



# Corporate Presentation

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April 2024

*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 clinical trials in the U.S. and our ability to resolve any issues to the satisfaction of the FDA or any regulatory agency in a timely manner, the expected timing, progress, or success of our clinical development programs, especially for deucricitibant, which is in late-stage global clinical trials, our ability to replicate the efficacy and safety demonstrated in the RAPIDe-1 and CHAPTER-1 Phase 2 study in ongoing and future nonclinical studies and clinical trials, risks the COVID-19 pandemic, which may adversely impact our business, nonclinical studies, and clinical trials, the outcome and timing of regulatory approvals and the value of our ordinary shares, the timing, costs and other limitations involved in obtaining regulatory approval for our product candidates, deucricitibant immediate-release capsules (PHVS416) and deucricitibant 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, 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, our expectations regarding the time during which we will be an emerging growth company under the JOBS Act or a foreign private issuer, changes and uncertainty in general market, political and economic conditions, including as a result of inflation and 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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# Focused on unmet need in the treatment of hereditary angioedema (HAE) and other bradykinin-mediated diseases



## Competitive product profile

- Deep expertise in bradykinin/B2 receptor 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 currently enrolling
  - 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**

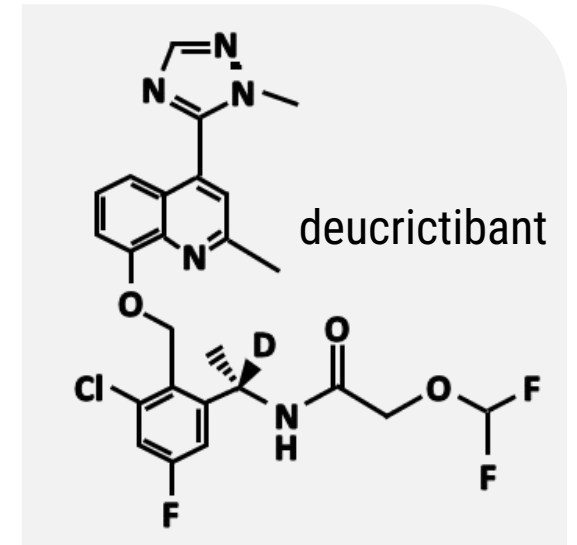


## Strong fundamentals

- **World-wide operations:** the Netherlands, U.S., and Switzerland (headquarters)
- Strong financial position, cash runway at least two years:
  - Approximately **€391M cash as of Dec 31, 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**

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

- Currently in late-stage 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



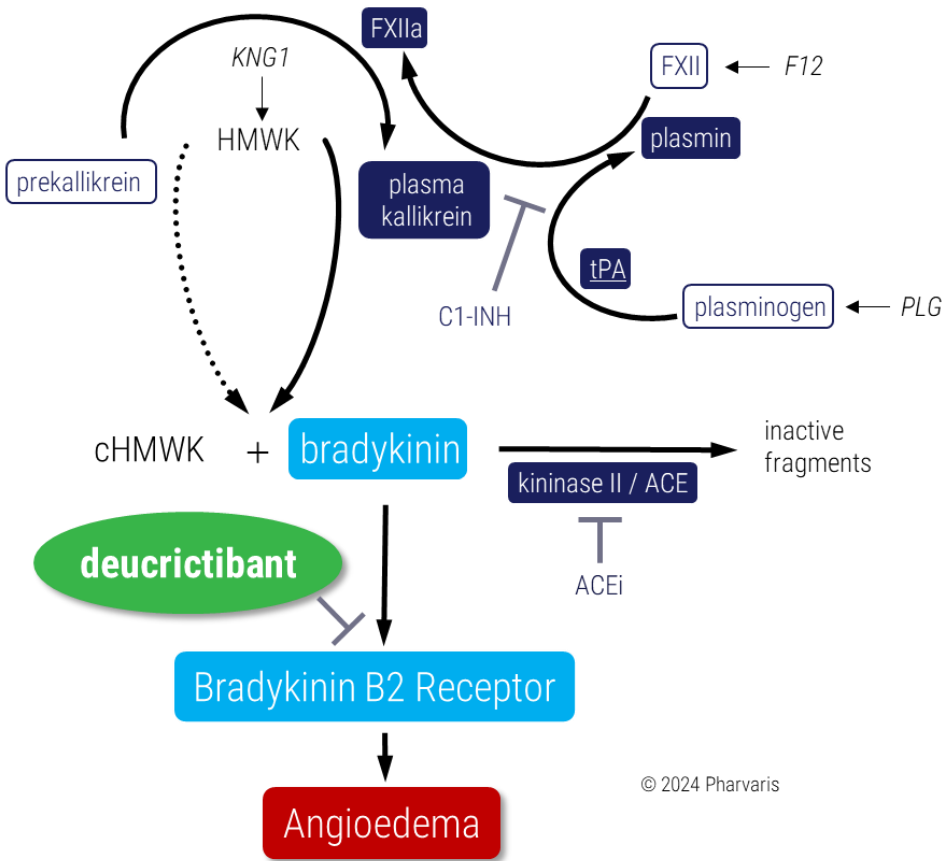
We aspire to develop **novel, oral alternatives** that **improve the standard of care** for people living with HAE and other bradykinin-mediated diseases

Source: Lesage et al, Frontiers in Pharmacology 2020, [doi: 10.3389/fphar.2020.00916](https://doi.org/10.3389/fphar.2020.00916); Lesage et al, Int. Immunopharmacology 2022, [doi.org/10.1016/j.intimp.2022.108523](https://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>

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

Hereditary	HAE due to C1INH deficiency	<b>HAE Type 1</b>
		<b>HAE Type 2</b>
	HAE with normal C1INH	<b>HAE-FXII</b>
		<b>HAE-PLG</b>
		<b>HAE-KNG</b>
		<b>HAE-HSST</b>
		HAE-ANGPT
		HAE-MYOF
Acquired		<b>HAE-unknown</b>
	C1INH deficiency (AAE C1-INH)	<b>Lymphoproliferative disorders, B-cell malignancies</b>
		<b>Autoimmune disorders</b>
		<b>Other disorders</b>
	Drug-induced	<b>ACE-inhibitor</b>
		Other
	Idiopathic	<b>Histamine independent</b>
		Histamine dependent

***bold** = known or potential role for bradykinin involvement in disease*



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**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 (<https://2023.haenetworkshop.hu/program/index.php>, <https://www.linkedin.com/feed/update/urn:li:activity:7060638305842778112/>); Shi et al 2021 Clin Immunol. 230 ([doi.org/10.1016/j.clim.2021.108819](https://doi.org/10.1016/j.clim.2021.108819)), Magerl et al 2023: DANCE Classification (GA²LEN UCARE, Dec. 7-9)

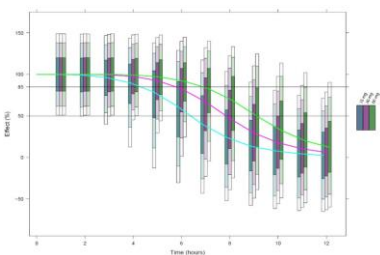
**Notes:** HMWK: high-molecular-weight kininogen; cHMWK: cleaved high-molecular-weight kininogen; FXII(a): Factor XII(a); ACE(i): angiotensin-converting enzyme (inhibitor); tPA: tissue plasminogen activator; KNG1: gene encoding HMWK; PLG: gene encoding plasminogen; FXII: gene encoding FXII; ANGPT: gene encoding angiopoietin; MYOF: gene encoding myoferlin; HSST: gene encoding heparan sulfate sulfotransferase; SCLS: systemic capillary leak syndrome

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

Bradykinin, injected *IV* in healthy volunteers, induces a transient, limited change in cardiac parameters (heart rate ↑, blood pressure ↓) which can be blocked by pre-injection of a bradykinin B2 receptor antagonist (e.g., icatibant or deucricitbant)

## clinical

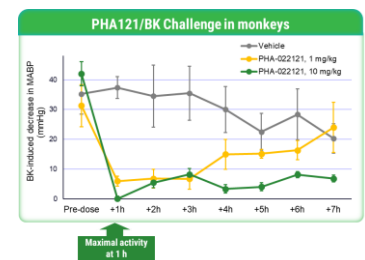
### Icatibant development program (shared mechanism)



As assessed by FDA, exposure of icatibant above  $EC_{85}$  for 6 hours correlates with clinical activity

## nonclinical

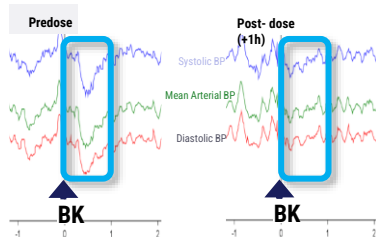
### Non-human primate study



Oral deucricitbant suppresses BK effect in NHP faster than SQ icatibant; target exposures for Phase 1

## clinical

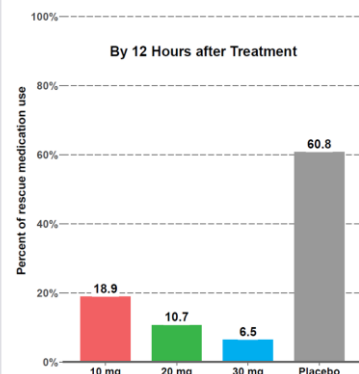
### Phase 1 healthy volunteer study



$EC_{85}$  assessed in humans at 13.8 ng/mL; target exposure for studies in people living with HAE

## clinical

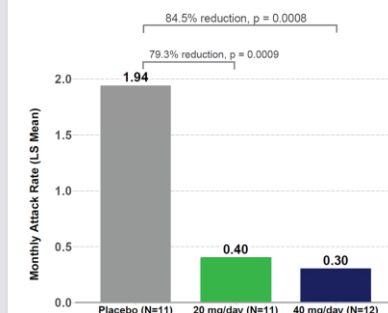
### RAPIDe-1 Phase 2 on-demand



Clinical efficacy correlates with exposure exceeding and remaining above  $EC_{85}$

## clinical

### CHAPTER-1 Phase 2 prophylaxis



Clinical efficacy demonstrated based on dose prediction targeting exposure above  $EC_{85}$

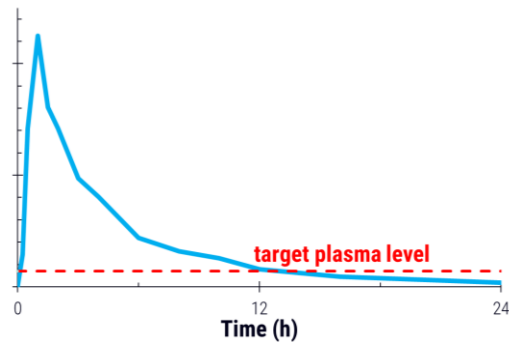
[https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2011/022150Orig1s000ClinPharmR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022150Orig1s000ClinPharmR.pdf); Maurer et al 2020: Long-term effectiveness and safety of icatibant for the on-demand treatment of hereditary angioedema attacks: 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;  $EC_{85}$ : effective concentration achieving 85% inhibition of bradykinin effect

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

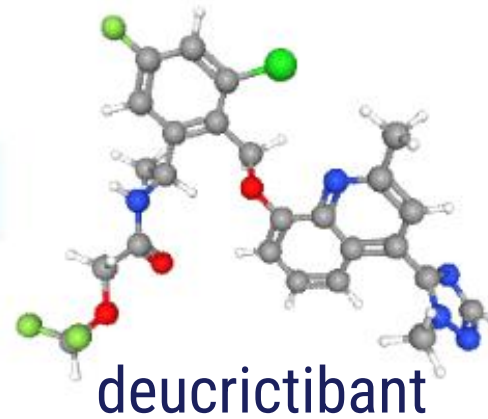
## deucrictibant (PHVS416)

Immediate-release capsule

rapid absorption



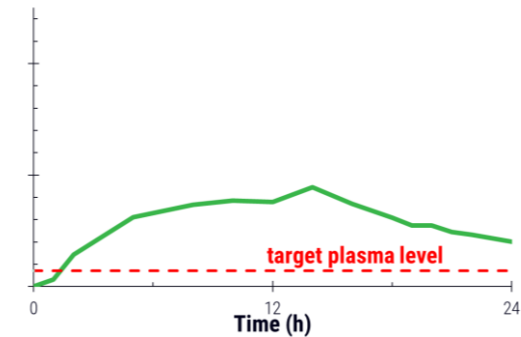
Aim to provide rapid and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form\*



## deucrictibant (PHVS719)

Extended-release tablet

sustained absorption



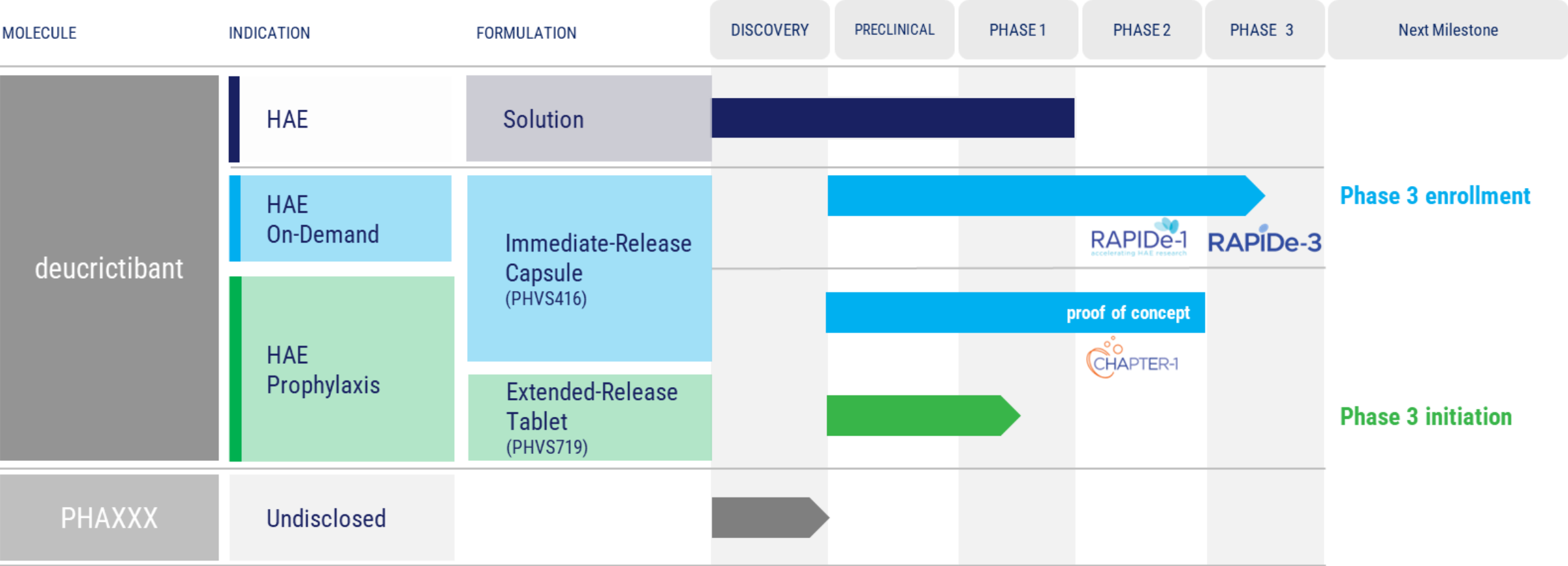
Aim to provide sustained exposure of attack-preventing medicine in a convenient, small oral dosage form\*

