PHARVARIS

Pioneering science for patient choice

November 2023

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

Competitive product profile

Orally available, small molecule targeting the **validated bradykinin B2 receptor pathway**

Clinical proof-of-mechanism using surrogate endpoint with higher potency and duration than previously observed for icatibant

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

PK/PD profile supports use in both **on-demand and prophylactic settings; Phase 2 studies underway***

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

Novel lead series with strong IP (primary CoM granted in multiple territories; initial term to 2038); FDA **orphan drug designation**

World-wide operations: the Netherlands, USA, and Switzerland (headquarters)

Strong financial position; **€158M cash, runway into 1Q25**

Experienced management **team with successful track record** in HAE drug design and development

*The FDA has placed a hold on clinical trials of deucrictibant for long-term prophylaxis of HAE in the U.S.; see slide 15 for an update on our clinical program

Experienced management with deep expertise in development and rare diseases

Berndt Modig
Chief Executive Officer

Jerini · ProSensa

Anne Lesage, Ph.D.
Chief Early Development Officer

Johnson & Johnson

Morgan Conn, Ph.D.
Chief Business Officer

PTC Therapeutics

Peng Lu, M.D., Ph.D.
Chief Medical Officer

Roche · Takeda · Shire · abbvie

Wim Souverijns, Ph.D.
Chief Community Engagement and Commercial Officer

Amgen · Celgene · Obseva

Jochen Knolle, Ph.D.
Chief Scientific and Operating Officer

Hoechst · Jerini

Joan Schmidt, J.D.
Chief Legal Officer

novo nordisk · dbv technologies · Arena Pharmaceuticals

Annick Deschoolmeester
Chief Human Resources Officer

Allergan · Shire · pwc · Takeda

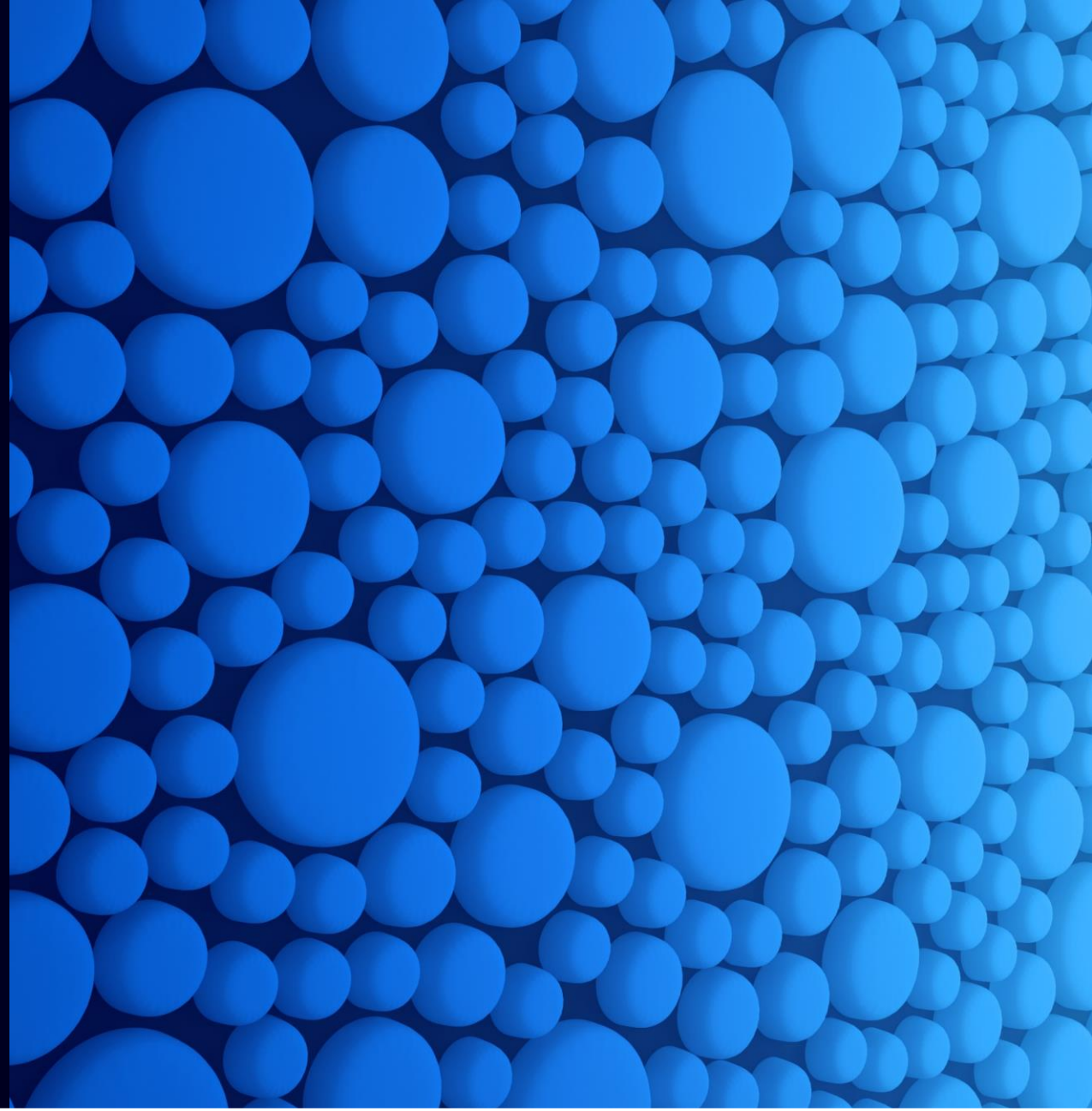
Stefan Abele, Ph.D.
Chief Technical Operations Officer

idorsia · Actelion

Anna Nijdam
Principal Accounting Officer

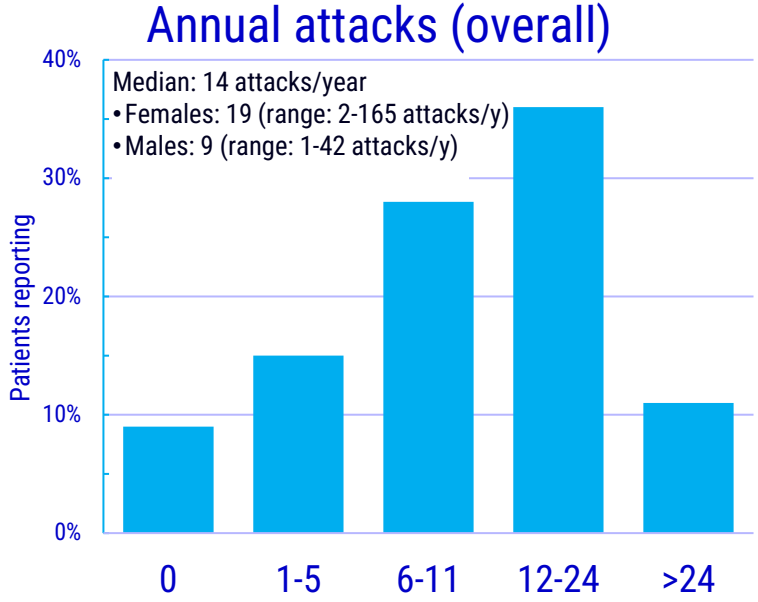
EY

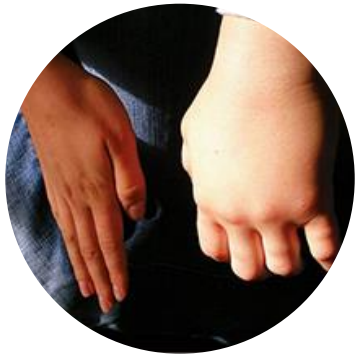
Hereditary Angioedema (HAE)

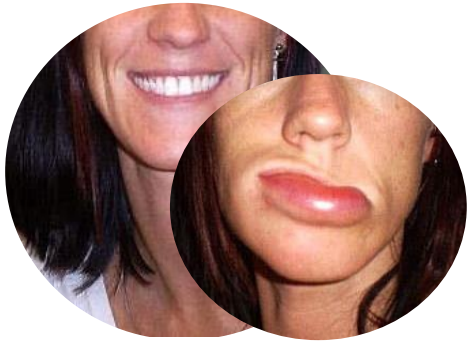


HAE: A rare, life-long genetic condition with significant burden from unpredictable, debilitating, and potentially lethal attacks of swelling

