSCS and TOS: definitions**

- Validated patient-reported outcome measures to comprehensively capture symptom severity and change of HAE attacks
- MSCS (Mean Symptom Complex Severity) score is a point-in-time measure of symptom severity:
  - Patients rated the severity of each affected symptom on a categorical scale (0 = normal, 1 = mild, 2 = moderate, 3 = severe)
  - Calculated as average score from all affected anatomic sites of attack (symptom complexes or SC) pretreatment
  - Decrease in MSCS score reflects improvement in symptom severity
- TOS (Treatment Outcome Score) is a measure of symptom response to treatment:
  - Patient assessment of response for each affected SC recorded on categorical scale (significant improvement [100], improvement [50], same [0], worsening [-50], significant worsening [-100])
  - Calculated as weighted average of the response at all SC using pre-treatment severity as the weight
  - TOS value >0 reflects improvement in symptoms from pre-treatment

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## **Greater improvement in MSCS and TOS with PHVS416 than placebo**

	Placebo	PHVS416 10 mg	PHVS416 20 mg	PHVS416 30 mg	Combined PHVS416
Change in MSCS score at 4 hours					
n	40	32	26	27	85
least-squares mean (95% CI)	-0.29 (-0.51, -0.08)	-1.08 (-1.33, -0.83)	-0.91 (-1.19, -0.62)	-0.68 (-0.95, -0.40)	-0.90 (-1.06, -0.75)
Difference (PHVS416 – Placebo, LSMD) p-value		-0.79 <0.0001 <sup>†</sup>	-0.61 0.0008	-0.39 0.0291	-0.61
TOS at 4 hours					
n	40	32	25	28	85
least-squares mean (95% CI)	-3.62 (-19.68, 12.45)	60.52 (41.74, 79.29)	59.08 (37.58, 80.57)	67.44 (47.15, 87.74)	62.57 (50.95, 74.19)
Difference (PHVS416 – Placebo, LSMD) p-value		64.13 <0.0001 <sup>†</sup>	62.69 <0.0001	71.06 <0.0001	66.05

thominal p-value; MSCS = Mean Symptom Complex Severity, TOS = Treatment Outcome Score, CI = confidence interval, LSMD = least-squares mean difference; least-squares mean, LSMD, CIs, and p-values for MSCS change from pre-treatment/TOS come from mixed-effect models with repeated measures (MMRM). Data after rescue medication use is not included. The combined PHVS416 result is based on post-hoc analysis using similar MMRM with all three active doses combined vs placebo

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## Time to symptom relief by TOS PRO demonstrated consistent efficacy at all doses

	Placebo	PHVS416 10 mg	PHVS416 20 mg	PHVS416 30 mg	Combined PHVS416
Number of attacks	49	36	28	29	93
Attacks achieving <u>"a little better"</u> for all SCs at two consecutive time points - n (%)*	18 ( <b>36.7</b> %)	32 (88.9%)	25 (89.3%)	27 (93.1%)	84 ( <b>90.3</b> %)
Median (95% CI) time by KM estimate (hours)	<b>7.62</b> (3.95, NE)	1.89 (0.97, 3.97)	2.15 (1.75, 4.00)	1.98 (1.80, 3.87)	<b>1.98</b> (1.88, 3.87)
Attacks achieving <u>"a lot better or resolved"</u> for all SCs at any time point – n (%)*	13 <b>(26.5%</b> )	30 (83.3%)	23 (82.1%)	25 (86.2%)	78 <b>(83.9%</b> )
Median (95% CI) time by KM estimate (hours)	<b>23.28</b> (5.78, 47.17)	4.02 (3.93, 5.77)	5.93 (3.90, 8.58)	<b>4.12</b> (3.92, 7.22)	<b>5.23</b> (3.98, 5.78)

<sup>\*</sup> Within 48 hours assessments

TOS = Treatment Outcome Score. PRO = Patient Reported Outcome. SC = Symptom Complex. KM = Kaplan-Meier. NE = Not Estimable

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