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

\*Aspirational; to be confirmed with clinical data



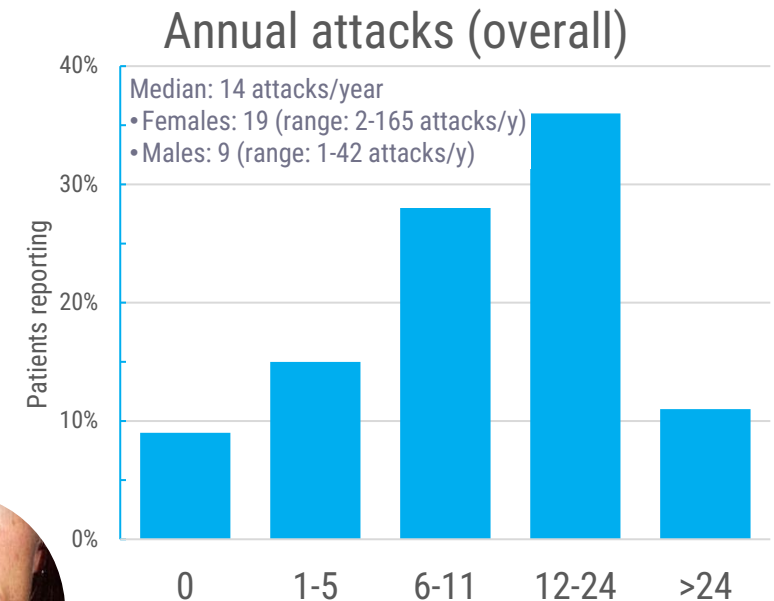
# Wholly-owned pipeline focused on bradykinin B2 receptor mechanism





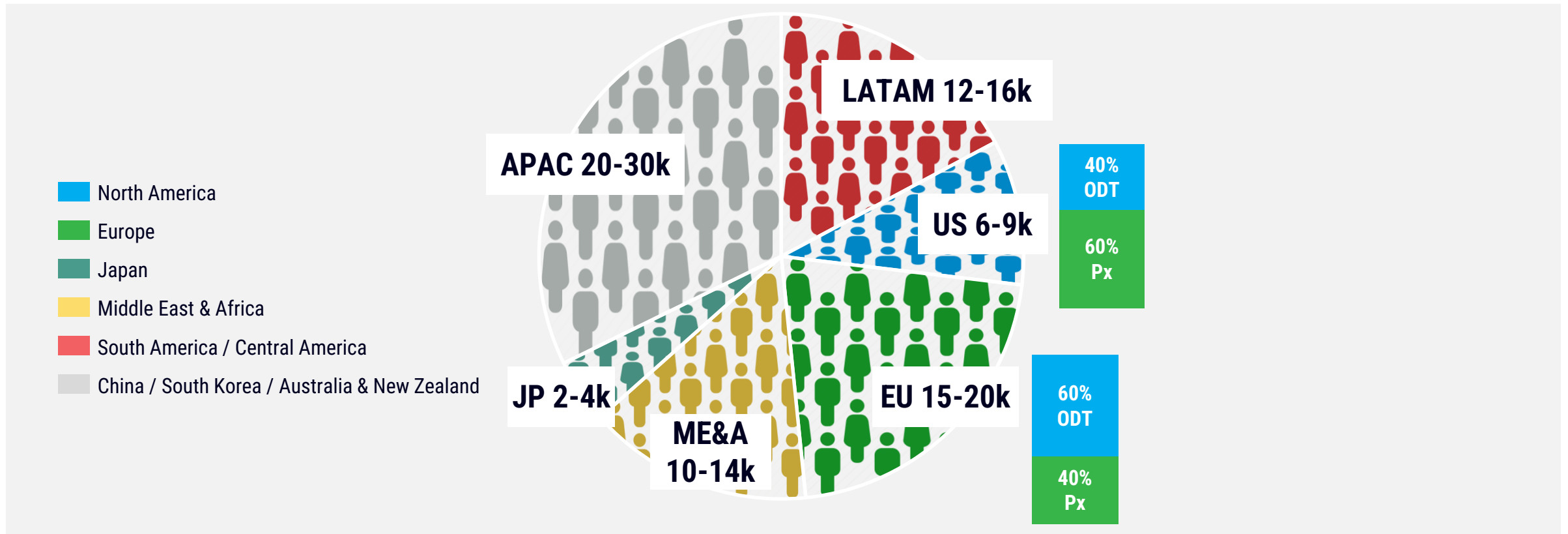
# HAE: A rare, life-long genetic condition with significant burden from unpredictable, debilitating, and potentially lethal attacks of swelling

- 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>; 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 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**

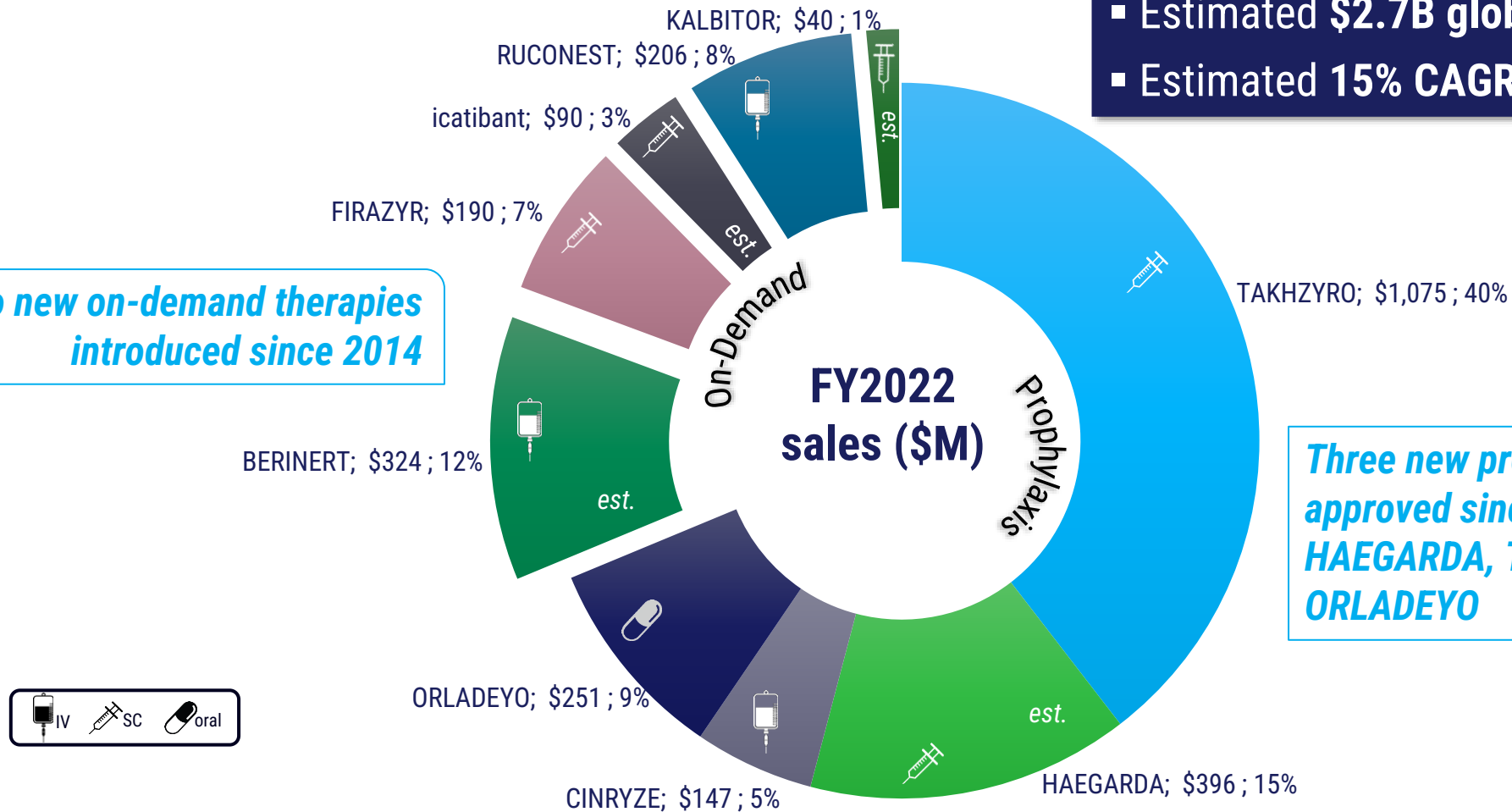
Source: Proprietary company research 2022

# 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

*No new on-demand therapies introduced since 2014*

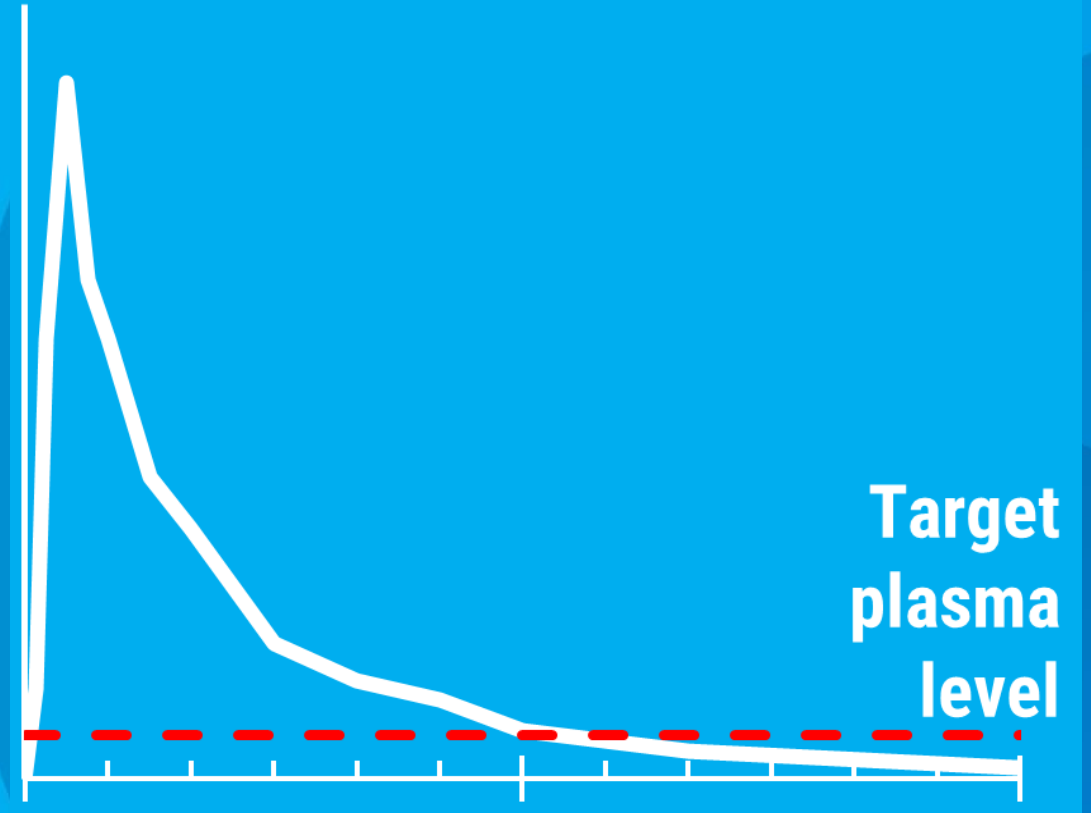
*Three new prophylactic products approved since 2017: HAEGARDA, TAKHZYRO, and ORLADEYO*



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

*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** ...

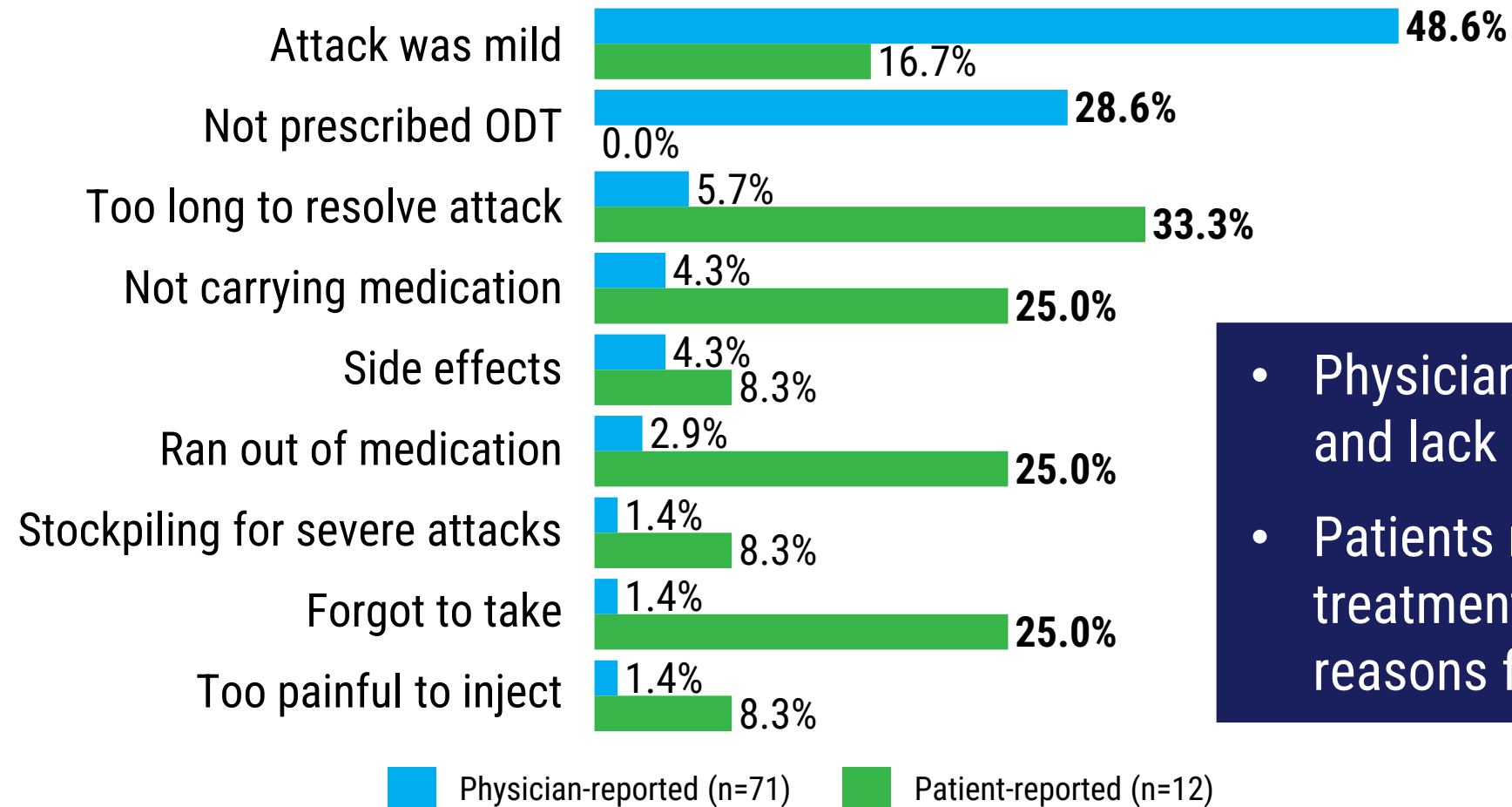


... while finding a place to administer the drug causes an **extra burden**

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** ...