- 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

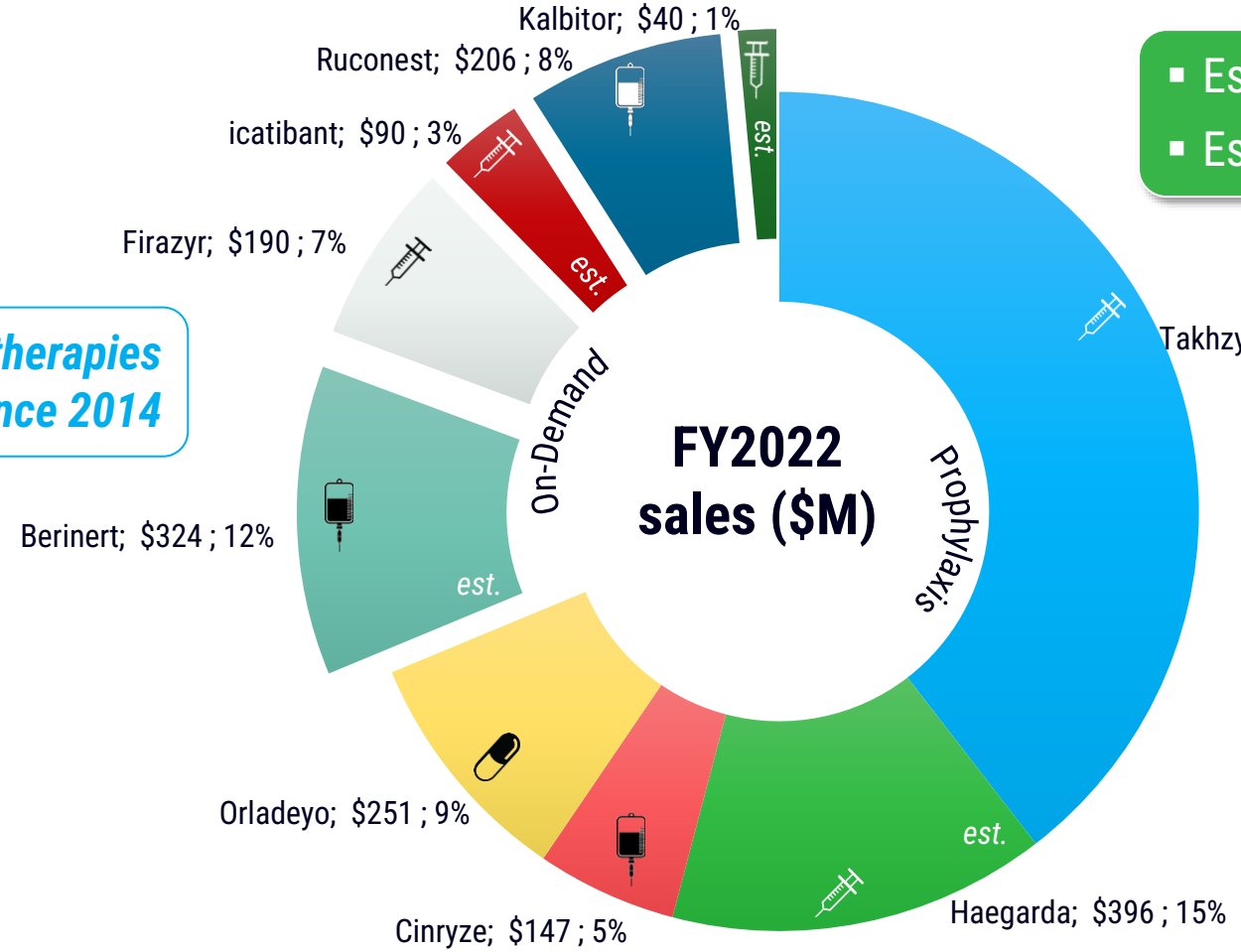






Nordenfelt et al, Acta Derm. Venereol 2016: 96: 540-545

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

IV SC oral

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

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

Efficacy is patients' prime concern …

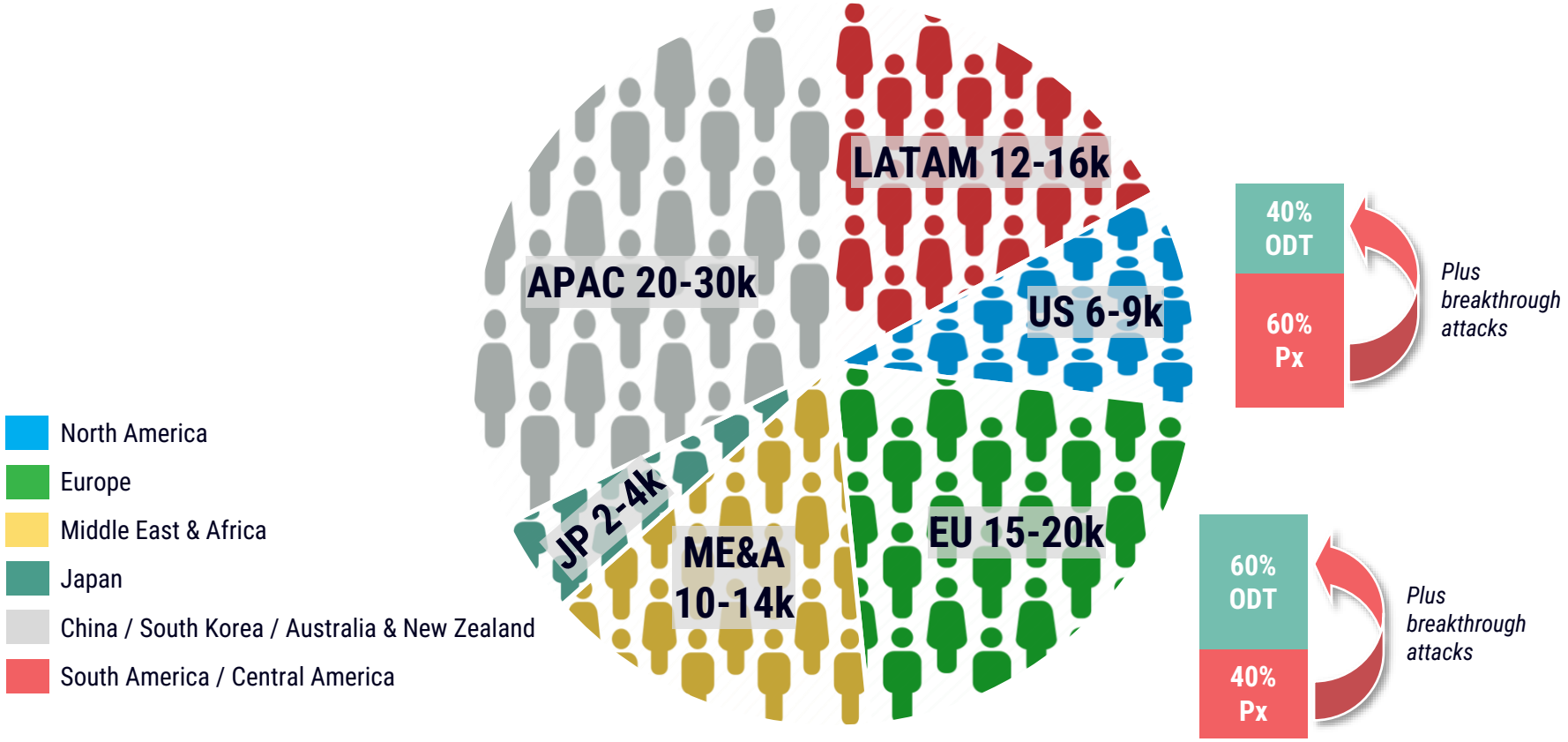
… but **safety & tolerability** are pushing patients to explore alternatives …

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

People living with HAE desire HAE therapy that can deliver on ALL fronts

Proprietary company research 2022

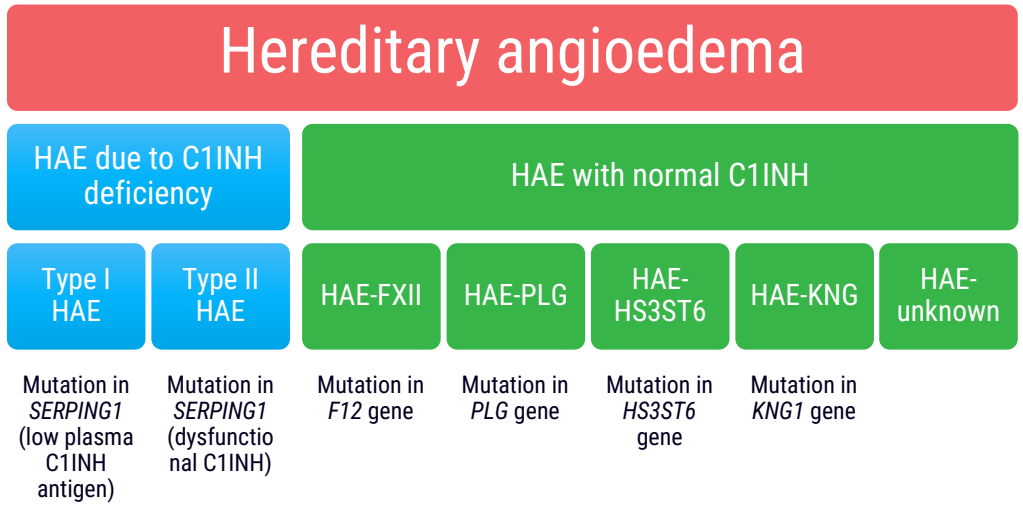
Significant global unmet need: Potentially up to 100,000 people living with HAE

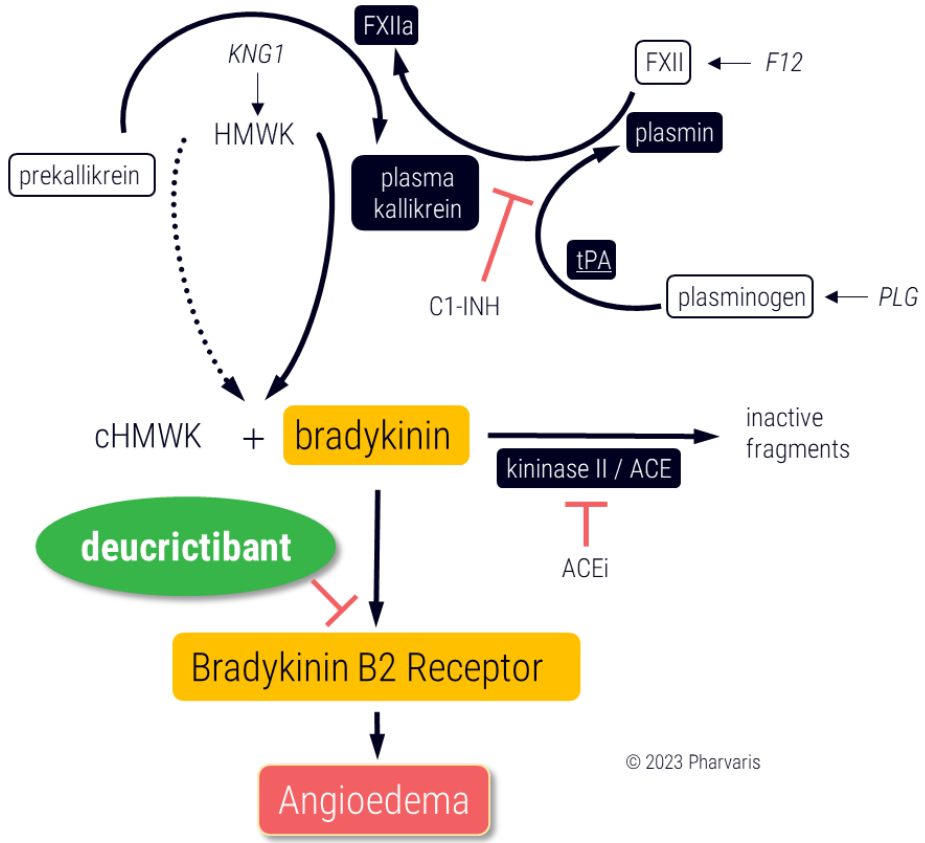


Proprietary company research 2022; Maurer et al. Consensus on diagnosis and management of Hereditary Angioedema in the Middle East: A Delphi initiative. World Allergy Organization Journal (2023);16:1-2; Zuraw et al. NEJM 2008;359:1027-1036; HAEi (haei.org), The State of Management of HAE in Latin America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

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

Genetic causes lead to elevated levels of bradykinin



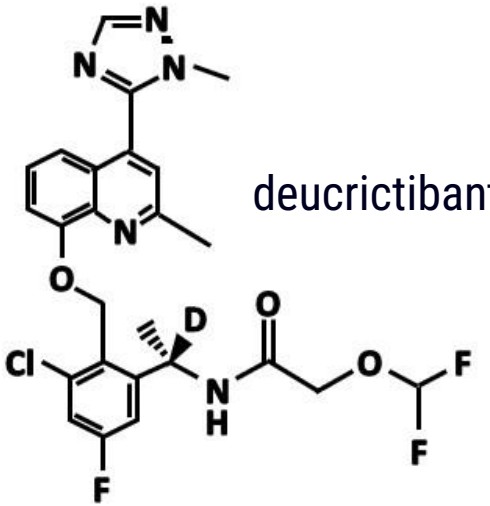


HMWK: high-molecular-weight kininogen; cHMWK: cleaved high-molecular-weight kininogen; FXII(a): Factor XII(a); ACE(i): angiotensin-converting enzyme (inhibitor); tPA: tissue plasminogen activator; KNG1: gene encoding HMWK; PLG: gene encoding plasminogen; F12: gene encoding FXII

Busse 2020 J Allergy Clin Immunol Pract; Bork et al 2021 J Allergy Clin Immunol

Pharvaris has discovered the first orally bioavailable bradykinin B2 receptor antagonist

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



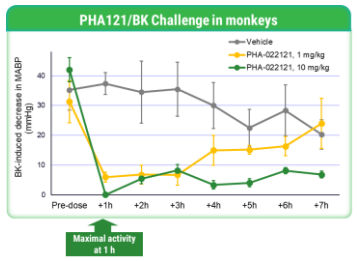
deucrictibant

We aspire to develop **novel, oral alternatives** that **improve** the **standard of care** for people living with HAE

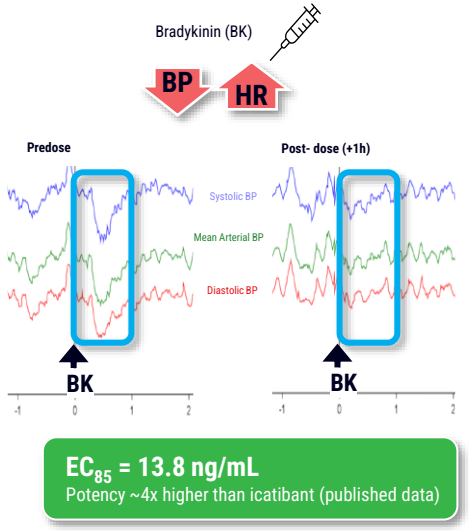
Lesage et al, *Frontiers in Pharmacology 2020, doi: 10.3389/fphar.2020.00916; ; Lesage* et al, *Int. Immunopharmacology 2022, doi.org/10.1016/j.intimp.2022.108523;* https://ir.pharvaris.com/static-files/0361cd85-6000-490b-932b-d305e1f3ca1b; https://ir.pharvaris.com/static-files/81a9499d-0769-4b89-8ecd-8ace5ca521d3;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

Predictive value of our unique *in vivo* surrogate-marker model, the BK challenge, allows for derisking of our clinical studies

Primate bradykinin challenge



Healthy volunteer bradykinin challenge

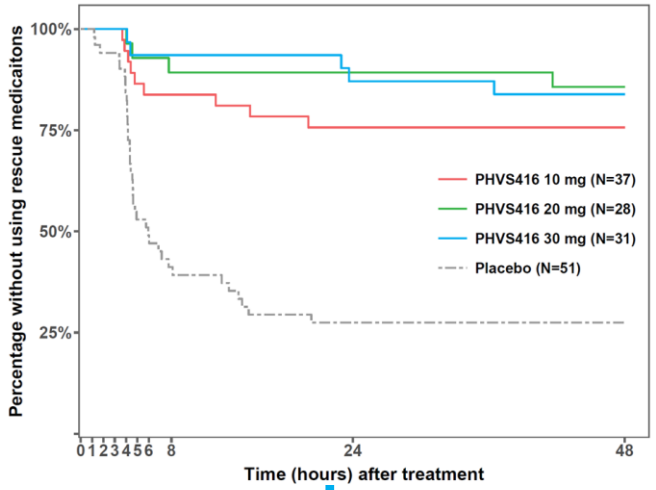


EC_{85} = 13.8 ng/mL
Potency ~4x higher than icatibant (published data)

Phase 2 clinical dose selection

On-demand (RAPIDe-1)
Prophylaxis (CHAPTER-1)