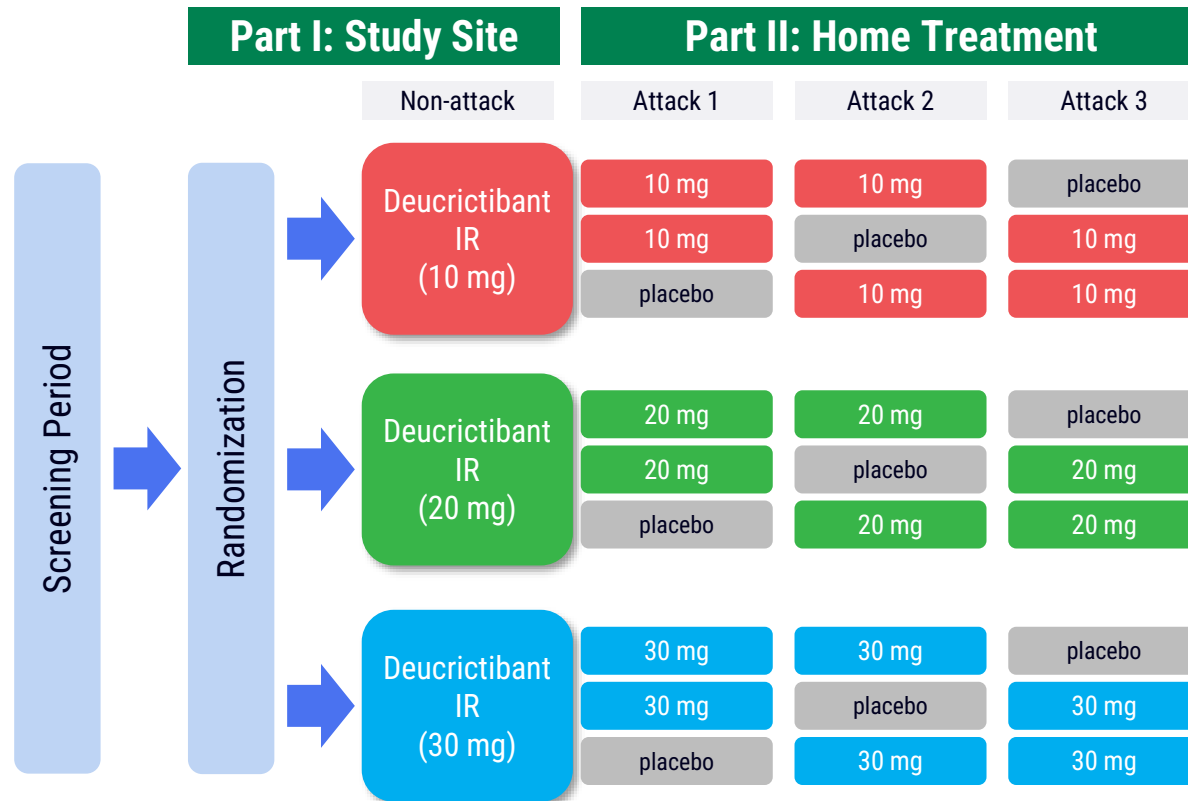
... with **single dose durability** ...

... 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 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 deucricitibant in clinic for PK and safety assessment
  - Part II: patients treated three attacks with two deucricitibant 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

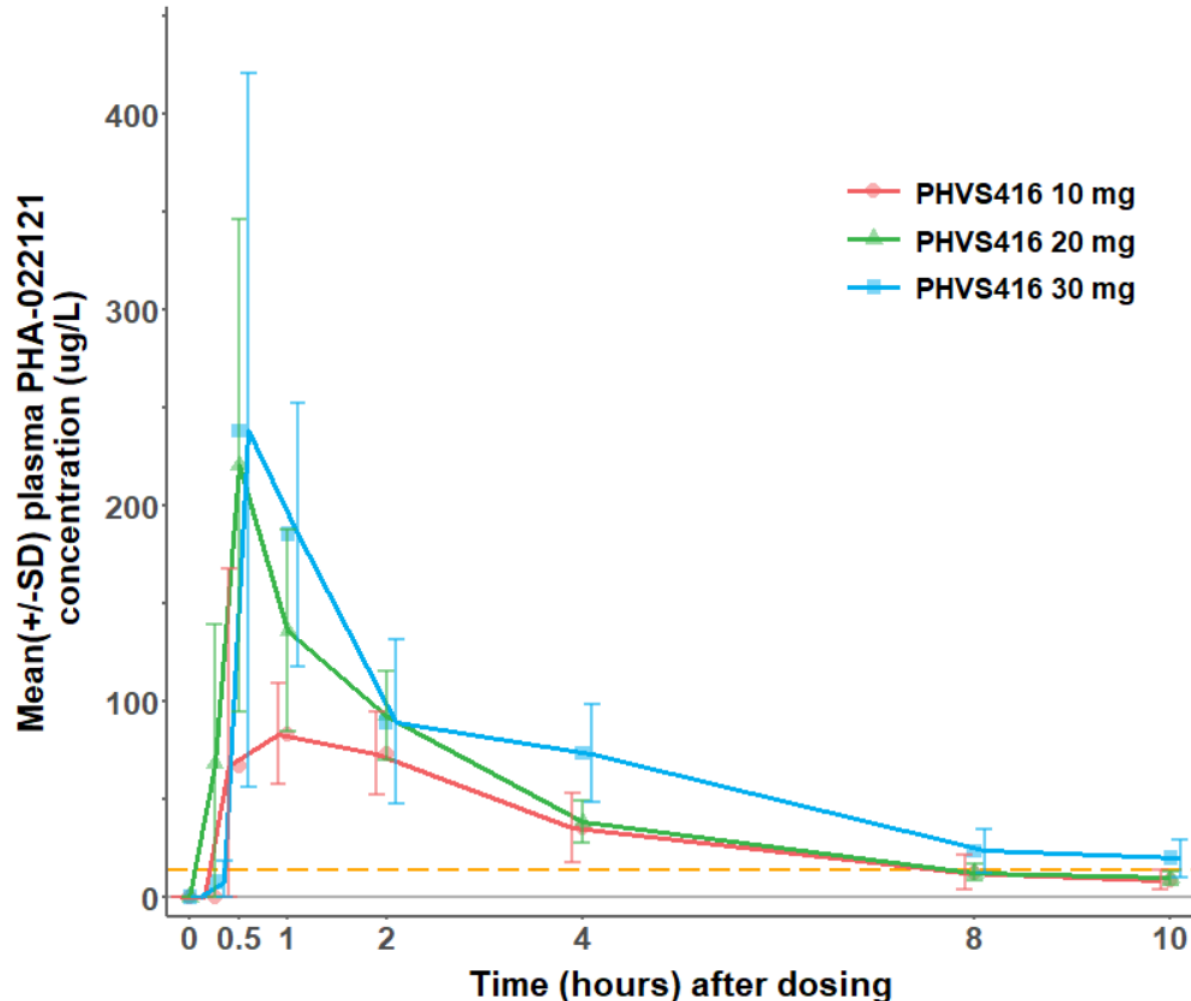
Source: [www.hae-rapide.com](http://www.hae-rapide.com); <https://clinicaltrials.gov/ct2/show/NCT04618211>; <https://hae-rapide.us/>; <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2020-003445-11>

# 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**
- 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

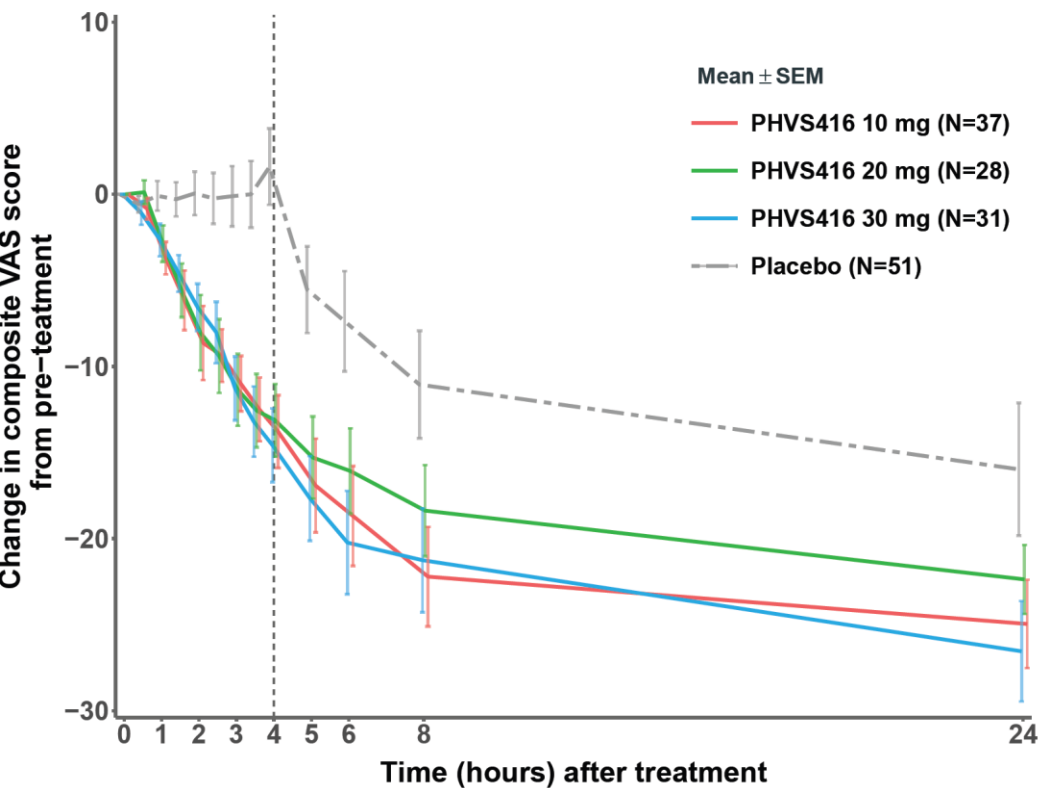
**Consistent outcomes** observed  
across all endpoints and types of measurements

# 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: Deucrictibant IR significantly reduced attack symptoms by VAS-3 at 4h

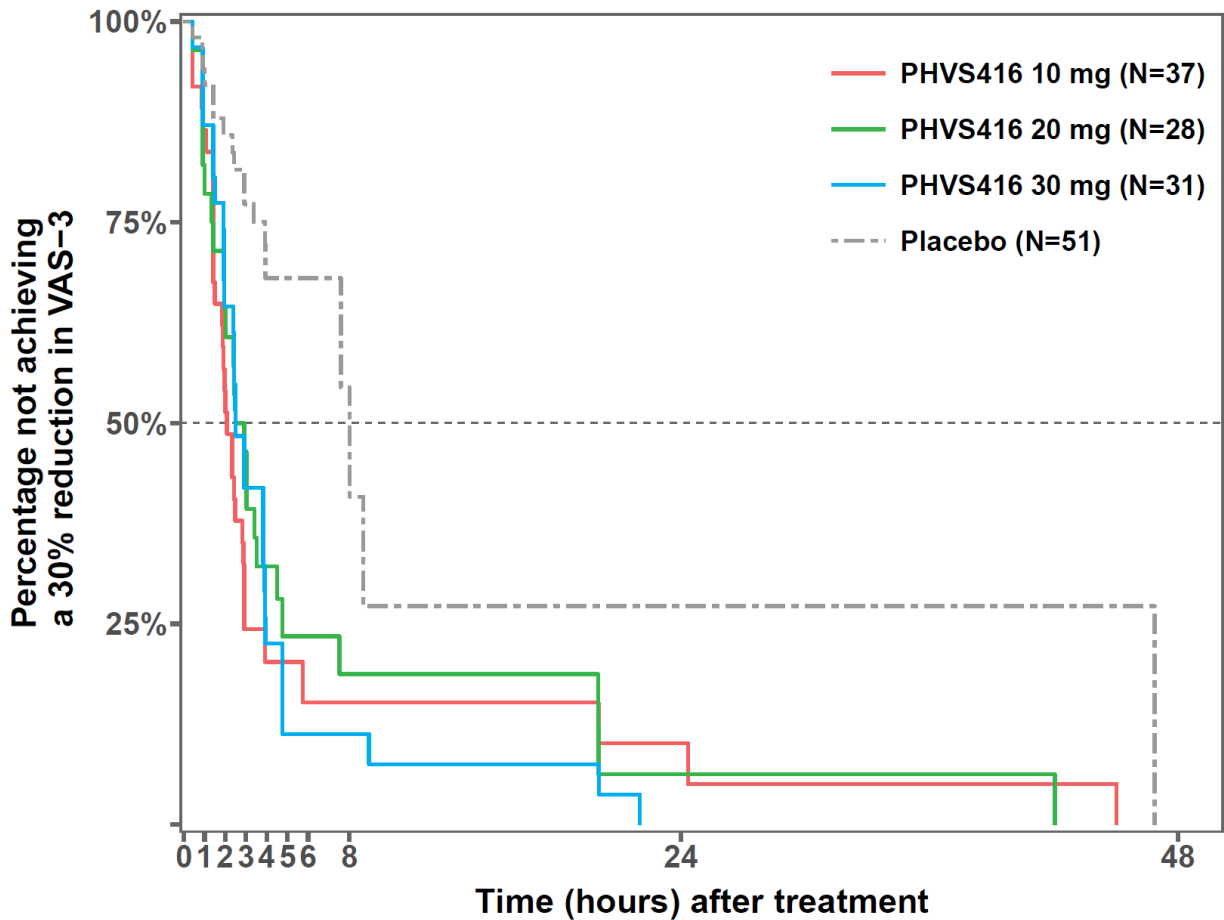


Difference from placebo in change from pre-treatment to 4 h post-treatment, least-squares mean (95% CI)		
PHVS416 10 mg	-16.75 (-21.52, -11.97)	p < 0.0001 <sup>†</sup>
PHVS416 20 mg	-15.02 (-20.22, -9.81)	p < 0.0001
PHVS416 30 mg	-16.28 (-21.27, -11.29)	p < 0.0001
Combined PHVS416	-16.08 (-19.87, -12.29)	

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

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



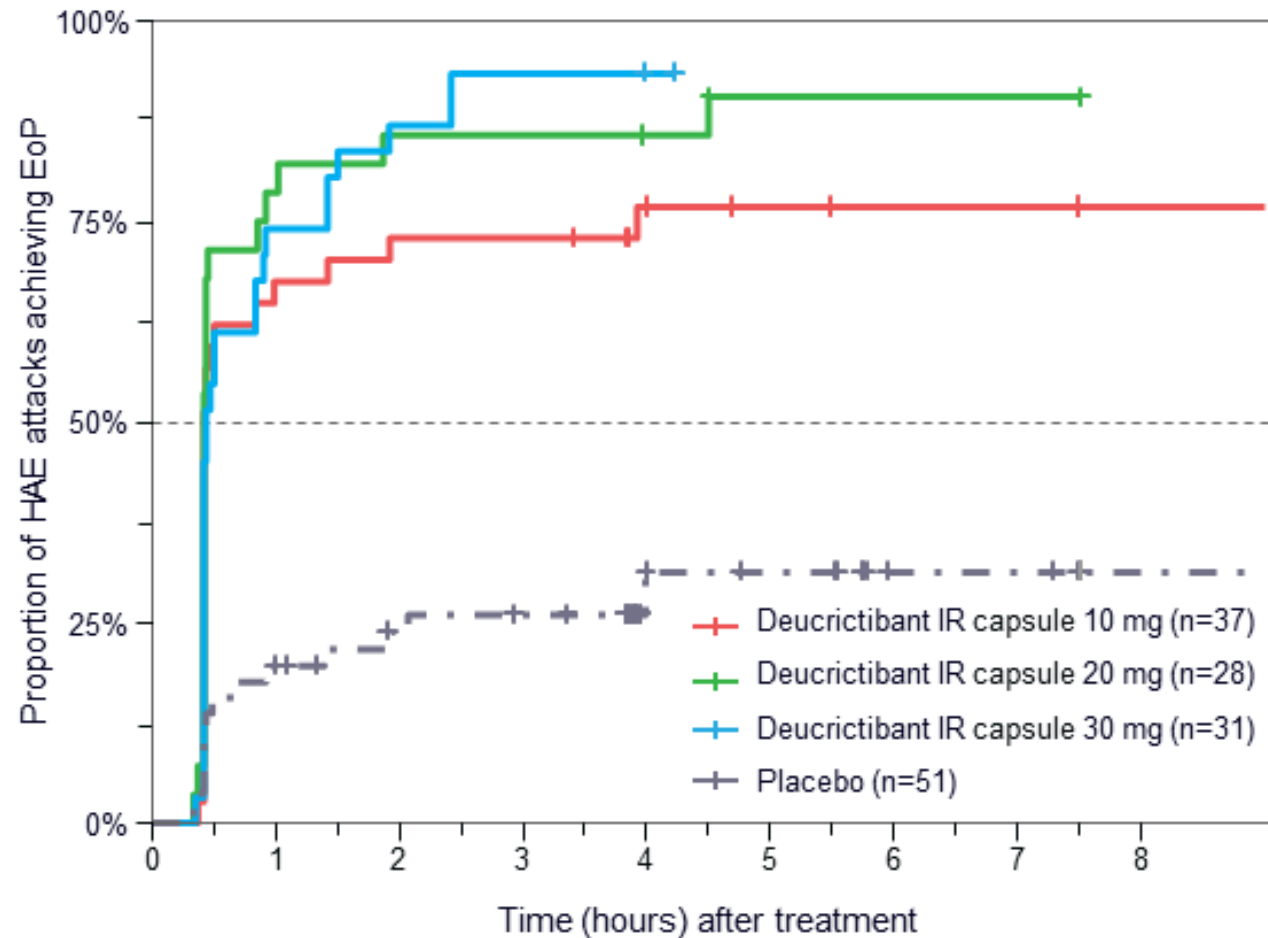
## Median time in hours (95% CI)

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.