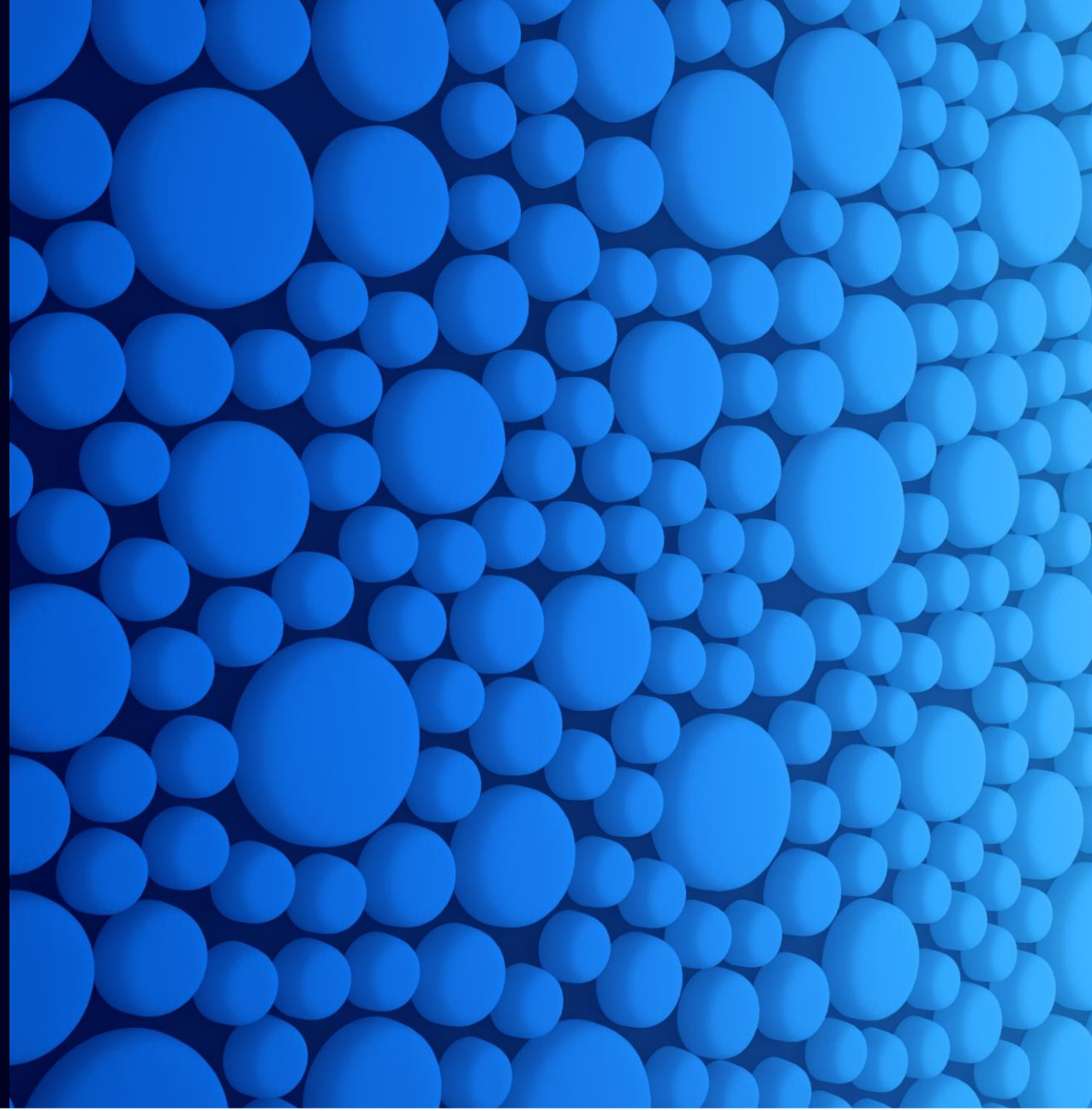
RAPIDe-1 on-demand study in people living with HAE



On-demand dose confirmation

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

Product Strategy

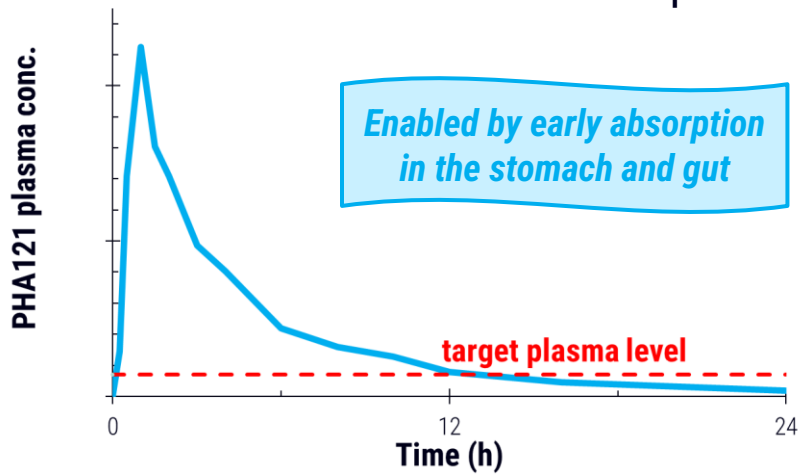


On-demand and prophylaxis: Developing two oral products utilizing the same active ingredient

deucrictibant

PHVS416

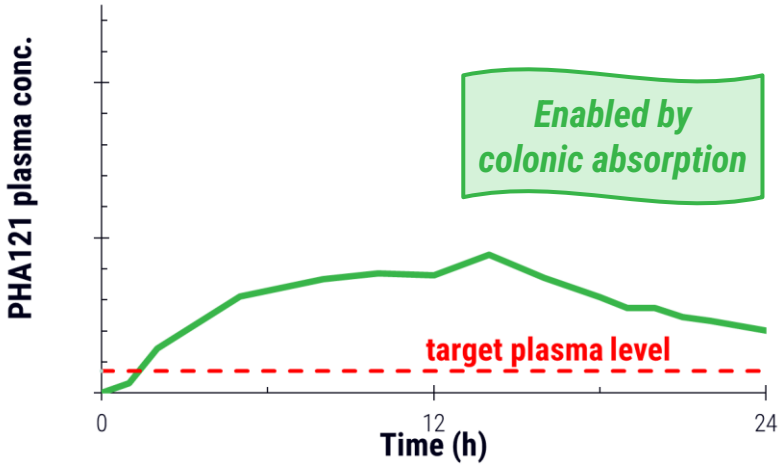
Immediate-release capsules



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

PHVS719

Extended-release tablets



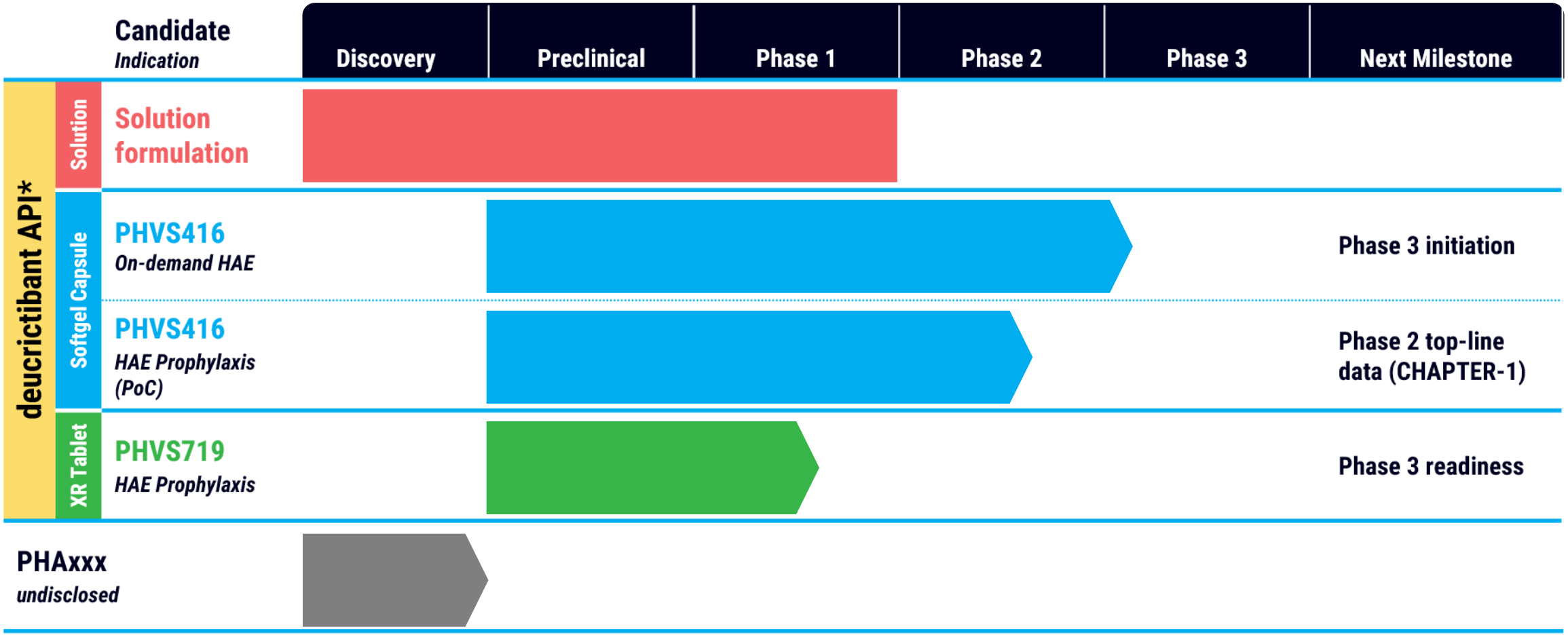
Aim to provide sustained exposure of attack-preventing medicine in a convenient, small oral dosage form*

*Aspirational; to be confirmed with clinical data

Regulatory update

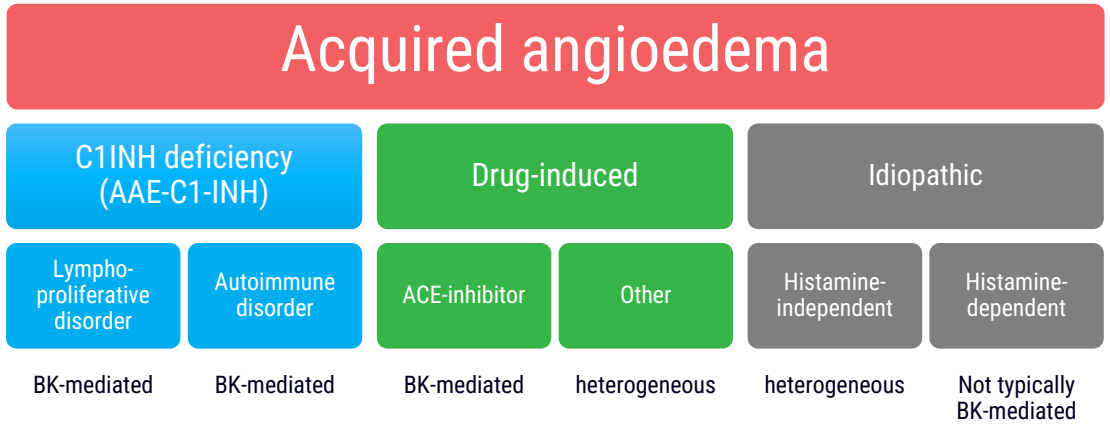
- In August 2022, the U.S. Food & Drug Administration (FDA) placed a hold on clinical trials of deucrictibant in the U.S. based on its review of nonclinical data
  - The agency requested that Pharvaris conduct an additional long-term rodent toxicology study and update the Investigator's Brochure
  -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

Wholly-owned pipeline focused on bradykinin B2 receptor mechanism



* The FDA has placed a hold on clinical trials of deucrictibant for long-term prophylaxis in the U.S.; see slide 15 for an update on our clinical program

Bradykinin-mediated disease also includes acquired angioedemas



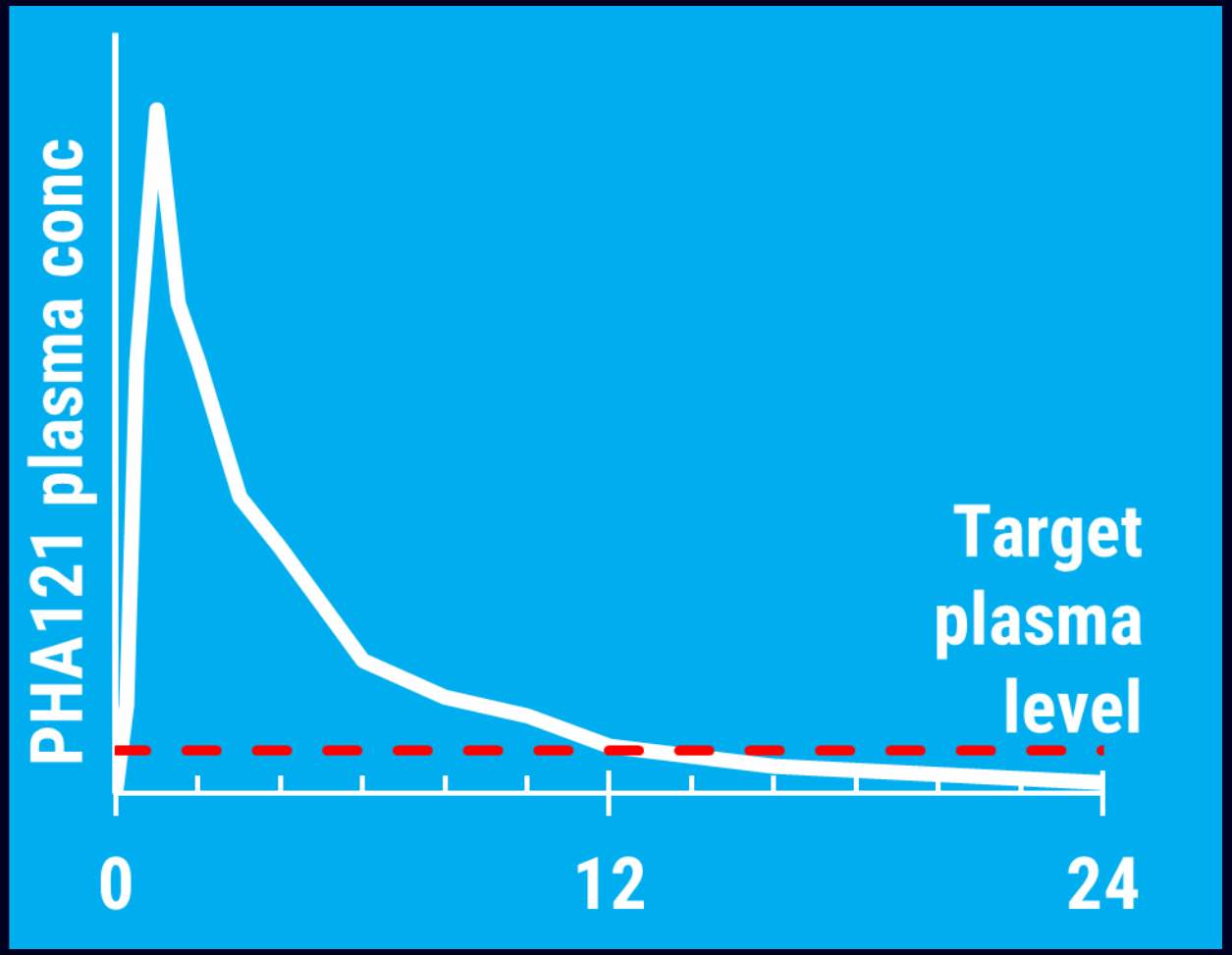
No products approved for treatment of bradykinin-dependent acquired angioedemas

- Therapies approved broadly for HAE are used for treatment
- An independent investigator-initiated trial (IIT) in AAE-C1-INH with PHVS416 has been conducted

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/)

PHVS416/On-Demand

Immediate-release deucrictibant capsules



On-demand treatment of HAE attacks: No new approvals beyond injectable options have left a significant unmet need

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

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

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** …

1

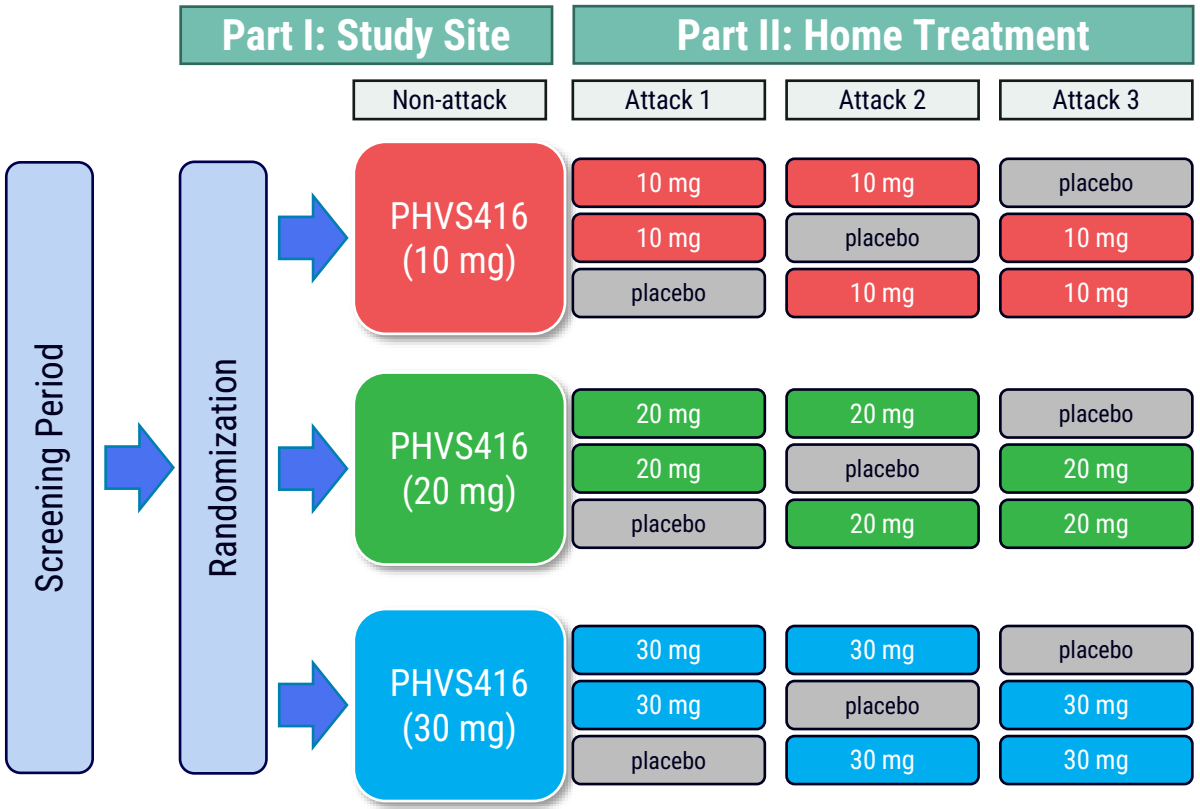
… with **single dose durability** …

… in an **oral** pill

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

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

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



- **Primary objective:** to evaluate angioedema symptom relief within four hours in acute attacks of patients with HAE type 1 or 2
- **Study design:** Placebo-controlled, three dose levels
  - Part I: patients randomized and received a single dose of 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

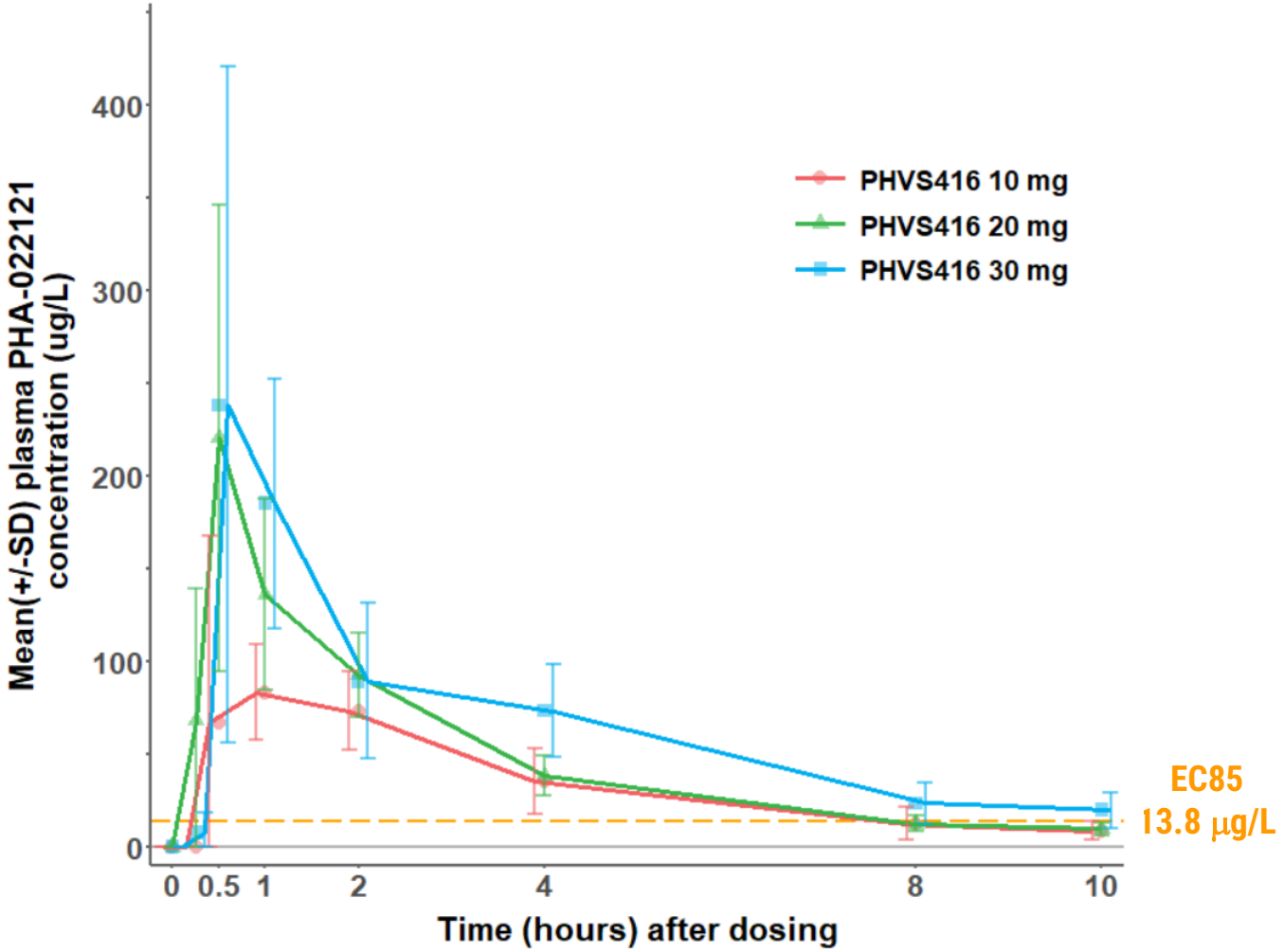
www.hae-rapide.com; https://clinicaltrials.gov/ct2/show/NCT04618211; https://hae-rapide.us/; https://www.clinicaltrialsregister.eu/ctr-search/search?query=2020-003445-11

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**
- PHVS416 demonstrated **rapid onset of action**, **symptom relief**, and **resolution** of HAE attacks
- PHVS416 **substantially reduced** the use of **rescue medications**
- PHVS416 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

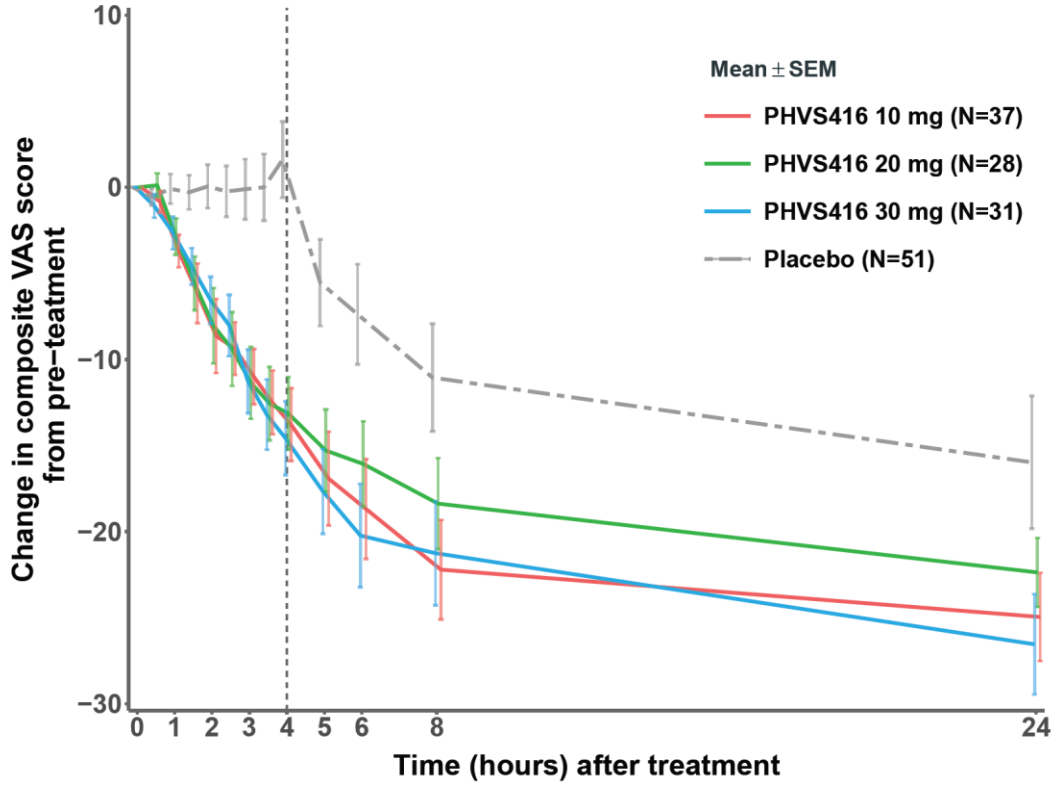
Consistent outcomes observed
across all endpoints and types of measurements