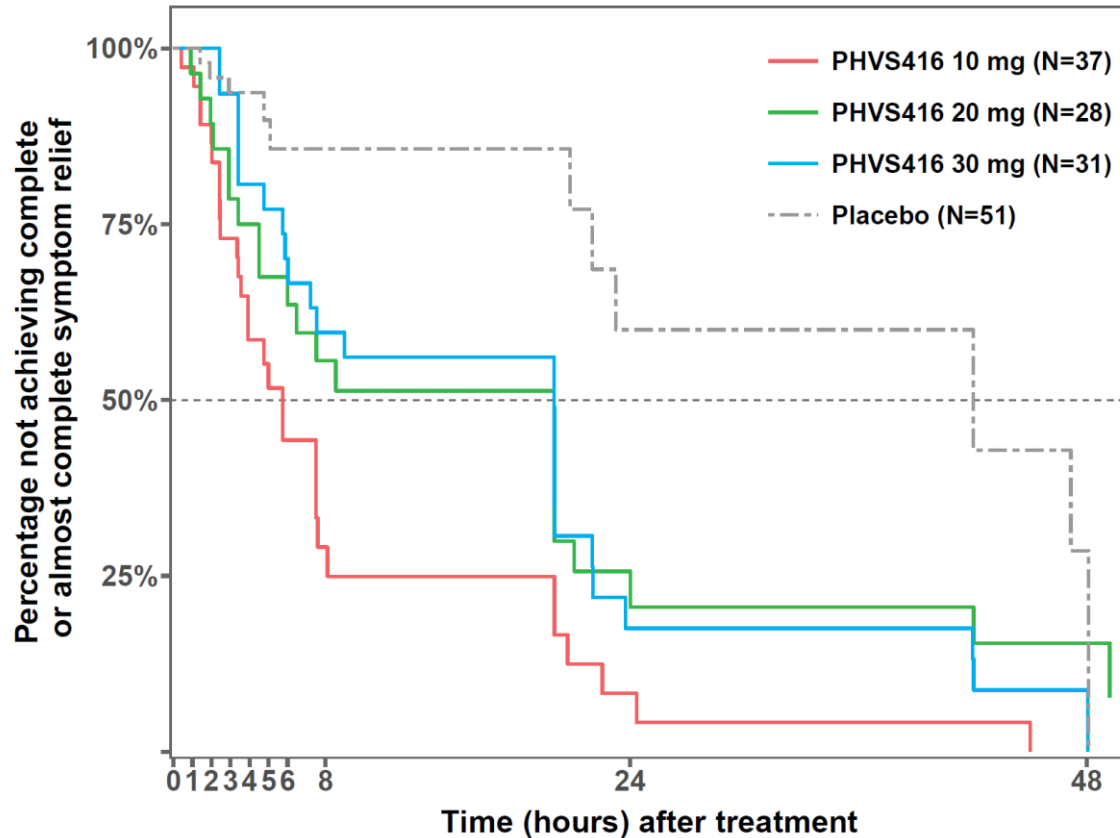
# In a post-hoc analysis, patients on deucricitibant achieved end of progression by VAS-3 within 25 to 26 min



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



# Deucrictibant IR significantly reduced time to almost complete or complete symptom relief (all individual VAS $\leq 10$ )



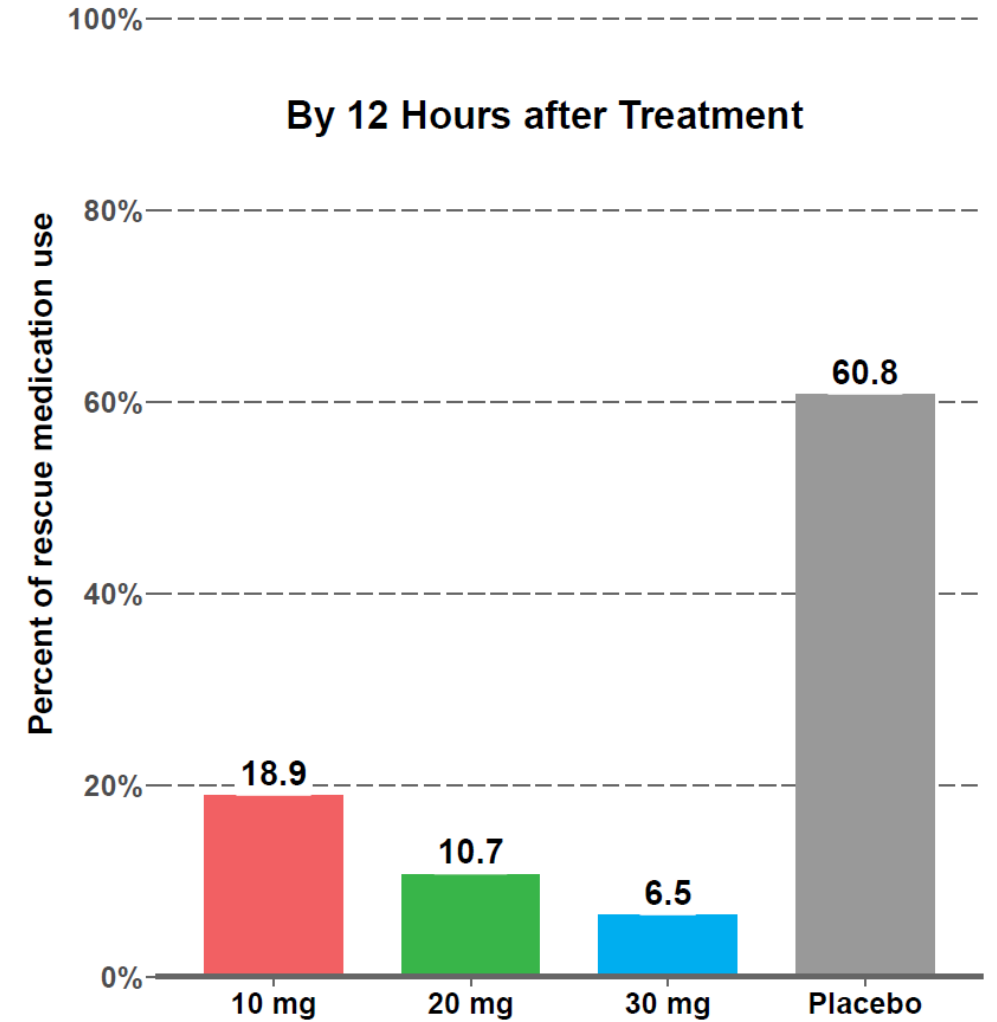
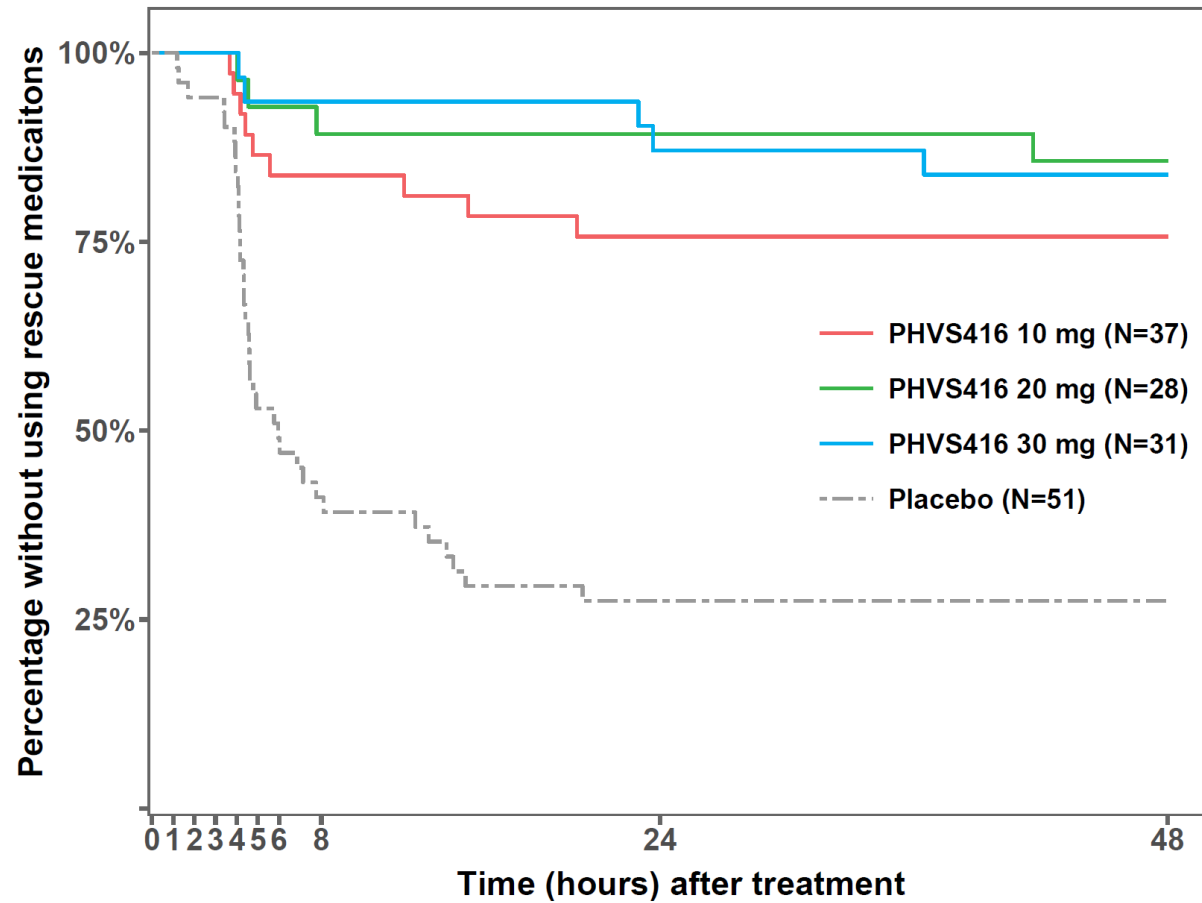
## Median time in hours (95% CI)

Placebo	42.0 (22.0, 48.1)	
Deucrictibant IR 10 mg	5.8 (3.6, 7.5)	$p < 0.0001^\dagger$
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.

# Patients treating with deucricitbant IR used substantially less rescue medication



N = The number of attacks in the mITT Analysis Set

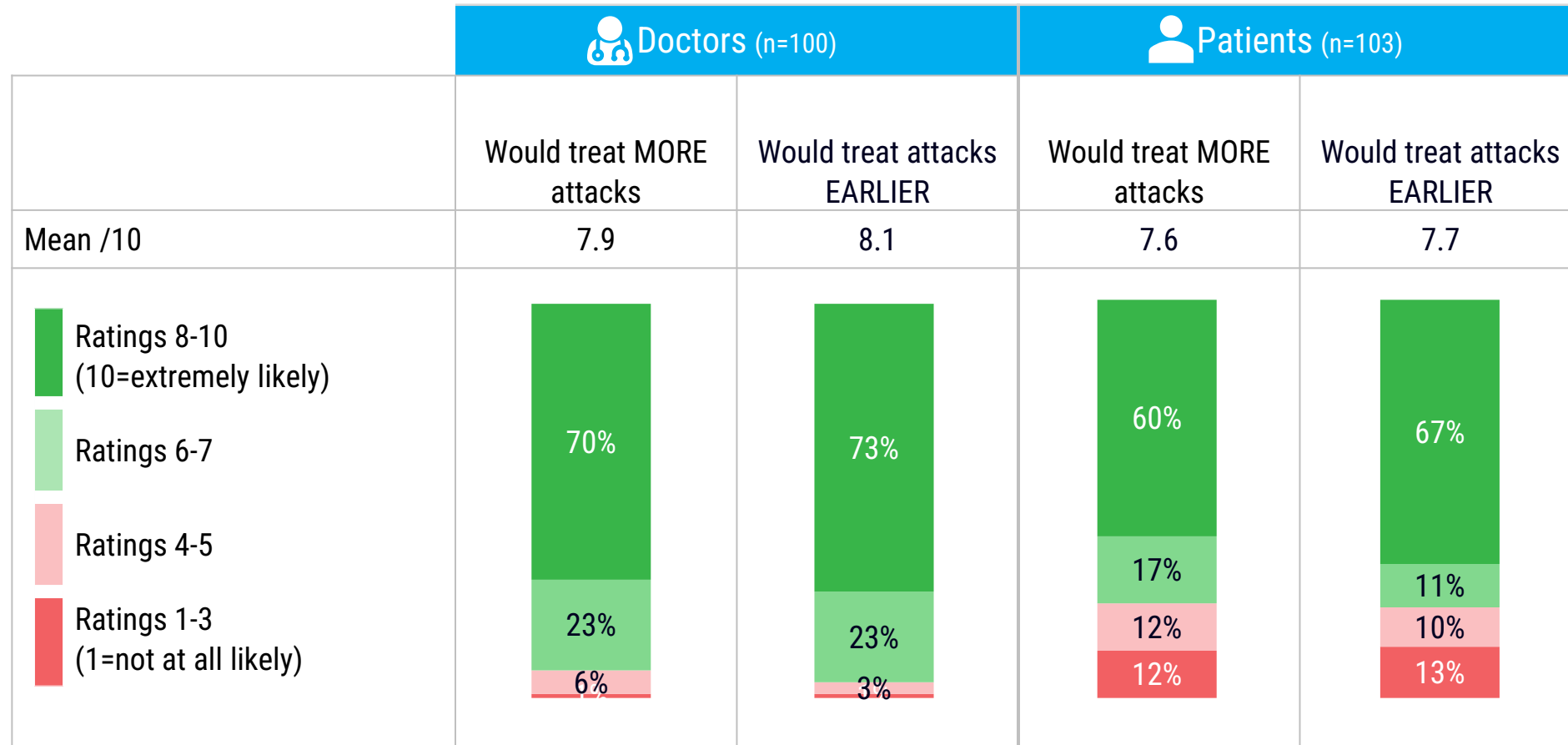
# Deucrictibant IR was well tolerated at all doses