PK profile in HAE patients: Rapid absorption confirmed 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: PHVS416 significantly reduces attack symptoms by VAS-3 at 4h

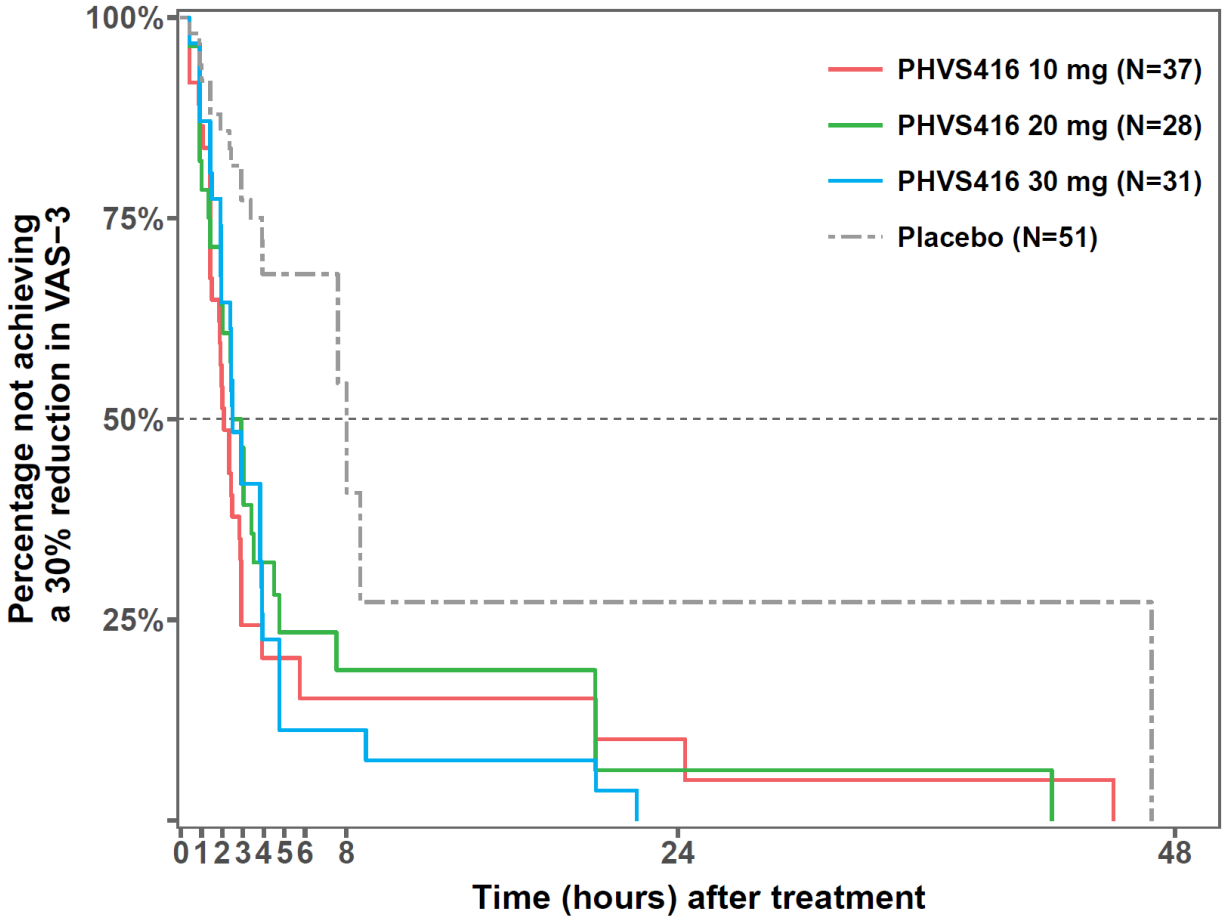


Difference from placebo in change from pre-treatment to 4 h post-treatment, least-squares mean (95% CI)		
PHVS416 10 mg	-16.75 (-21.52, -11.97)	p < 0.0001†
PHVS416 20 mg	-15.02 (-20.22, -9.81)	p < 0.0001
PHVS416 30 mg	-16.28 (-21.27, -11.29)	p < 0.0001
Combined PHVS416	-16.08 (-19.87, -12.29)	

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

†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

PHVS416 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†
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.

TOS Patient Reported Outcome (PRO)

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

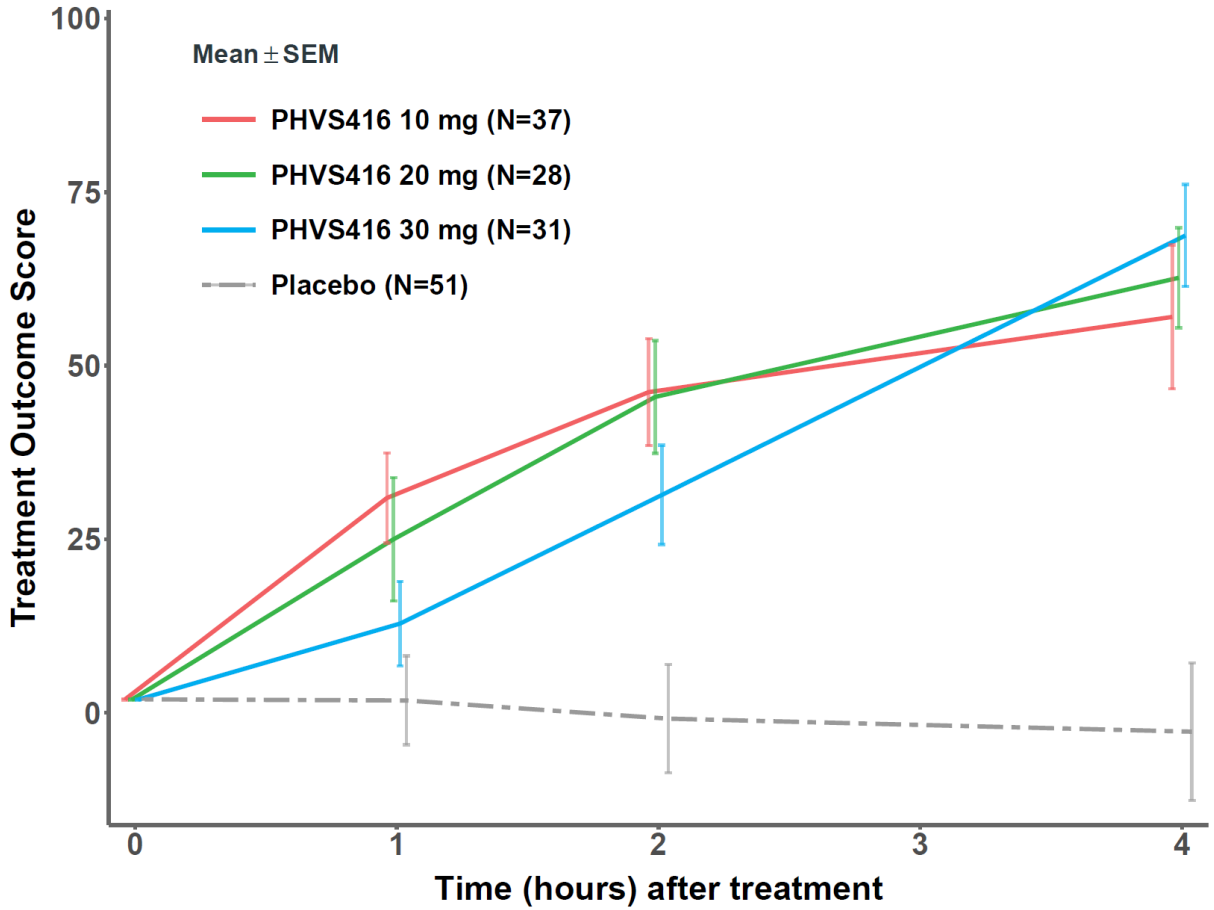
Internal head/neck	Stomach/GI	Genital/buttocks	External head/neck	Cutaneous

- At each timepoint, the change in attack symptom from pre-treatment is reported by patient

PRO – how do you feel now compared to before receiving study drug?

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

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

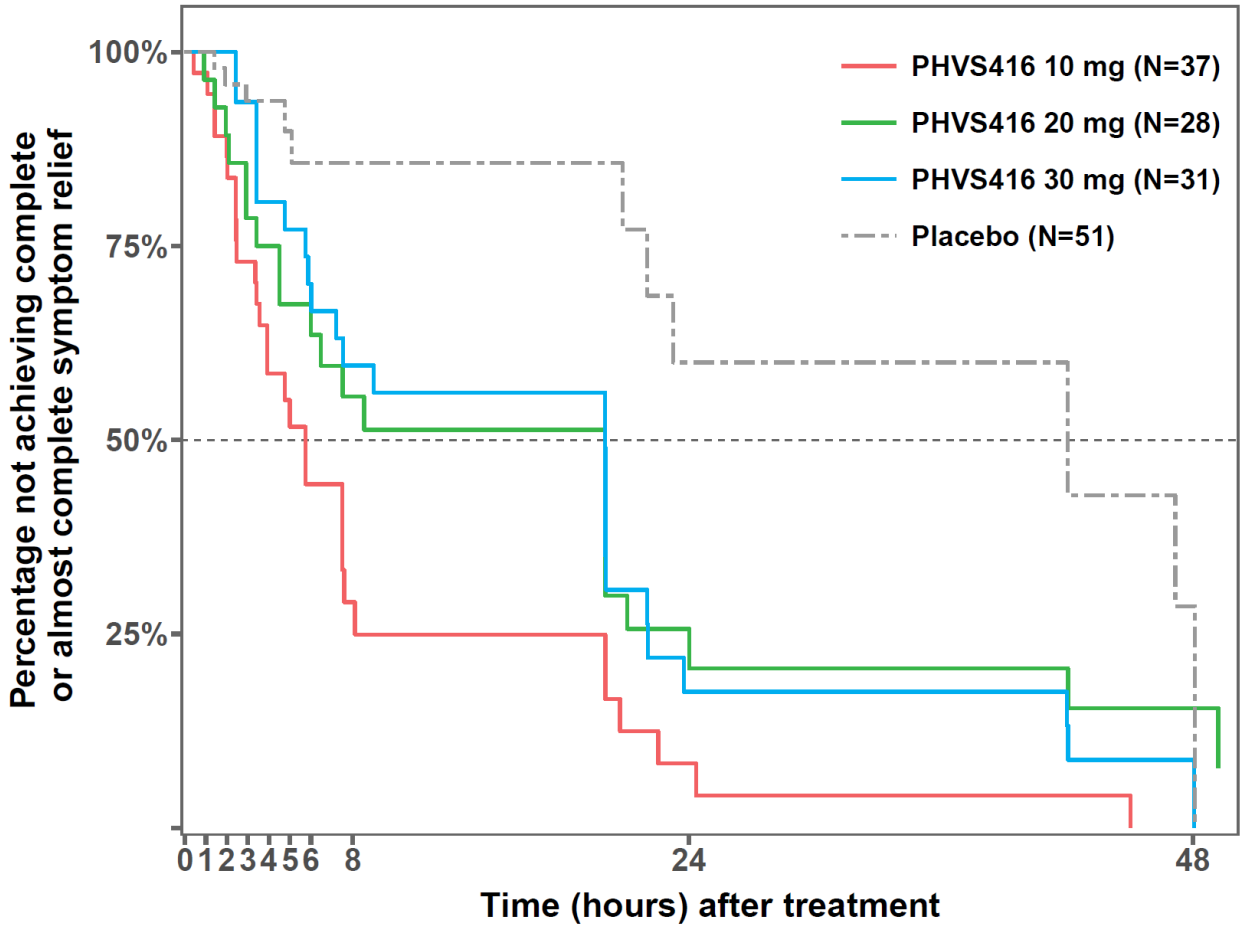


Difference from placebo in 4 h post-treatment least-squares mean (95% CI)		
PHVS416 10 mg	64.13 (40.35, 87.91)	p < 0.0001†
PHVS416 20 mg	62.69 (36.71, 88.67)	p < 0.0001
PHVS416 30 mg	71.06 (46.09, 96.03)	p < 0.0001
Combined PHVS416	66.05 (47.42, 84.69)	