- 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 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
<b>Subjects (Part I) or Attacks (Part II) with any treatment related AEs</b>	<b>1 (4.3%)</b>	<b>1 (4.2%)</b>	<b>-</b>	<b>1 (1.9%)</b>	<b>-</b>	<b>-</b>	<b>1 (2.8%)</b>
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



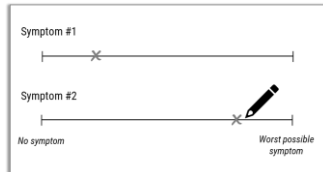
Source: Proprietary Pharvaris research, 2022 (representative sample of patients, n = 103, and doctors, n = 100)

# 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 severity
- Analog scale with an 'X' hand-marked to reflect severity of attack

**2008–2011**  
**Jerini-Shire**



## Why do we need change?

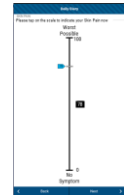
- Addressing user experience to leverage technology and accuracy of data collection<sup>1</sup>
- HAE ODT trials require frequent assessments to be recorded by participants; a digital tool is an accessible method for timely data input



## 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**

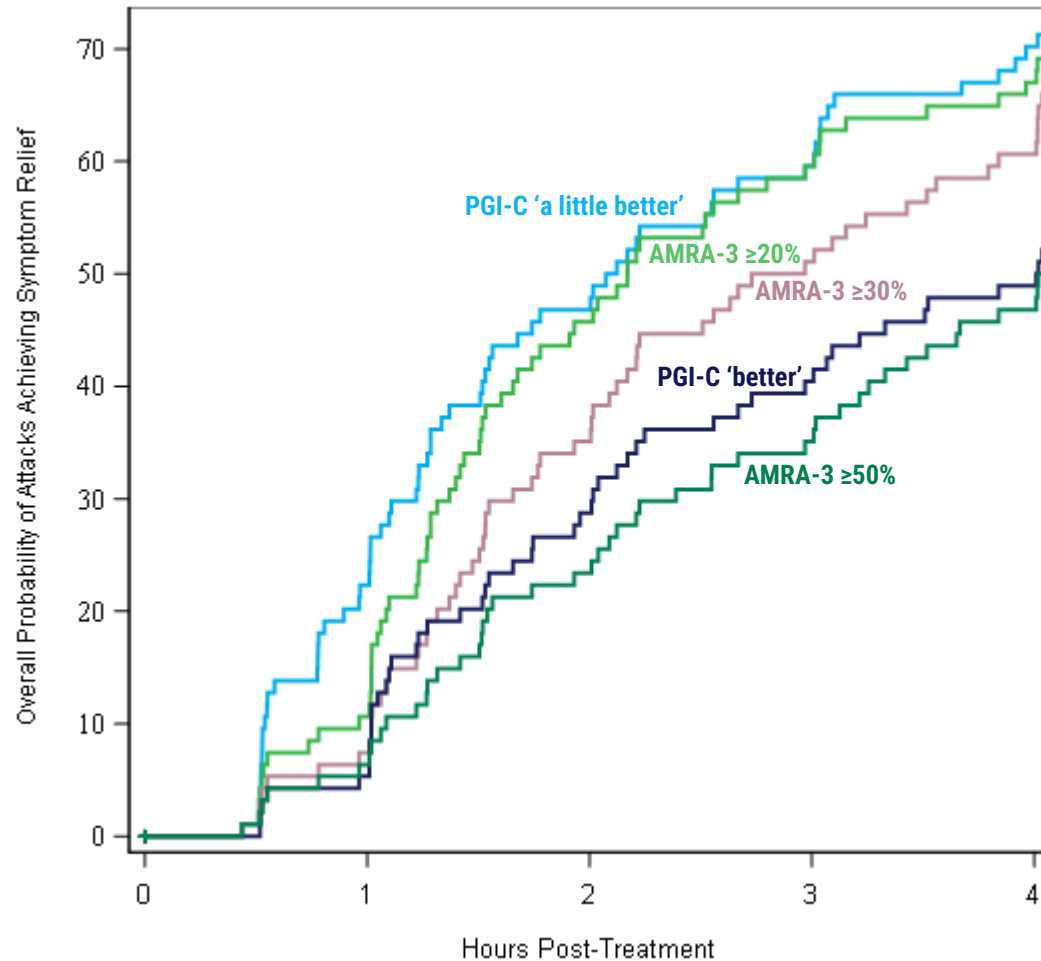


A numeric rating scale requires  
a self-explanatory name

## Angioedema symptom Rating scAle (AMRA)

<sup>1</sup> CDER. Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for Purpose Clinical Outcome Assessments. FDA. June 2022. Accessed December 18, 2023. <https://www.fda.gov/media/159500/download>

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



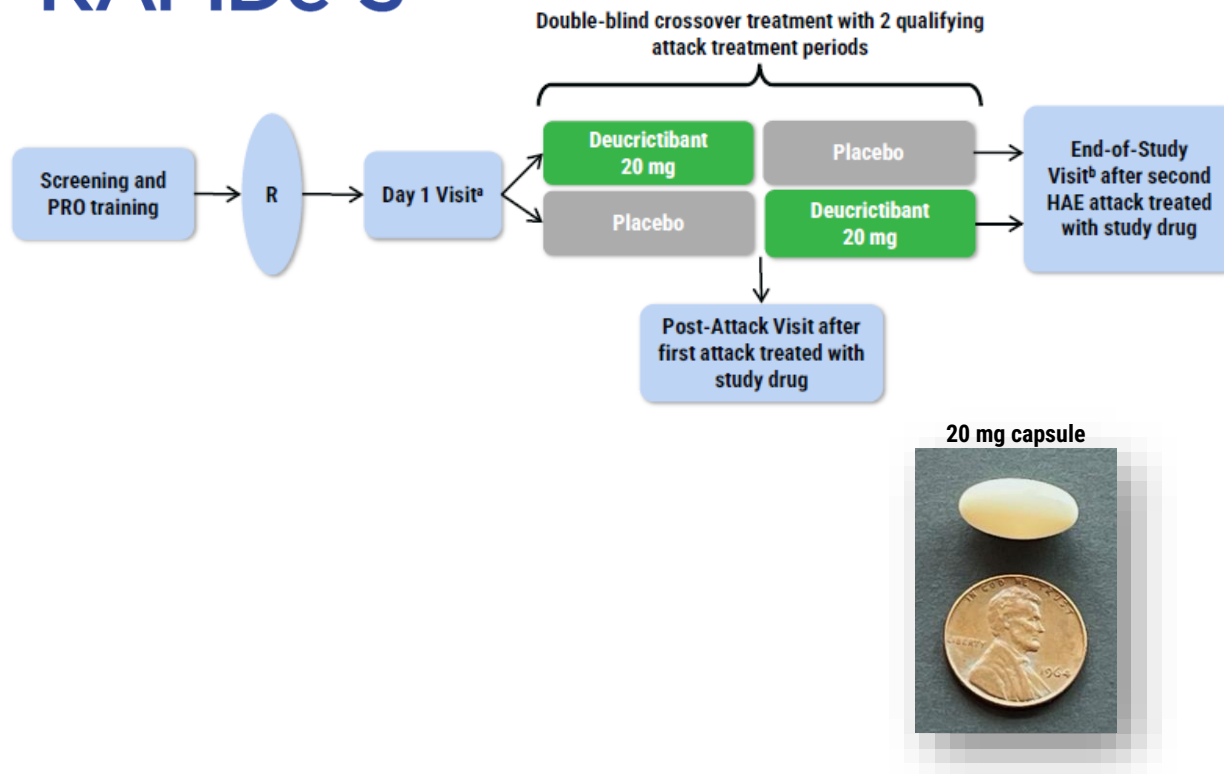
PRO instrument	Events (n)	Median time to, h (95% CI)
PGI-C "a little better"	90	2.147 (1.518, 3.017)
AMRA-3 20% reduction from pre-treatment	89	2.191 (1.655, 3.035)
AMRA-3 30% reduction from pre-treatment	89	2.990 (2.123, 4.011)
PGI-C "better"	92	3.925 (2.969, 5.055)
PGI-S 1-level reduction	91	4.012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

- **Similar median time to symptom relief using **AMRA-3  $\geq 20\%$  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](https://ir.pharvaris.com/static-files/f2d3d4ea-2526-4885-9951-a90015add462))

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

## RAPiDe-3



### ■ Endpoints

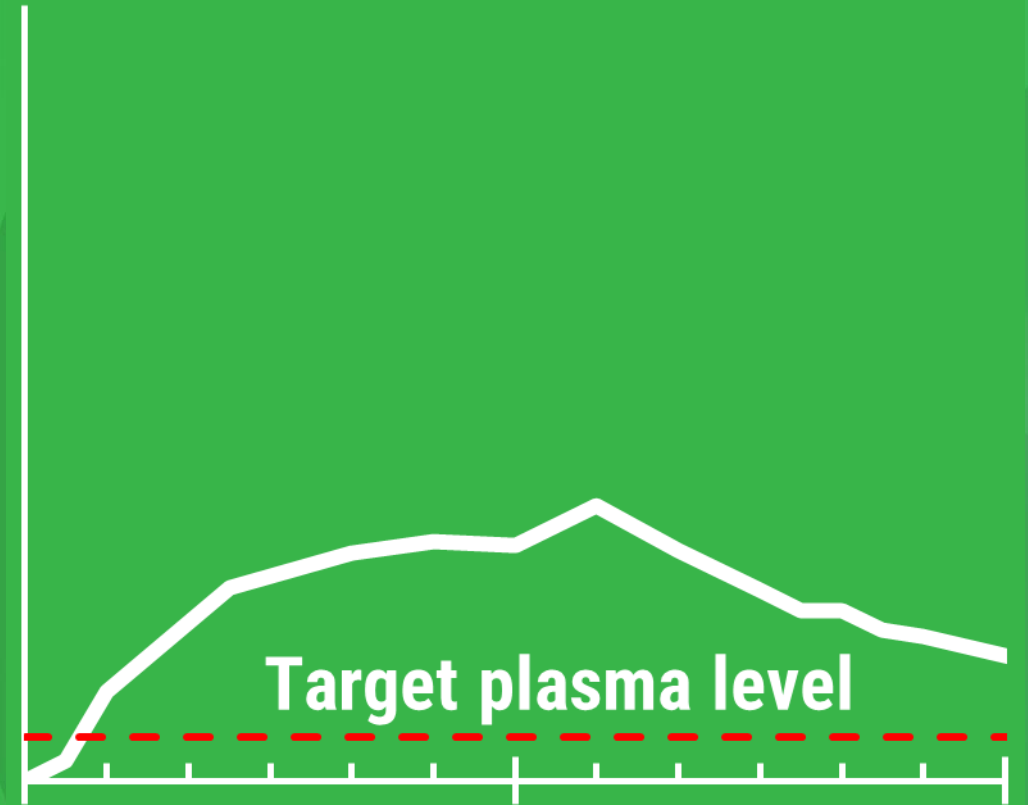
- Onset of symptom relief
  - Patient Global Impression of Change (PGI-C) rating of at least “a little better” for two consecutive timepoints within 12 hours post-treatment
- Secondary
  - Time to end of progression of attack symptoms, substantial symptom relief, and symptom resolution
    - PGI-C, Patient 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



## *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**

**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)

# 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

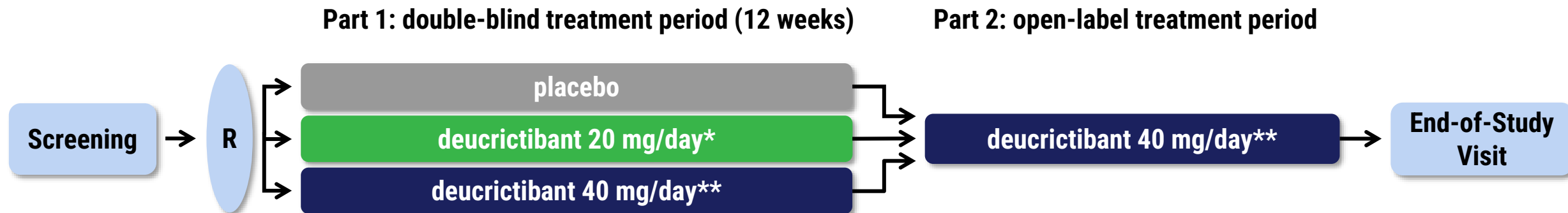
\*40 mg/day deucricitibant treatment group; %reduction in monthly attack rate is based on a Poisson regression model

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 deucritibant for long-term prophylaxis in HAE-1/2

- 34 participants enrolled in North America and Europe

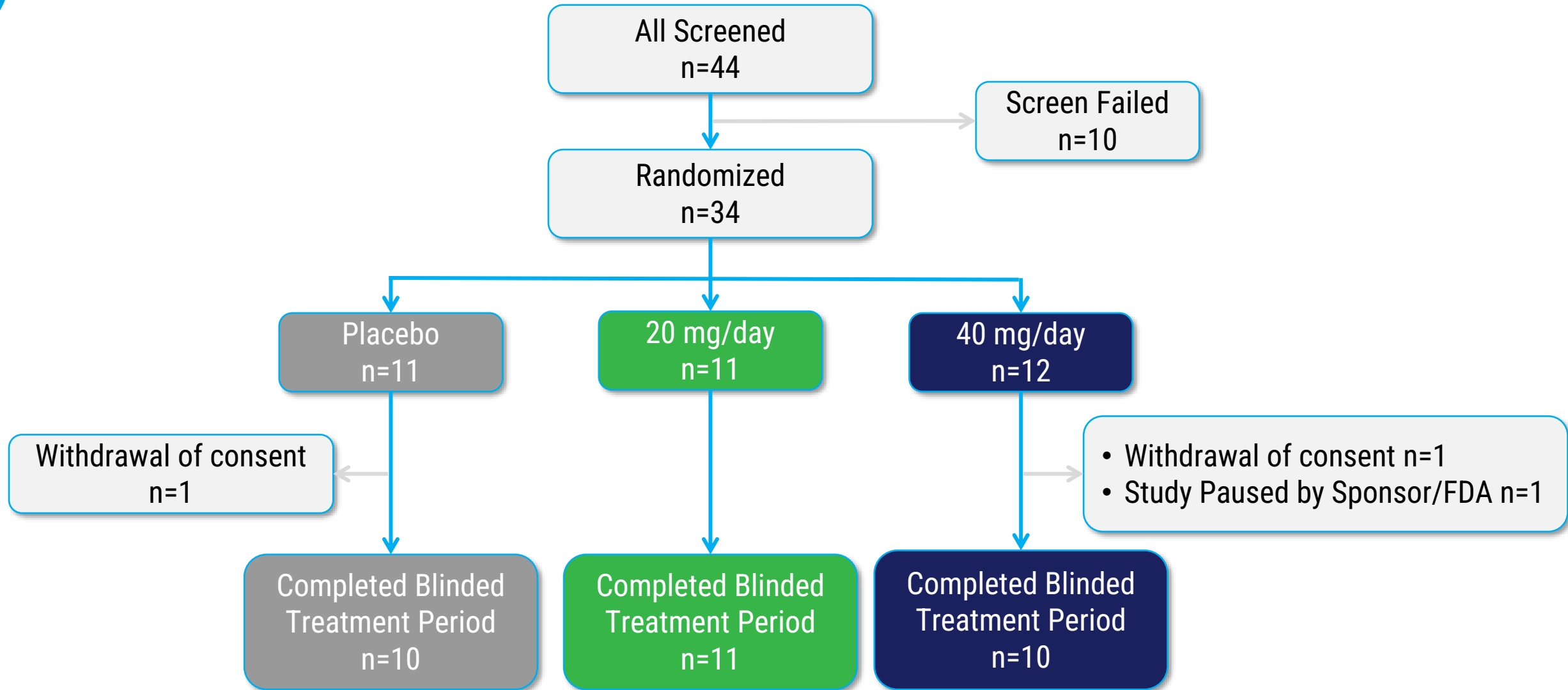


R = randomization;

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

\*\*deucritibant 40 mg/day = deucritibant 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 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/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)

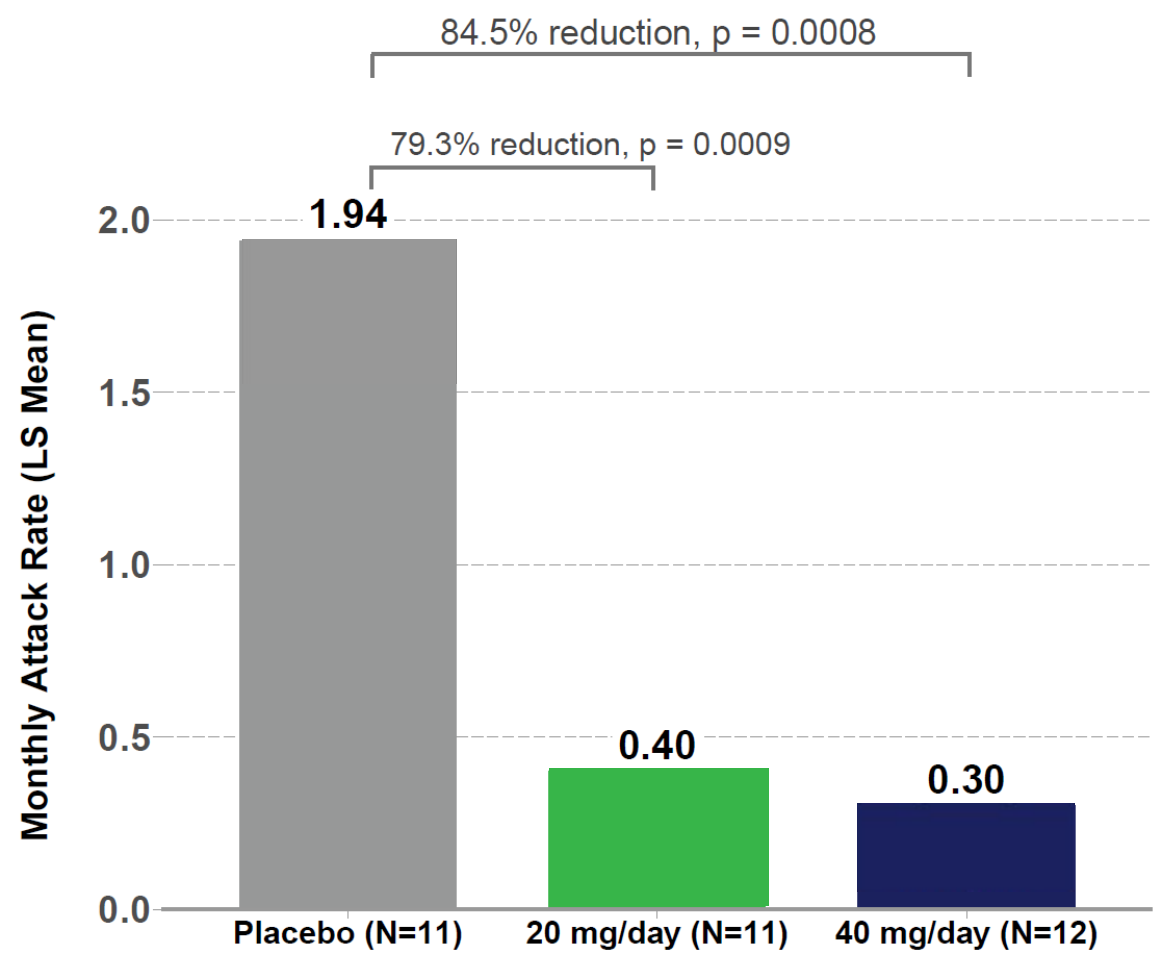
20 mg/day = deucricitibant immediate release (IR) capsules 10 mg twice daily.

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

N = number of randomized participants.

# Primary endpoint met: deucricitibant significantly reduced attack rate

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

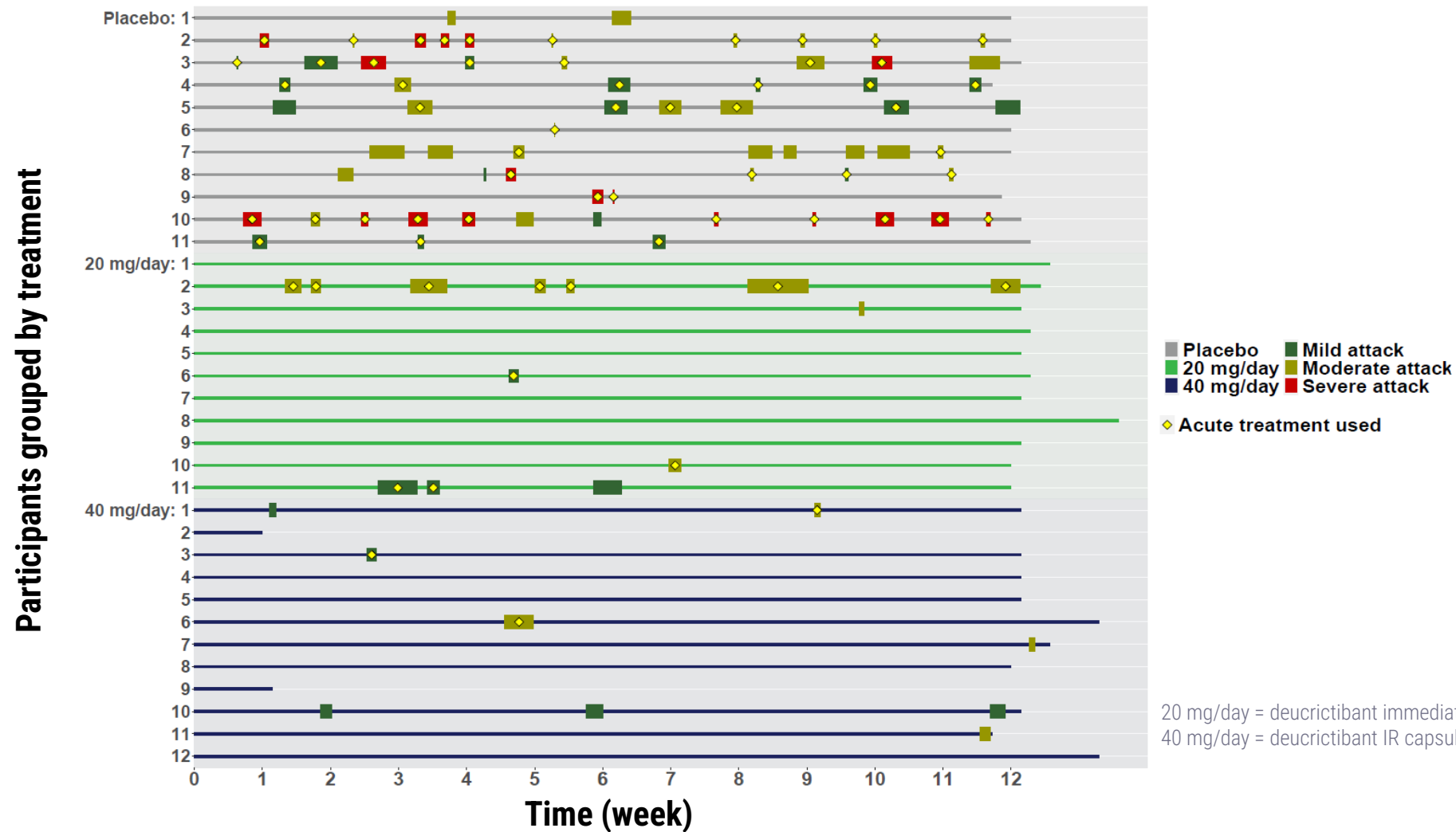


	Placebo N=11	20 mg/day N=11	40 mg/day N=12
Monthly attack rate – Median			
Baseline	1.67	1.67	1.74
On study	2.15	0	0.15
Change from baseline	0.33	-1.34	-1.59
% change from baseline	17%	-100%	-96%
Model-based inference			
LS mean	1.94	0.40	0.30
% reduction vs placebo		79.3%	84.5%
p-value		0.0009	0.0008

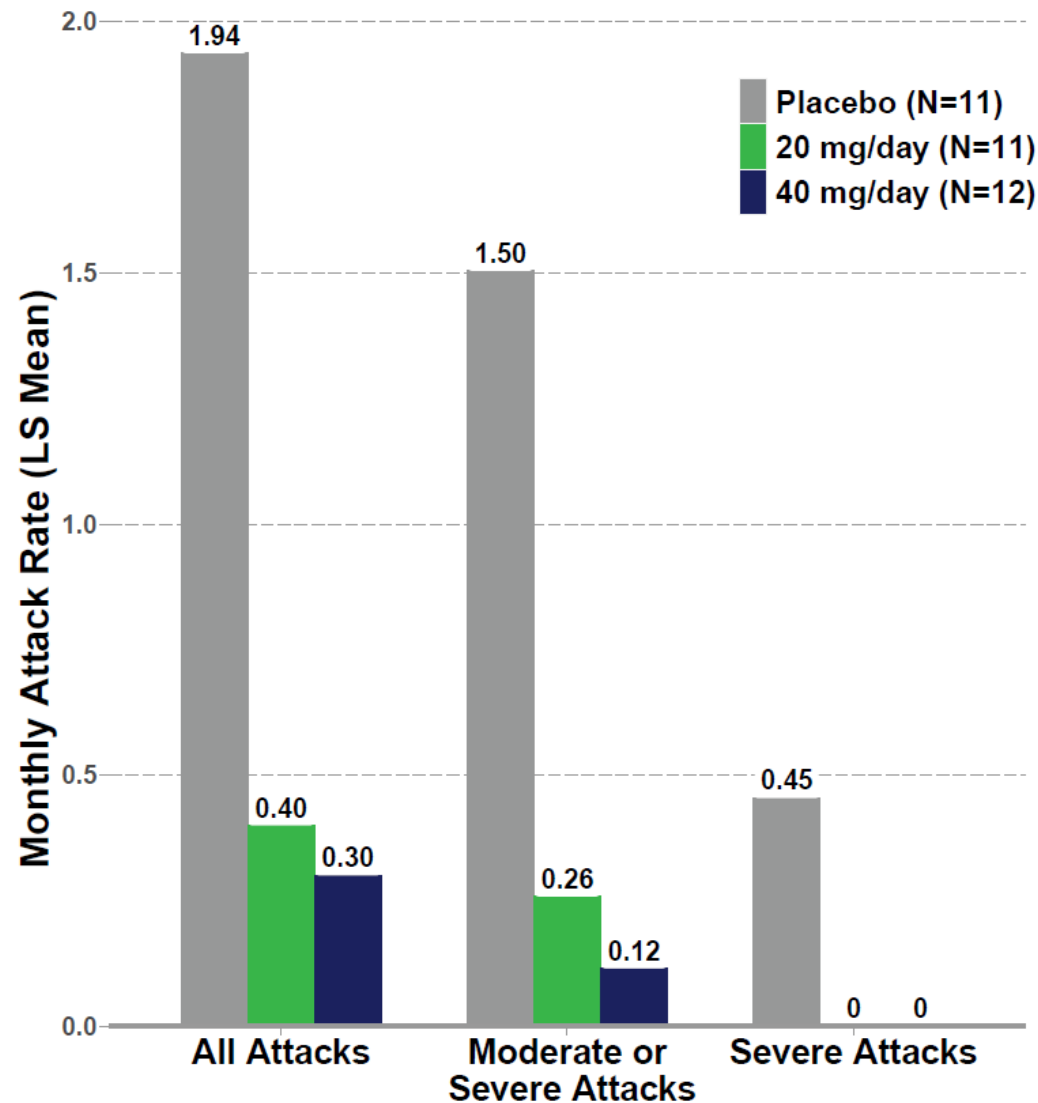
20 mg/day = deucricitibant immediate release (IR) capsules 10 mg twice daily.  
40 mg/day = deucricitibant IR capsules 20 mg twice daily.  
N = number of randomized participants.  
LS mean = least squares mean. Model-based inferences are based on a Poisson regression model adjusted for baseline attack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



# Significant attack reduction and no severe attacks with deucricitibant



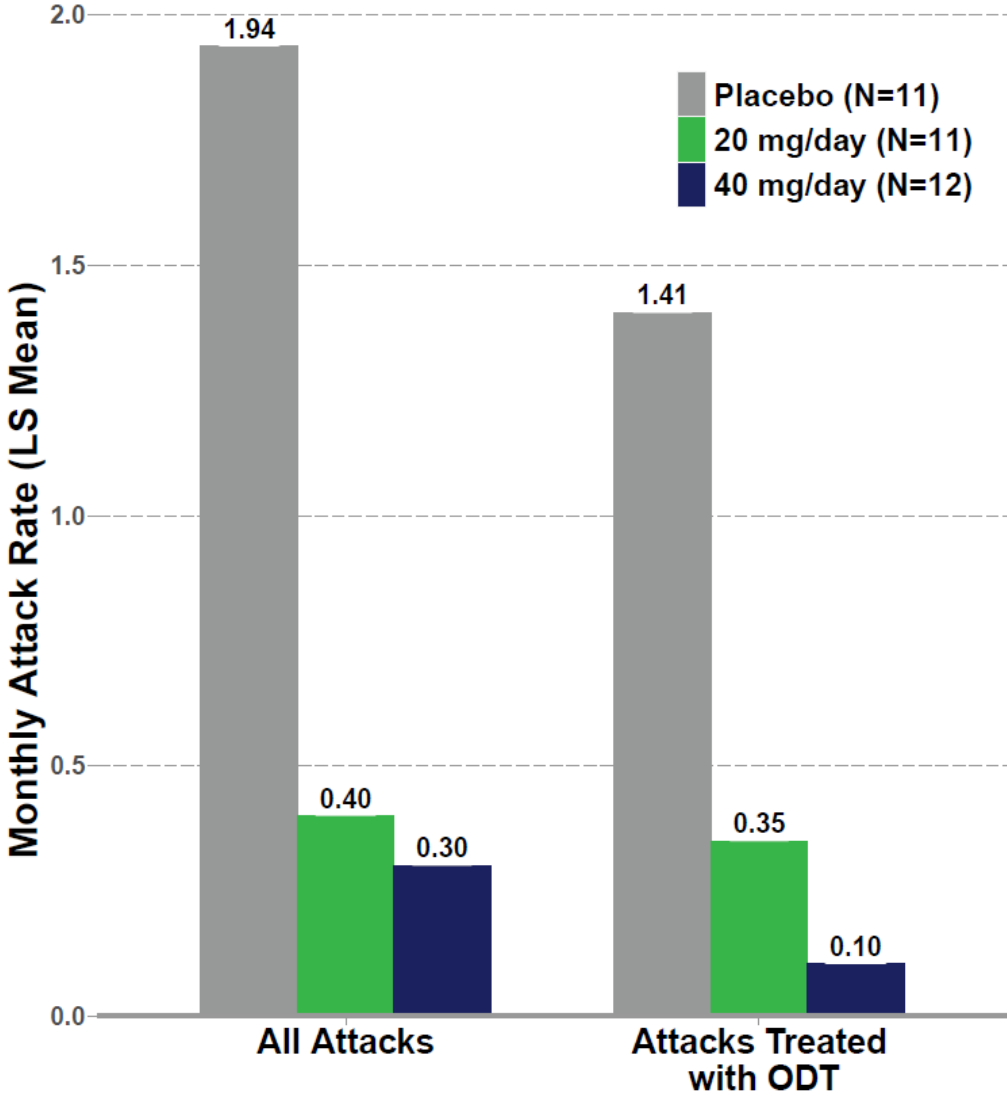
# 92.3% reduction in moderate or severe attacks at 40 mg/day dose



	Placebo N=11	20 mg/day N=11	40 mg/day N=12
Monthly attack rate of moderate or severe attacks			
LS mean	1.50	0.26	0.12
% reduction vs placebo		82.8%	92.3%
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.