Minimally Important Difference (MID) for TOS is **30**

Source: Vernon M, Rentz AM, Wyrwich KW, et al. *Qual Life Res.*2009; †Nominal p-value; N = The number of attacks in the mITT Analysis Set. TOS = Treatment Outcome Score. Figure is based on descriptive summary of mean and SEM. The least-squares mean differences, CIs, and p-values come from an MMRM. 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

PHVS416 significantly reduces time to almost complete or complete symptom relief (all individual VAS ≤ 10)

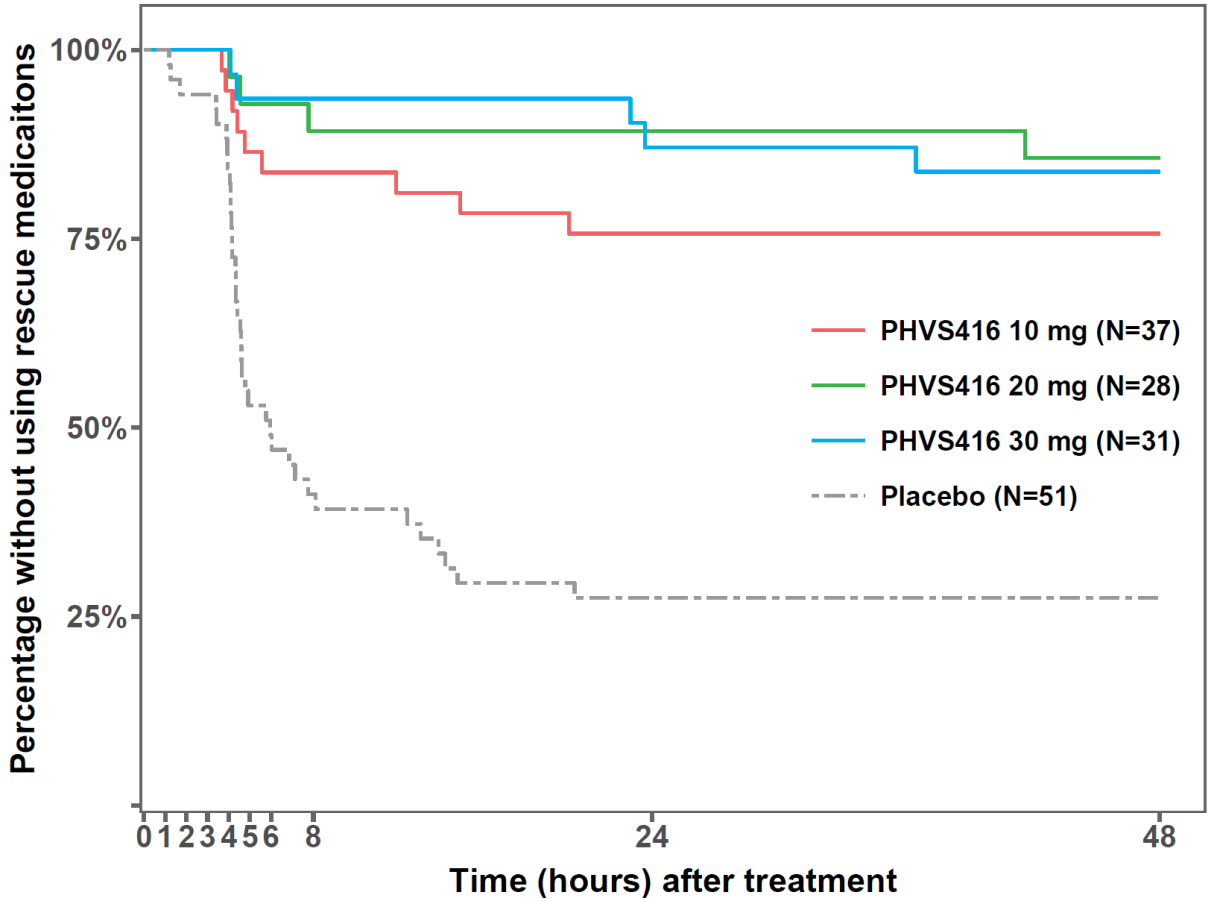


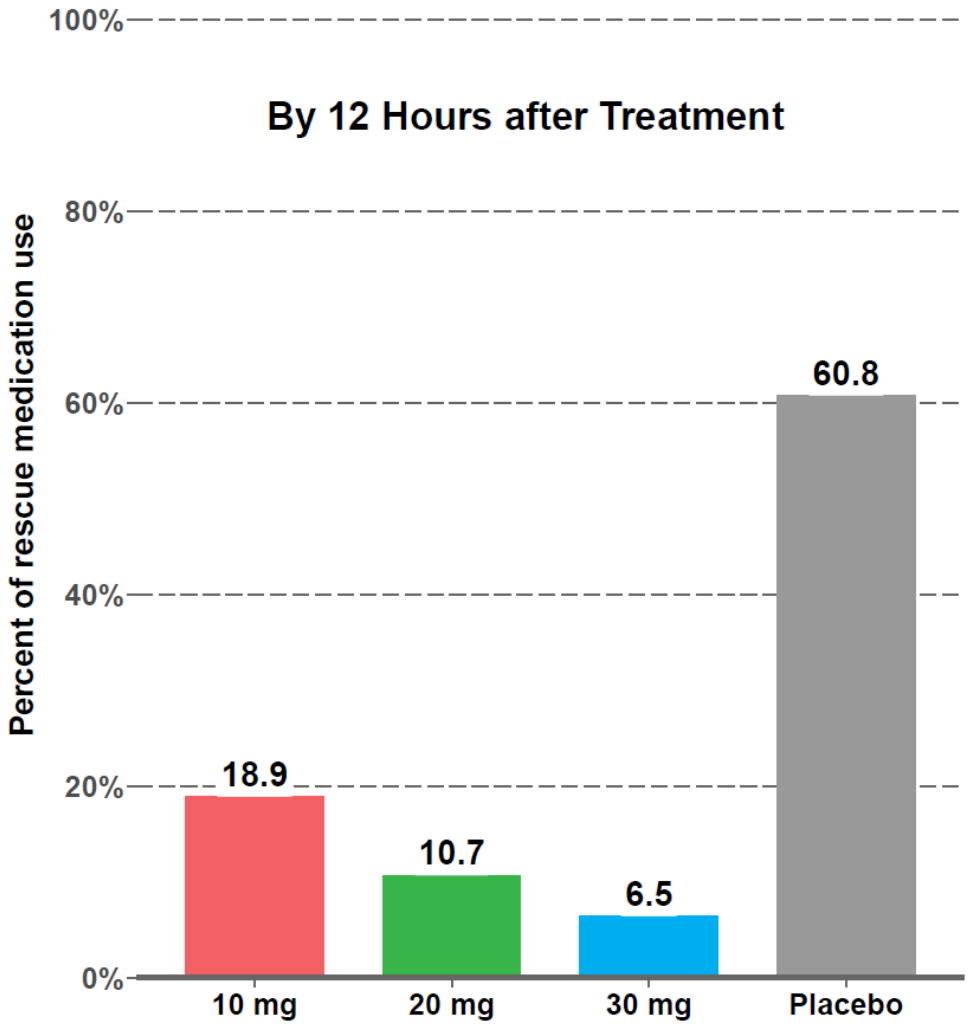
Median time in hours (95% CI)		
Placebo	42.0 (22.0, 48.1)	
PHVS416 10 mg	5.8 (3.6, 7.5)	p < 0.0001†
PHVS416 20 mg	20.0 (4.5, 20.0)	p = 0.0127
PHVS416 30 mg	20.0 (6.0, 20.1)	p = 0.0001
Combined PHVS416	7.5 (5.9, 20.0)	

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 PHVS416 used substantially less rescue medication





N = The number of attacks in the mITT Analysis Set

PHVS416 was well tolerated at all doses

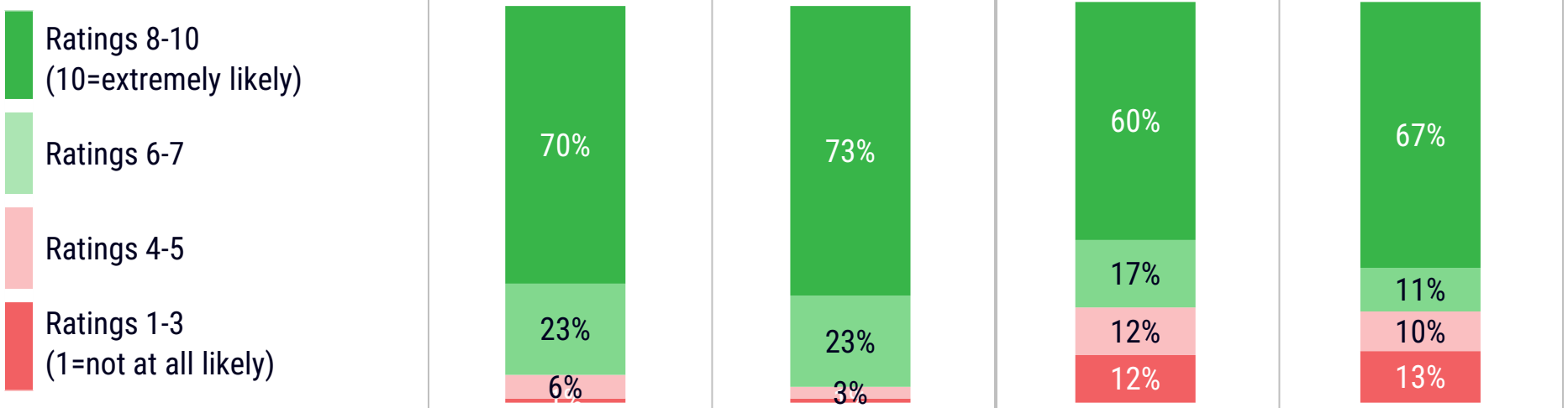
- No treatment-related SAEs or AEs of severe severity
- No AEs leading to treatment discontinuation
- No treatment-related AEs of laboratory parameters, vital signs, or ECG parameters
- Few treatment-related AEs reported within 48 h after administration of study drug

	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

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

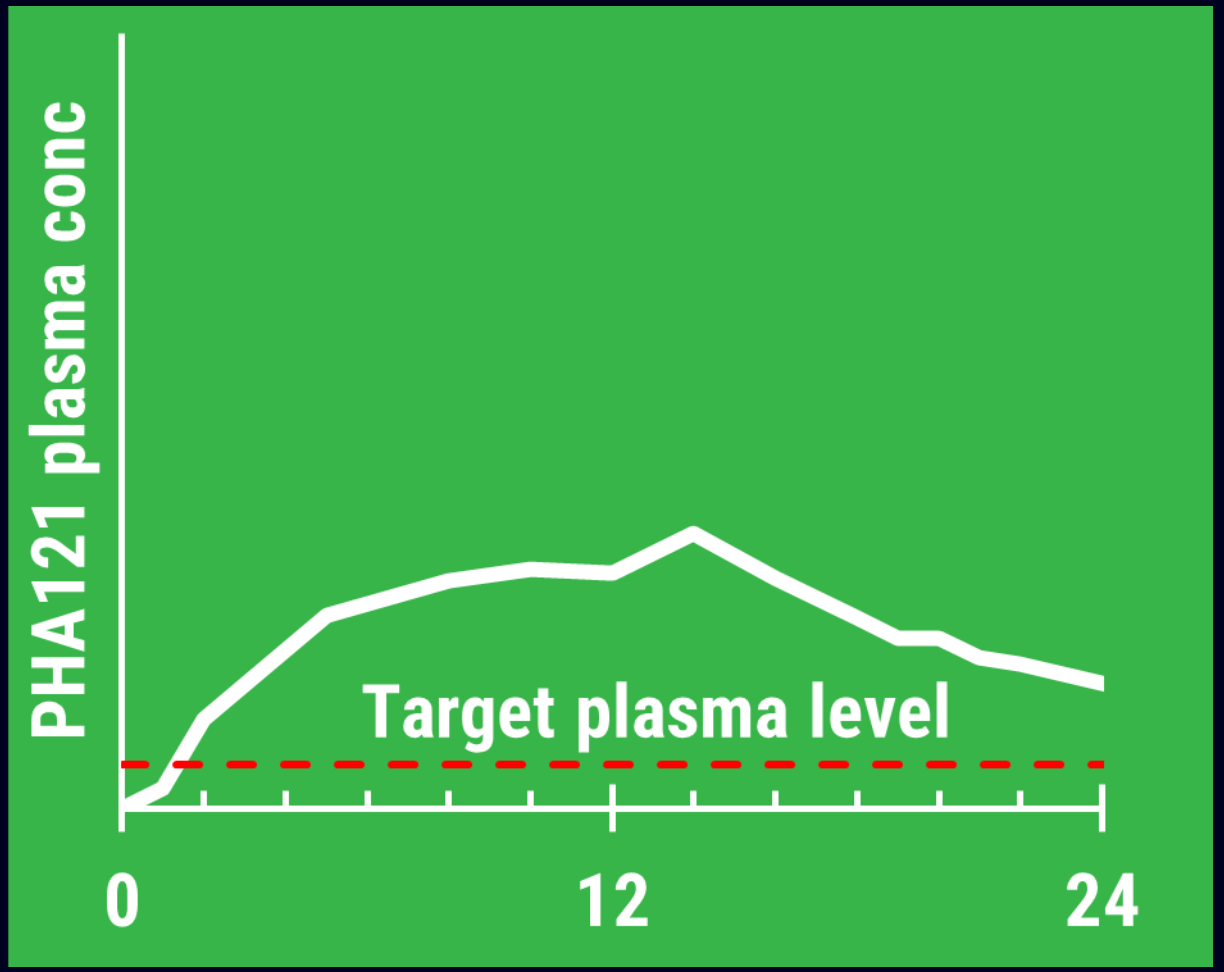
	Doctors (n=100)		Patients (n=103)	
Anticipated impact of ORAL acute therapy on attacks treated	Would treat MORE attacks	Would treat attacks EARLIER	Would treat MORE attacks	Would treat attacks EARLIER
Mean /10	7.9	8.1	7.6	7.7