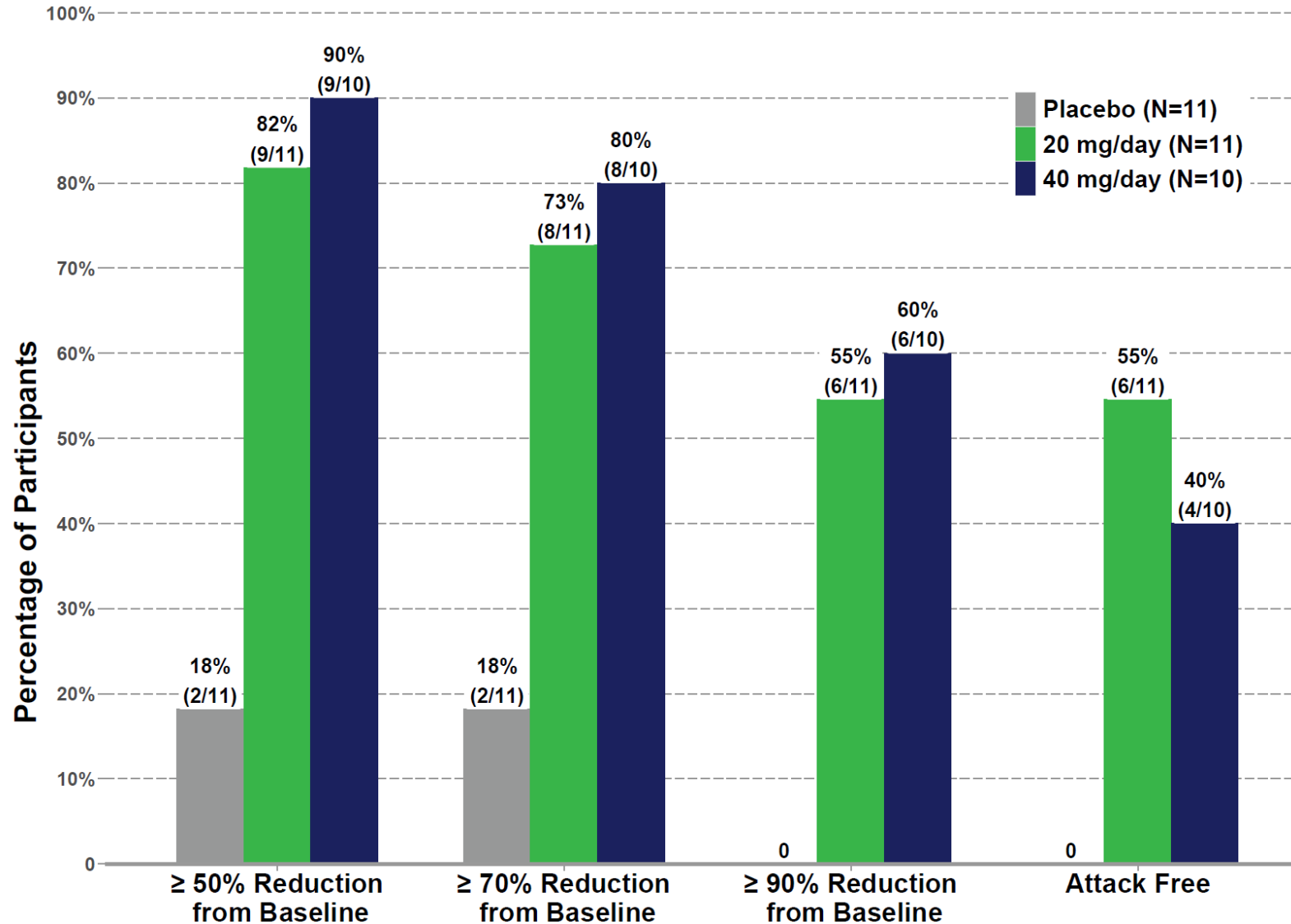
# 92.6% reduction in attacks treated with ODT at 40 mg/day dose



	Placebo 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

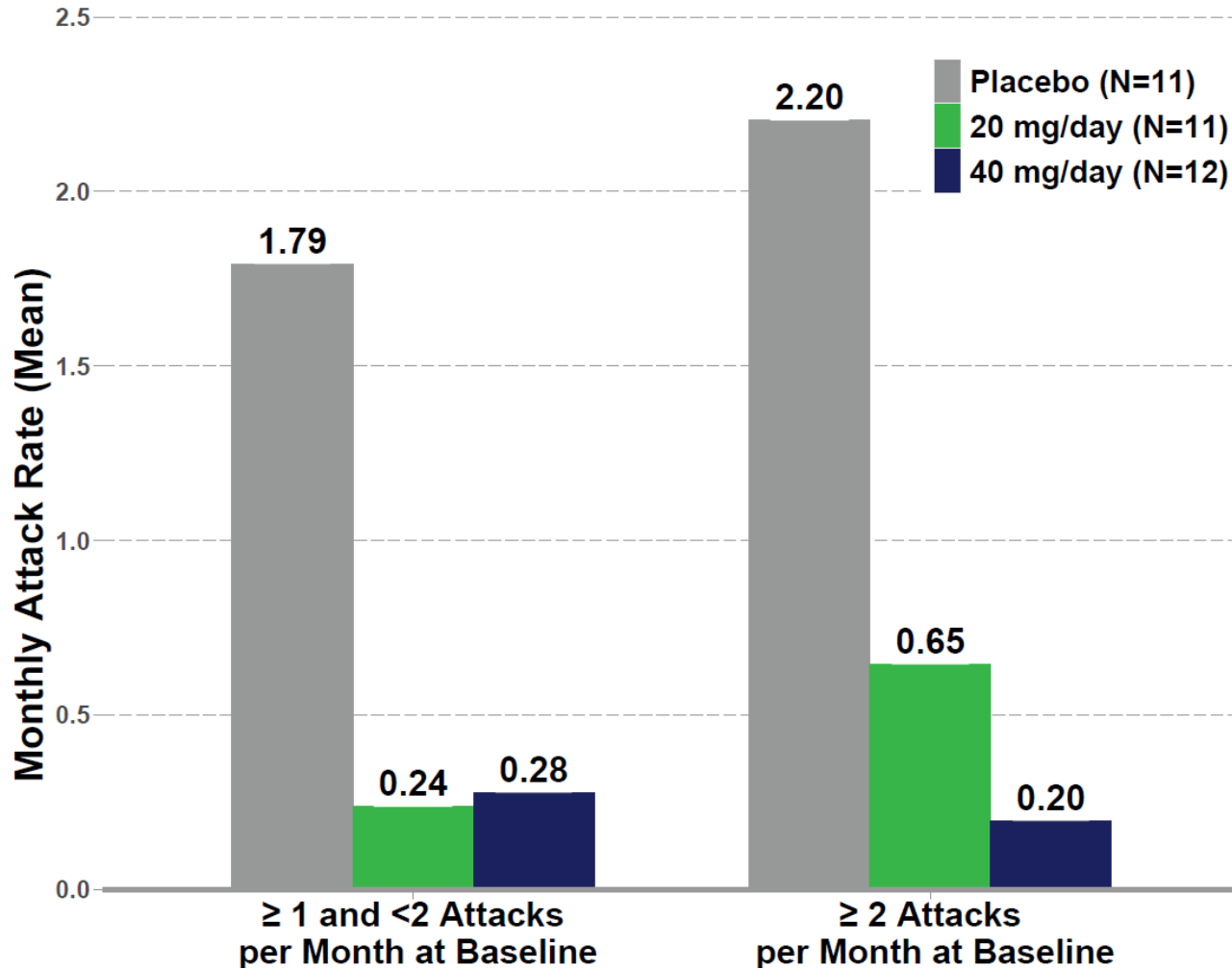
ODT = on-demand treatment (icatibant, C1-inhibitor (C1-INH))  
20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily;  
40 mg/day = deucricitabant IR capsules 20 mg twice daily.  
N = number of randomized participants.  
LS mean = least squares mean. Monthly attack rates are based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

# Substantial reduction of attack rate from baseline



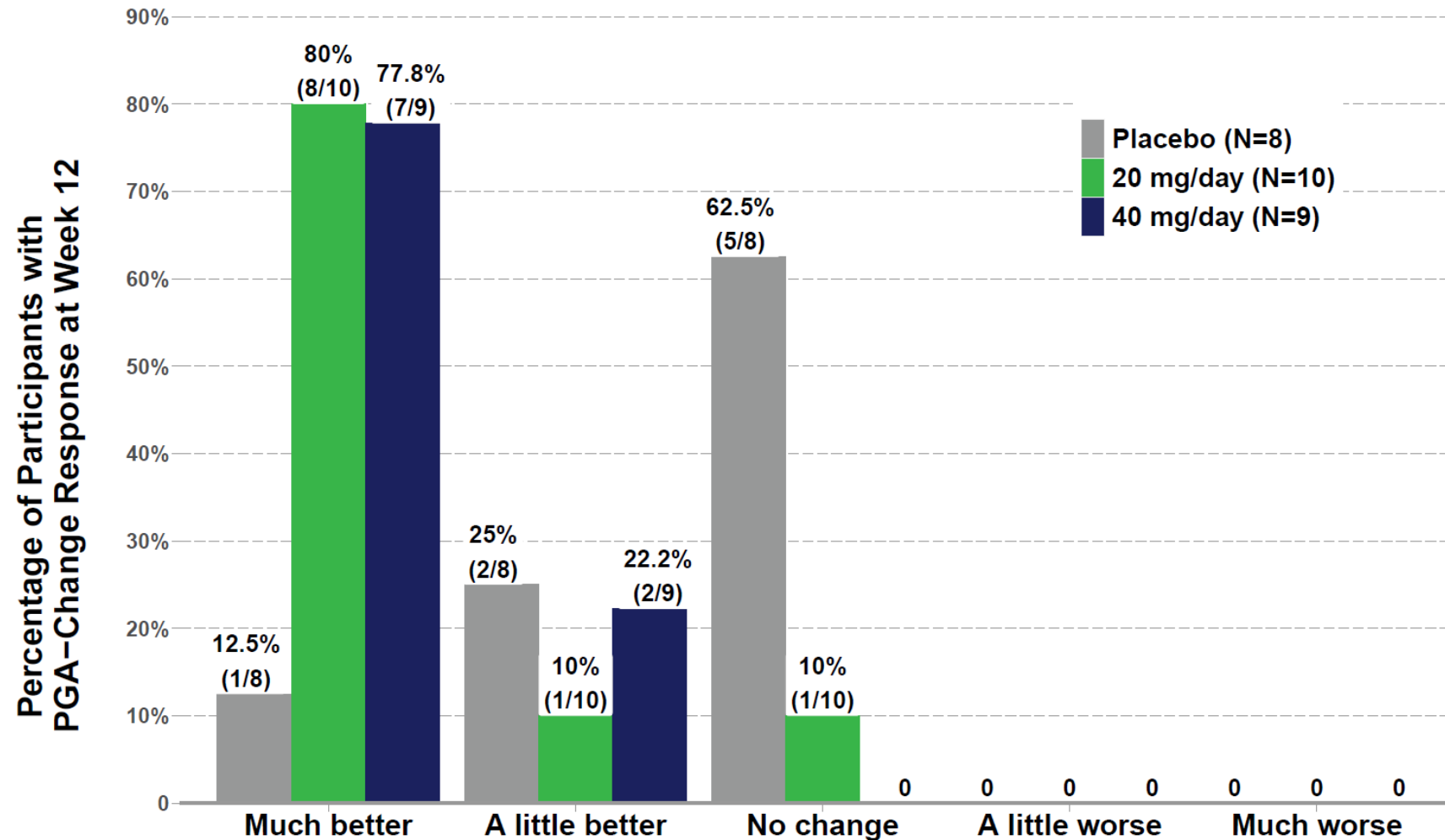
20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily.  
40 mg/day = deucricitabant IR capsules 20 mg twice daily.  
N = number of randomized participants.  
Results based on participants with at least 4 weeks of treatment.

# Consistent efficacy regardless of baseline attack rate



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

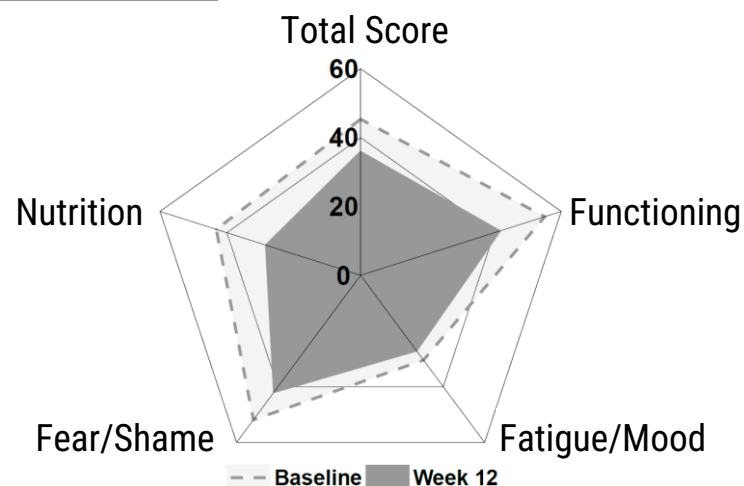
# All 40 mg/day participants reported an improvement in PGA-Change



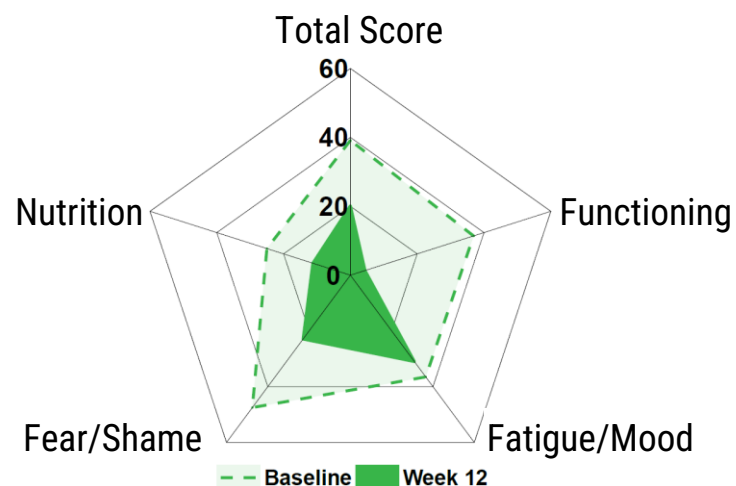
20 mg/day = deucricitabant immediate release (IR) capsules 10 mg twice daily. 40 mg/day = deucricitabant IR capsules 20 mg twice daily.  
PGA-Change = patient global assessment of change (question). N = number of participants with PGA-Change results at Week 12.