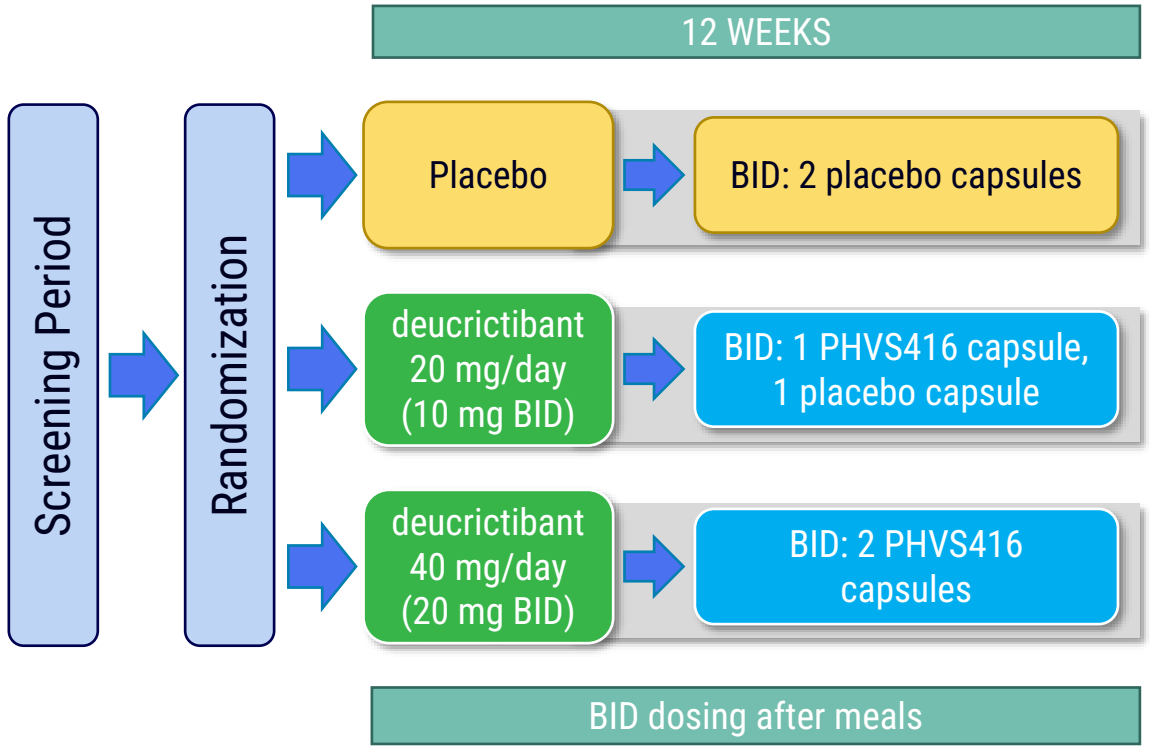
Proprietary Pharvaris research, 2022 (representative sample of patients, n = 103, and doctors, n = 100)

PHVS719/Prophylaxis

Extended-release deucrictibant tablets



HAE CHAPTER-1 study ongoing outside U.S.: Prevention of attacks in HAE (proof of concept with PHVS416)

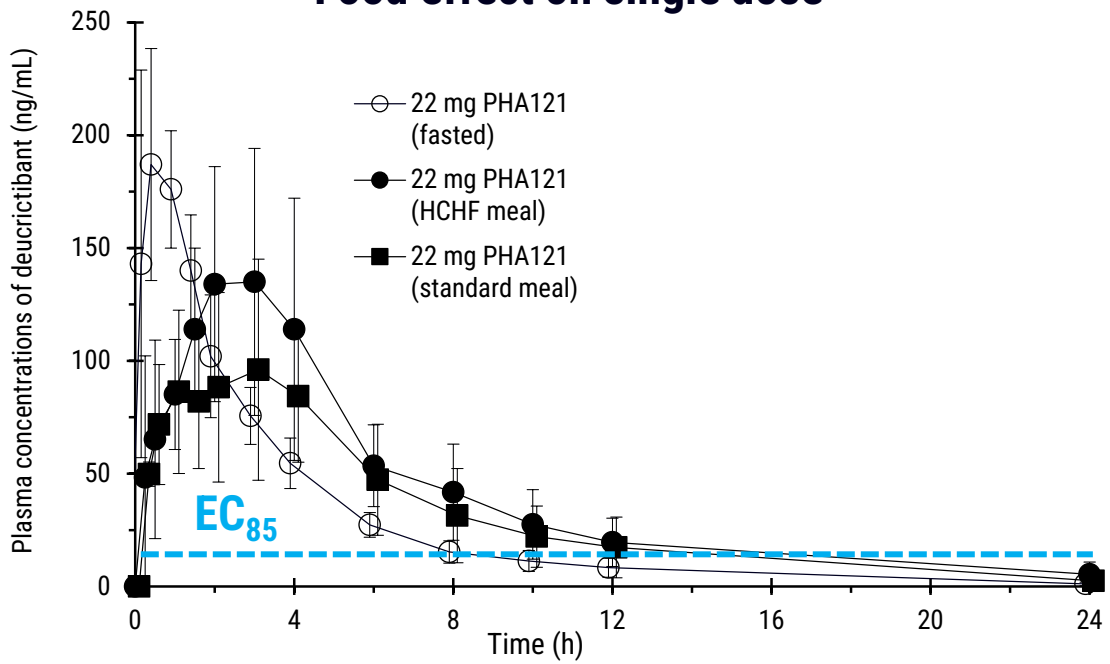


- Primary objective: assessing safety and efficacy of deucrictibant in preventing HAE attacks in patients with HAE type 1 or type 2
  - Placebo-controlled, 3 parallel arms, two doses
  - Includes open-label extension
- Primary endpoint: Number of investigator-confirmed HAE attacks
  - Secondary endpoints include moderate or severe HAE attacks, HAE attacks requiring acute treatment
- Enrolment complete; targeting 30 HAE patients globally
- Regulators in Canada, Europe, Israel, and the UK have been notified of U.S. clinical hold; the regulatory status of the CHAPTER-1 study outside the U.S. remains unchanged

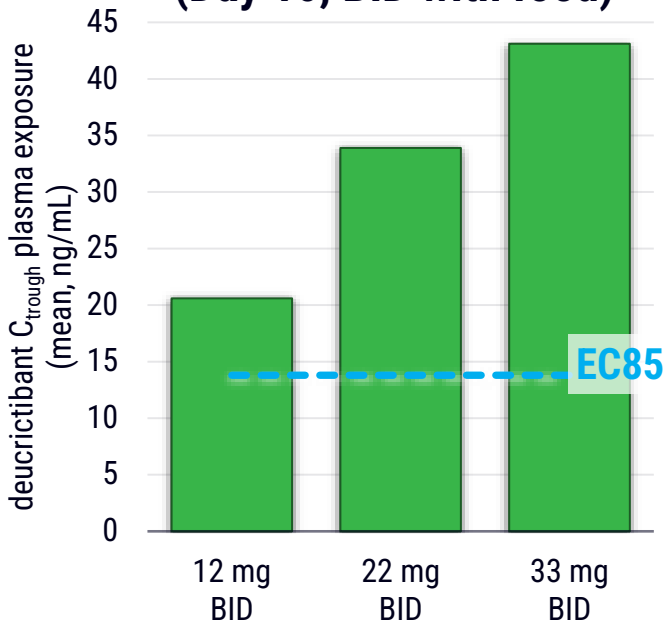
https://clinicaltrials.gov/ct2/show/NCT05047185, https://haechapter-1.com/

Phase 1 pharmacokinetics offer options to use PHVS416 immediate-release deucrictibant capsule as proof-of-concept in prophylactic development

Food effect on single dose



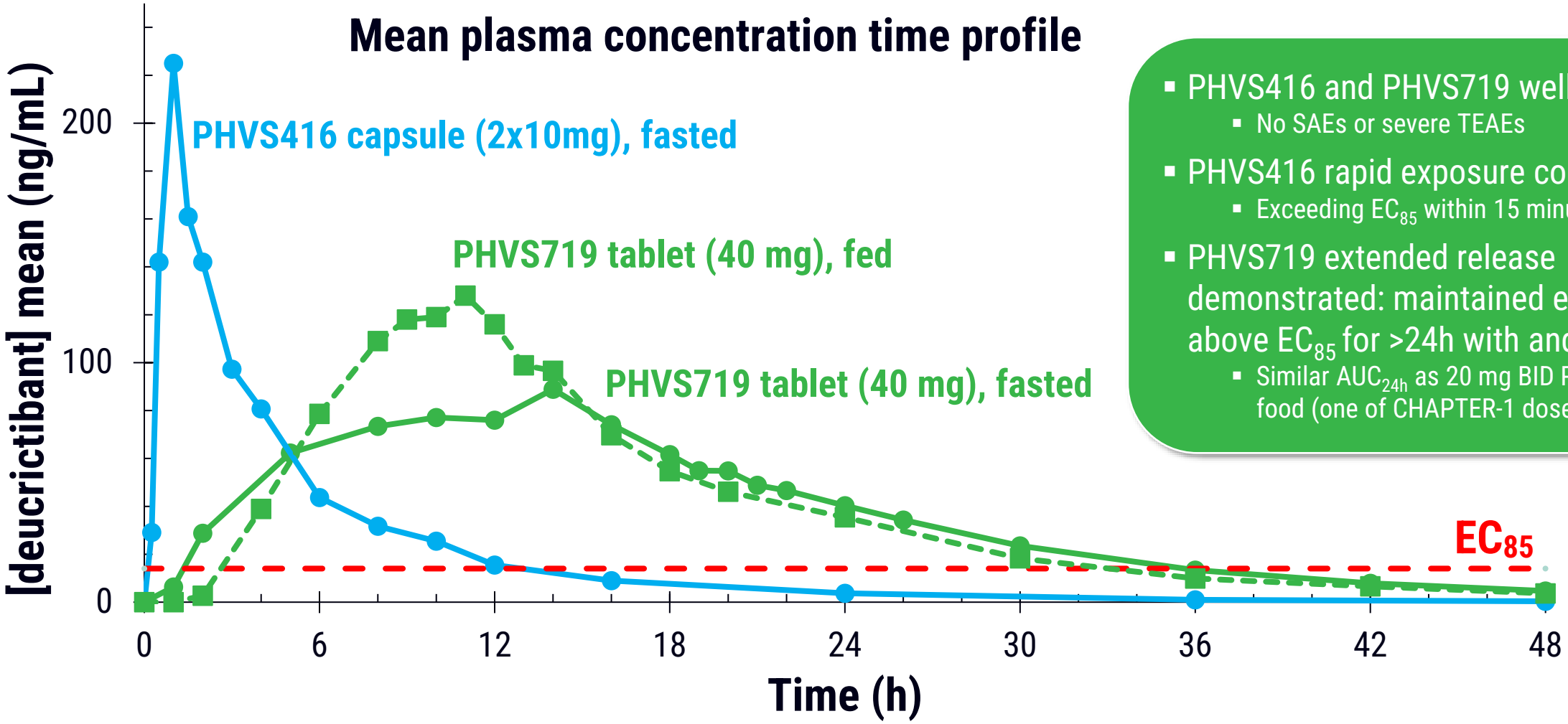
Multiple-dose C_{trough} (Day 10, BID with food)



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

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

PHVS719 single-dose PK study demonstrates QD potential; target for Phase 3 dosage form