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

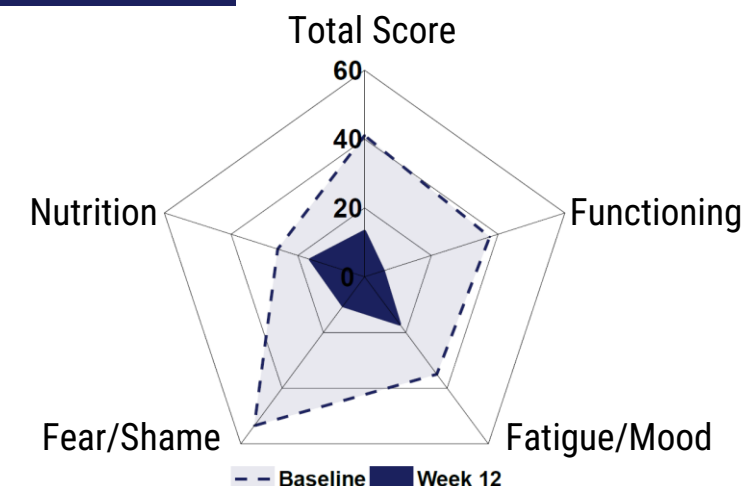
## Placebo



## 20 mg/day



## 40 mg/day



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

# Deucrictibant well-tolerated at both doses

			Placebo (N=11)		20 mg/day (N=11)		40 mg/day (N=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.



# 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)
<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 N=11	20 mg/day N=11	40 mg/day 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%)

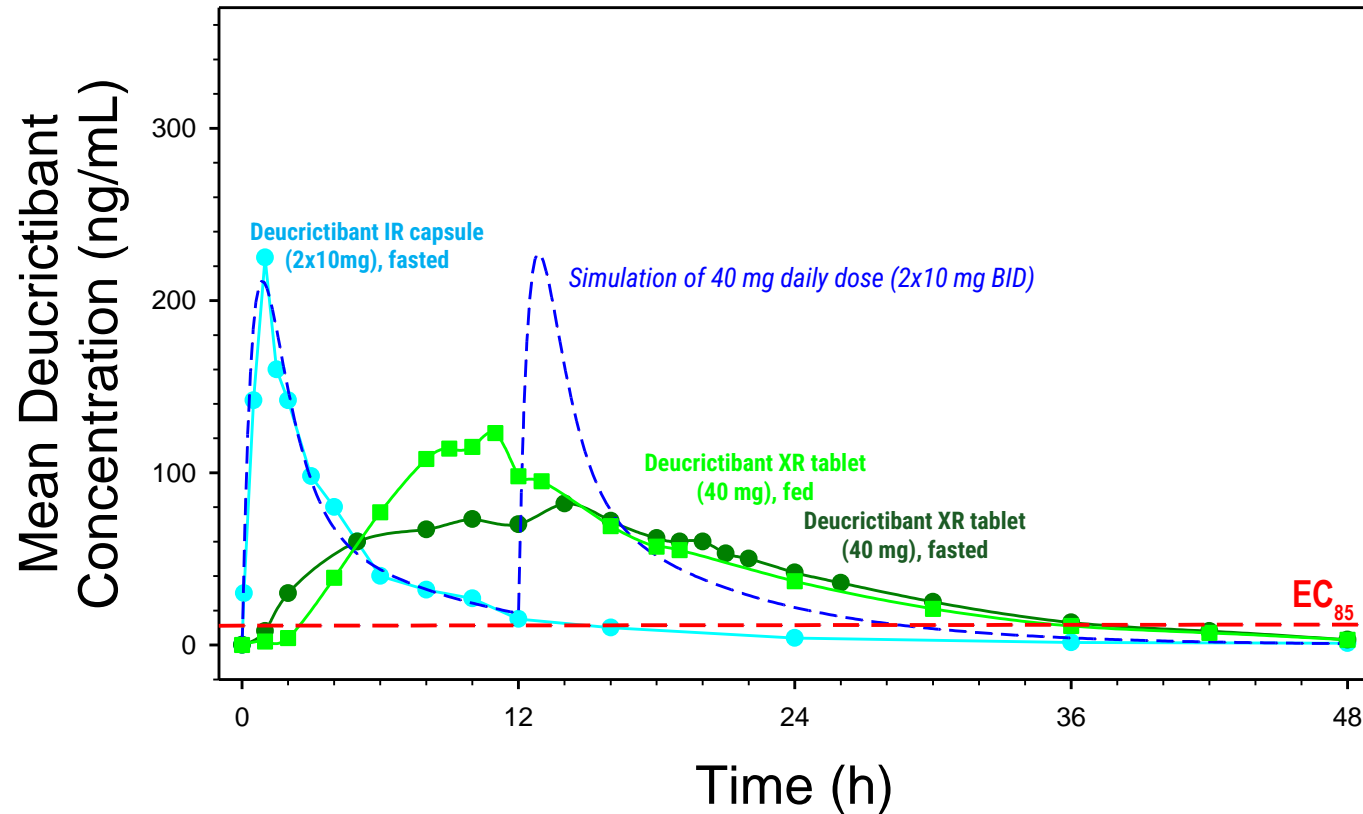
20 mg/day = deucricitibant immediate release (IR) capsules 10 mg twice daily; 40 mg/day = deucricitibant IR capsules 20 mg twice daily. N = number of randomized participants.

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 deucricitibant 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 deucricitibant with placebo.

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



- Deucricitbant IR and XR well tolerated
  - No SAEs or severe TEAEs
- Deucricitbant XR extended-release maintained exposure above  $EC_{85}$  for >24h with and without food
  - Similar  $AUC_{24h}$  as 40 mg deucricitbant IR dosed with food

**Deucricitbant XR anticipated to maintain higher trough exposure relative to BID deucricitbant IR**

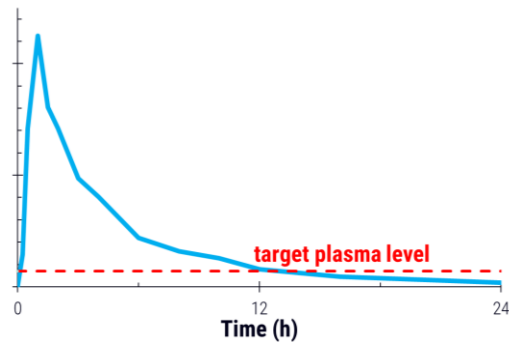
Source: Company data

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

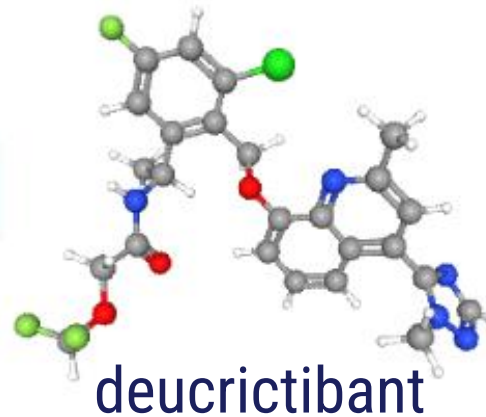
## deucrictibant (PHVS416)

Immediate-release capsule

rapid absorption



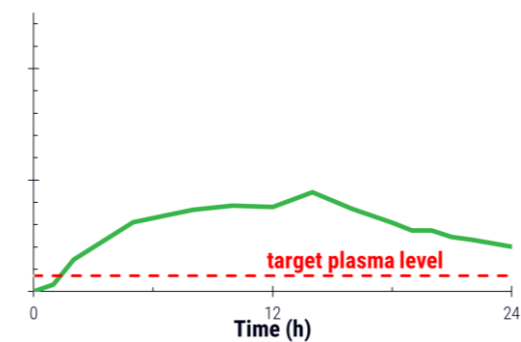
Aim to provide rapid and reliable symptom relief, through rapid exposure of attack-mitigating therapy in a convenient, small oral dosage form\*



## deucrictibant (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, deucrictibant has the potential to become the preferred option to treat and prevent HAE attacks**

\*Aspirational; to be confirmed with clinical data

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



## Competitive product profile

- Deep expertise in bradykinin/B2 receptor 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 currently enrolling
  - 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:
  - Approximately **€391M cash as of Dec 31, 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**

# PHARVARiS

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

NASDAQ: PHVS

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



# Appendix

Additional RAPIDe-1 top-line clinical data

# 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;  $\geq 30\%$  reduction from the pre-treatment score)
- Time to a  $\geq 50\%$  reduction in VAS-3 score from the pre-treatment score
- Time to almost complete and complete symptom relief (VAS; all 3 items  $\leq 10$ )
- 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



# 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
<b>Mean VAS-3 at pre-treatment</b>	27.76	26.16	25.46	29.73	27.11
<b>Change in VAS-3 at 4 hours</b>					
least-squares mean 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

# 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
<b>Time to onset of symptom relief by VAS-3 30% reduction<sup>a</sup></b>					
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	
<b>Time to VAS-3 50% reduction<sup>a</sup></b>					
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	
<b>Time to almost complete or complete symptom relief by VAS<sup>a</sup></b>					
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	
<b>Change in MSCS score at 4 hours<sup>b</sup></b>					
least-squares mean difference: PHVS416 - Placebo		-0.79	-0.61	-0.39	-0.61
p-value		<0.0001 <sup>†</sup>	0.0008	0.0291	
<b>TOS at 4 hours<sup>b</sup></b>					
least-squares mean difference: PHVS416 - Placebo		64.13	62.69	71.06	66.05
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

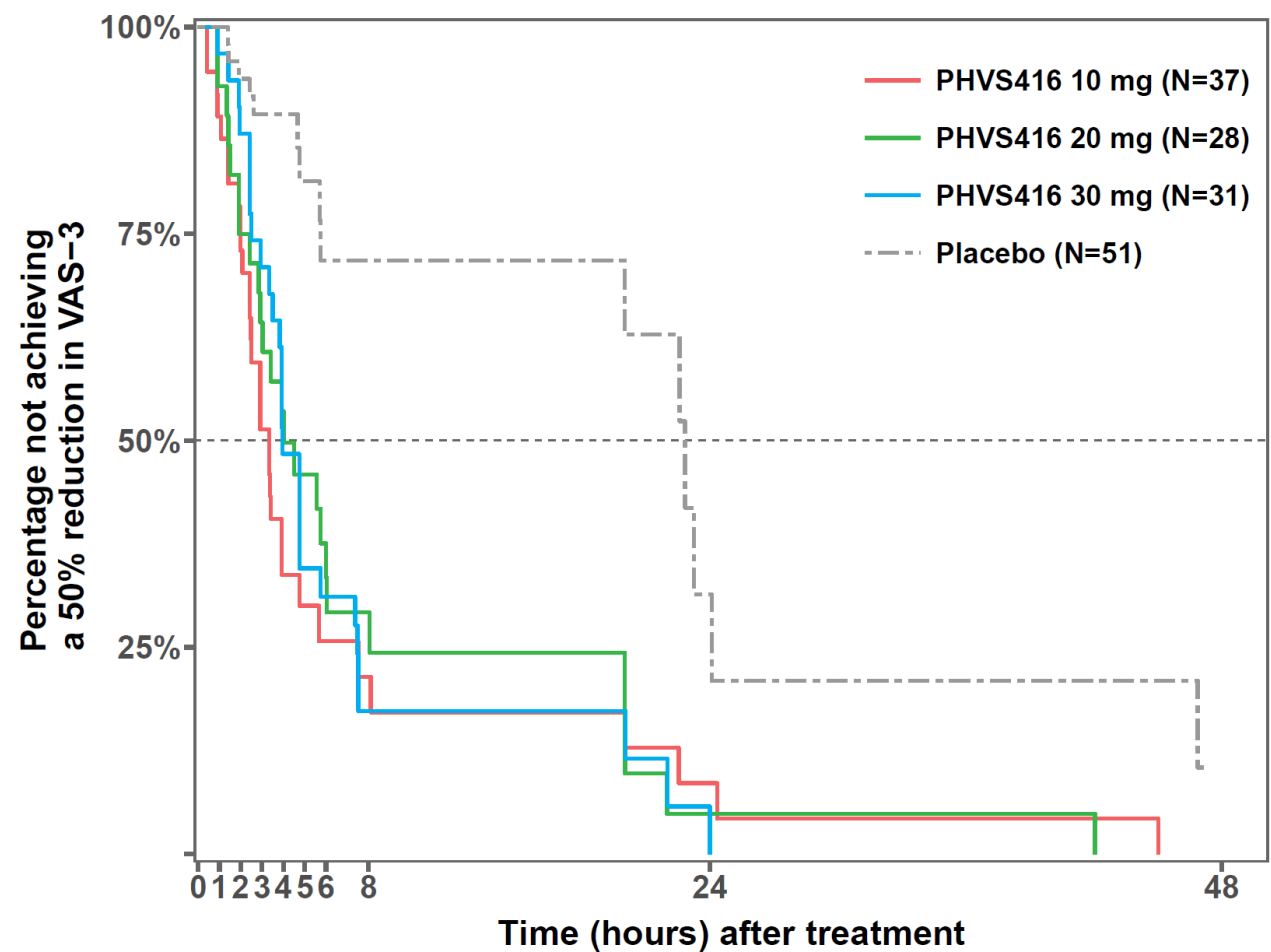
p-values for PHVS416 20mg and PHVS416 30mg are based on statistical tests in the pre-specified multiple comparison procedure, other p-values are nominal

<sup>a</sup>Hazard ratios and p-values are based on marginal Cox proportional hazards models

<sup>b</sup>p-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)

Placebo	22.8 (20.0, 24.1)	
PHVS416 10 mg	3.3 (2.4, 3.9)	$p < 0.0001^{\dagger}$
PHVS416 20 mg	4.0 (2.9, 6.0)	$p = 0.0003$
PHVS416 30 mg	4.0 (3.3, 5.8)	$p < 0.0001$
Combined PHVS416	3.9 (3.0, 4.8)	

*<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. 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.*

# 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) pre-treatment
  - 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

# Greater improvement in MSCS and TOS with PHVS416 than placebo

	Placebo	PHVS416 10 mg	PHVS416 20 mg	PHVS416 30 mg	Combined PHVS416
<b>Change in MSCS score at 4 hours</b>					
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)		-0.79	-0.61	-0.39	-0.61
p-value		<0.0001 <sup>†</sup>	0.0008	0.0291	
<b>TOS at 4 hours</b>					
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)		64.13	62.69	71.06	66.05
p-value		<0.0001 <sup>†</sup>	<0.0001	<0.0001	

<sup>†</sup>Nominal 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

# 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 (%) <sup>*</sup>	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 (%) <sup>*</sup>	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)	4.12 (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