- PHVS416 and PHVS719 well tolerated
  - No SAEs or severe TEAEs
- PHVS416 rapid exposure confirmed
  - Exceeding EC_{85} within 15 minutes
- PHVS719 extended release demonstrated: maintained exposure above EC_{85} for >24h with and without food
  - Similar AUC_{24h} as 20 mg BID PHVS416 with food (one of CHAPTER-1 doses)

Corporate summary and milestones

	HAE On-Demand (type 1 and type 2)	HAE Prophylaxis (type 1 and type 2)
PHVS416 deucrictibant immediate-release capsule	✓ RAPIDe-1 Ph2 top-line data meets all primary and key secondary endpoints ▪ Phase 3 initiation	▪ CHAPTER-1 Ph2 top-line data (expected YE23)
PHVS719 deucrictibant extended-release tablet	--	✓ Ph1 SD PK demonstrates once-daily potential ▪ Phase 3 readiness

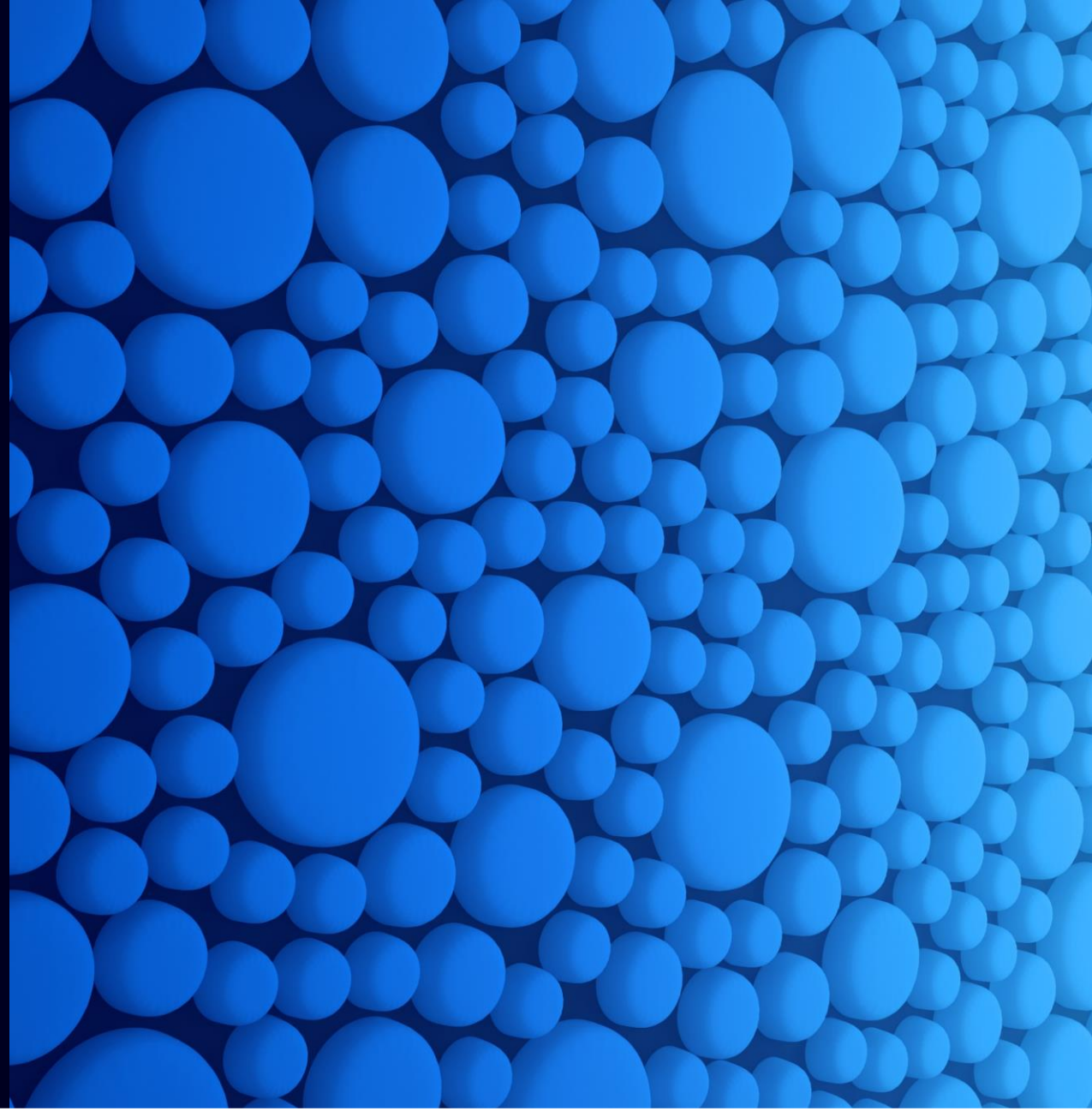
Financially strong: €158M cash; runway into 1Q25

PHARVARIS

Nasdaq: PHVS

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; ≥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

Results summary of primary efficacy endpoint

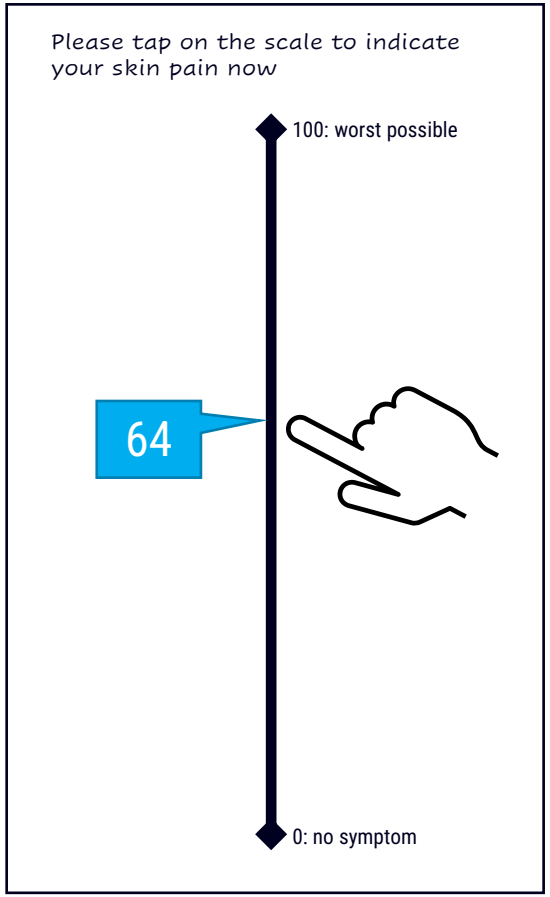
	Placebo N=51	PHVS416 10 mg N=37	PHVS416 20 mg N=28	PHVS416 30 mg N=31	Combined PHVS416* N=96
Mean VAS-3 at pre-treatment	27.76	26.16	25.46	29.73	27.11
Change in VAS-3 at 4 hours					
least-squares mean difference: PHVS416 - Placebo		-16.75	-15.02	-16.28	-16.08
p-value		<0.0001[†]	<0.0001	<0.0001	

[†]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

VAS-3 is a measure of HAE attack severity, based electronically captured numerically assisted visual scale

- Electronically captured patient-reported assessment of three symptoms
  - Skin pain, skin swelling, abdominal pain
- Patient indicates the severity of symptom on a sliding scale, from 0-100
- Once an attack qualifies and is treated, VAS-3 assessed every ~30 min until 4 hours post-treatment and then at 5, 6, 8, 24, 48 hours post-treatment

- Used in approval of two most recently approved on-demand therapies
  - FIRAZYR® icatibant and RUCONEST® C1 esterase inhibitor [recombinant]
- VAS, MSCS, TOS are only endpoints listed for attacks in FDA compendium of clinical outcome assessments (2021) as listed by Division of Pulmonology, Allergy and Critical Care



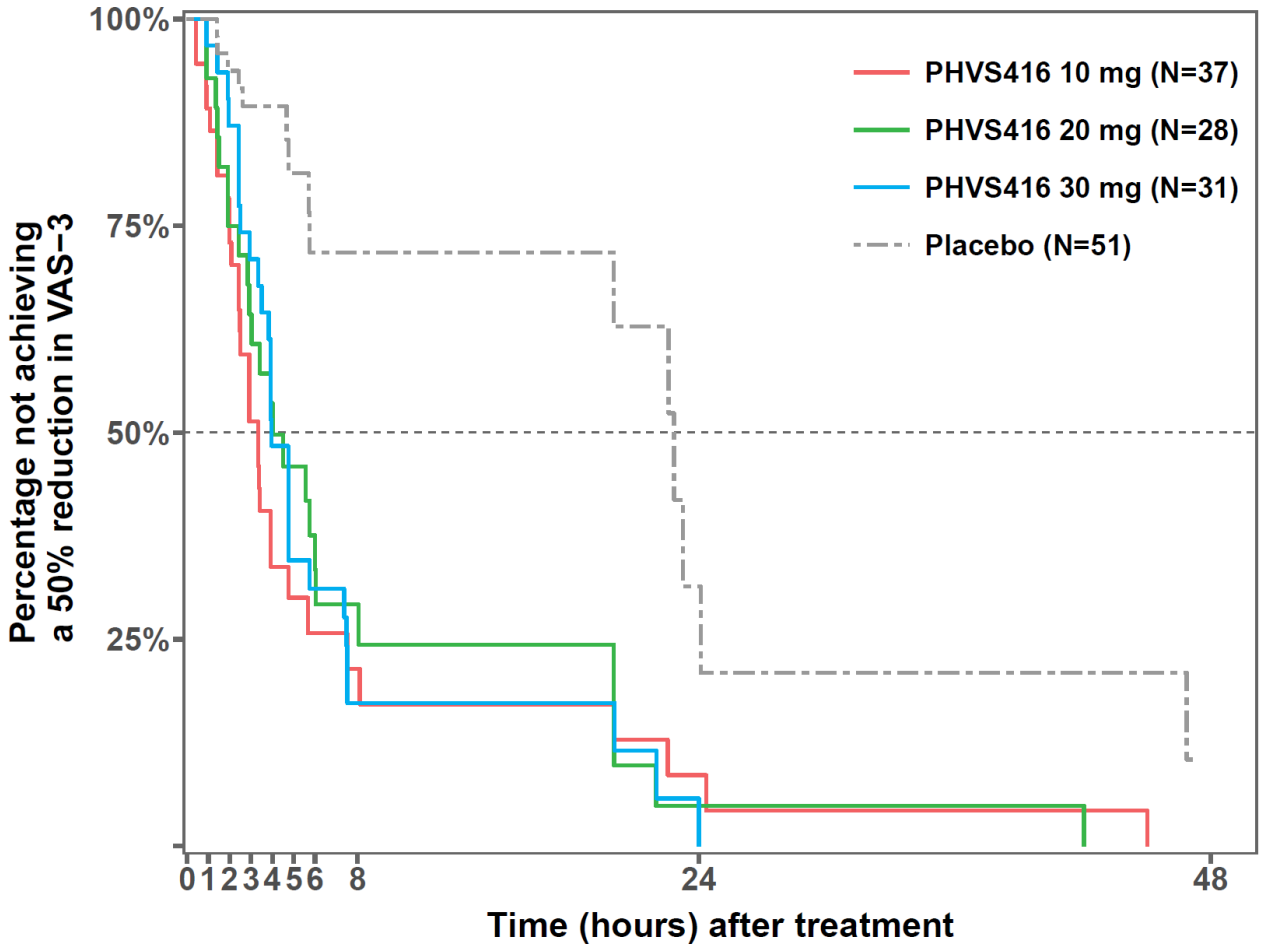
Firazyr is a registered trademark of Shire, and marketed by Takeda; Ruconest is a registered trademark of and marketed by Pharming; FDA 2021 COA compendium: https://www.fda.gov/drugs/development-resources/clinical-outcome-assessment-compendium

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[a]					
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[†]	0.0021	<0.0001	
Time to VAS-3 50% reduction[a]					
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[†]	0.0003	<0.0001	
Time to almost complete or complete symptom relief by VAS[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[†]	0.0127	0.0001	
Change in MSCS score at 4 hours[b]					
least-squares mean difference: PHVS416 - Placebo		-0.79	-0.61	-0.39	-0.61
p-value		<0.0001[†]	0.0008	0.0291	
TOS at 4 hours[b]					
least-squares mean difference: PHVS416 - Placebo		64.13	62.69	71.06	66.05
p-value		<0.0001[†]	<0.0001	<0.0001	

[†]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
[a]Hazard ratios and p-values are based on marginal Cox proportional hazards models
[b]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 reduces 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†
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)	

†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
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)		-0.79	-0.61	-0.39	-0.61
p-value		<0.0001†	0.0008	0.0291	
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)		64.13	62.69	71.06	66.05
p-value		<0.0001†	<0.0001	<0.0001	

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

* Within 48 hours assessments

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