PHARVARIS

RAPIDe-1 Phase 2 Top-line Data

December 8, 2022

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Agenda

Introduction

Berndt Modig, *CEO Pharvaris*

Review of RAPIDe-1 top-line Phase 2 data

Peng Lu, MD PhD, *CMO Pharvaris*

KOL perspective

Marcus Maurer, MD, *Professor of Dermatology and Allergy at the Charité – Universitätsmedizin Berlin; principal investigator on the RAPIDe-1 study*

Closing Remarks, Q&A

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Despite substantial progress there still is a 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

Company research, fall 2022, (patients n = 103, HCPs 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** …

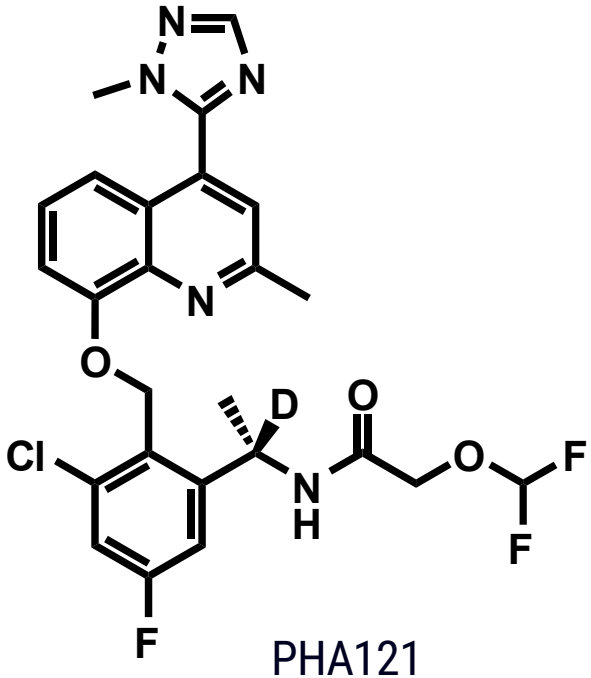
… in an **oral** pill

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

Company research, fall 2022, (patients n = 103, HCPs n = 100)

Pharvaris has discovered the first orally bioavailable bradykinin B2 receptor antagonist

- New molecular entity
- Potent inhibition of the bradykinin B2 receptor
- Rapid absorption, exposure, and tolerability in Phase 1
- Dose and exposure threshold predicted from human surrogate endpoint
  - Bradykinin challenge in healthy volunteers



PHA121

Pharvaris' mission is 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

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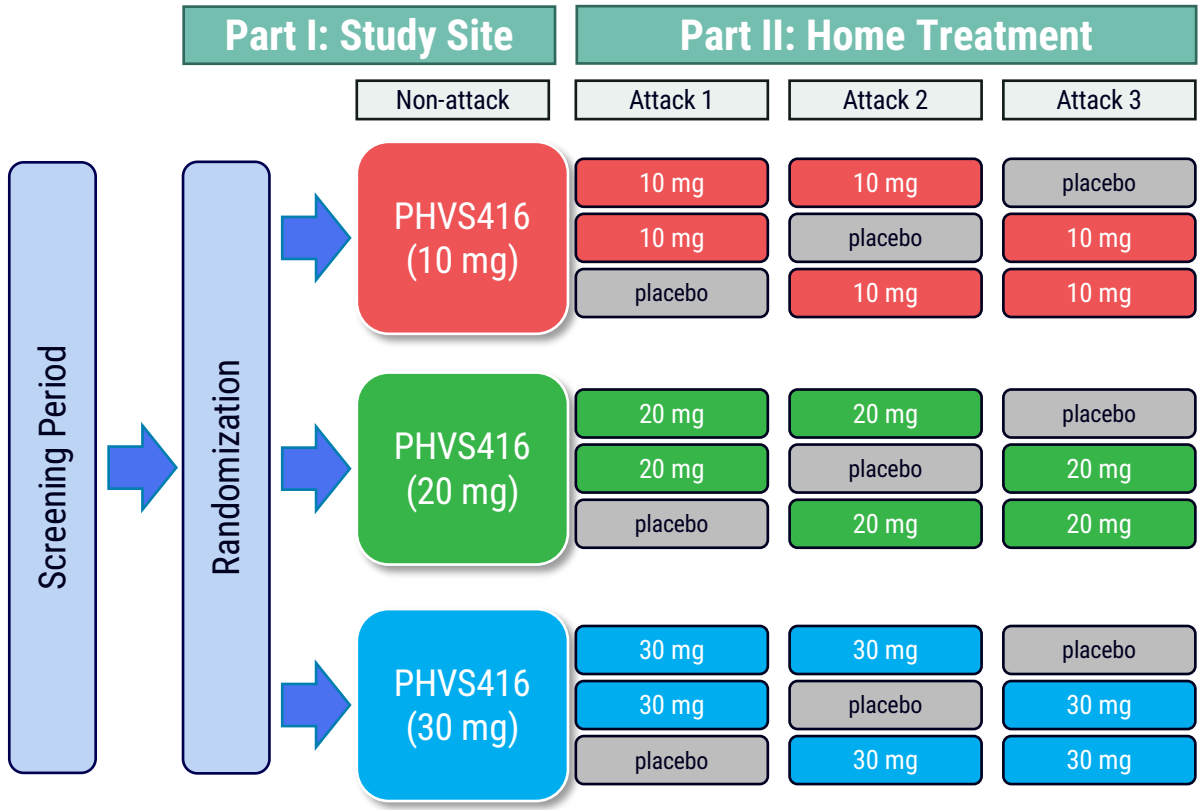
HAE RAPIDe-1 study: Phase 2 study of on-demand treatment of angioedema attacks in patients with Type I or II HAE



- **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 PHA121 in clinic for PK and safety assessment
  - Part II: patients treated three attacks with two PHA121 vs. one placebo
- 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

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

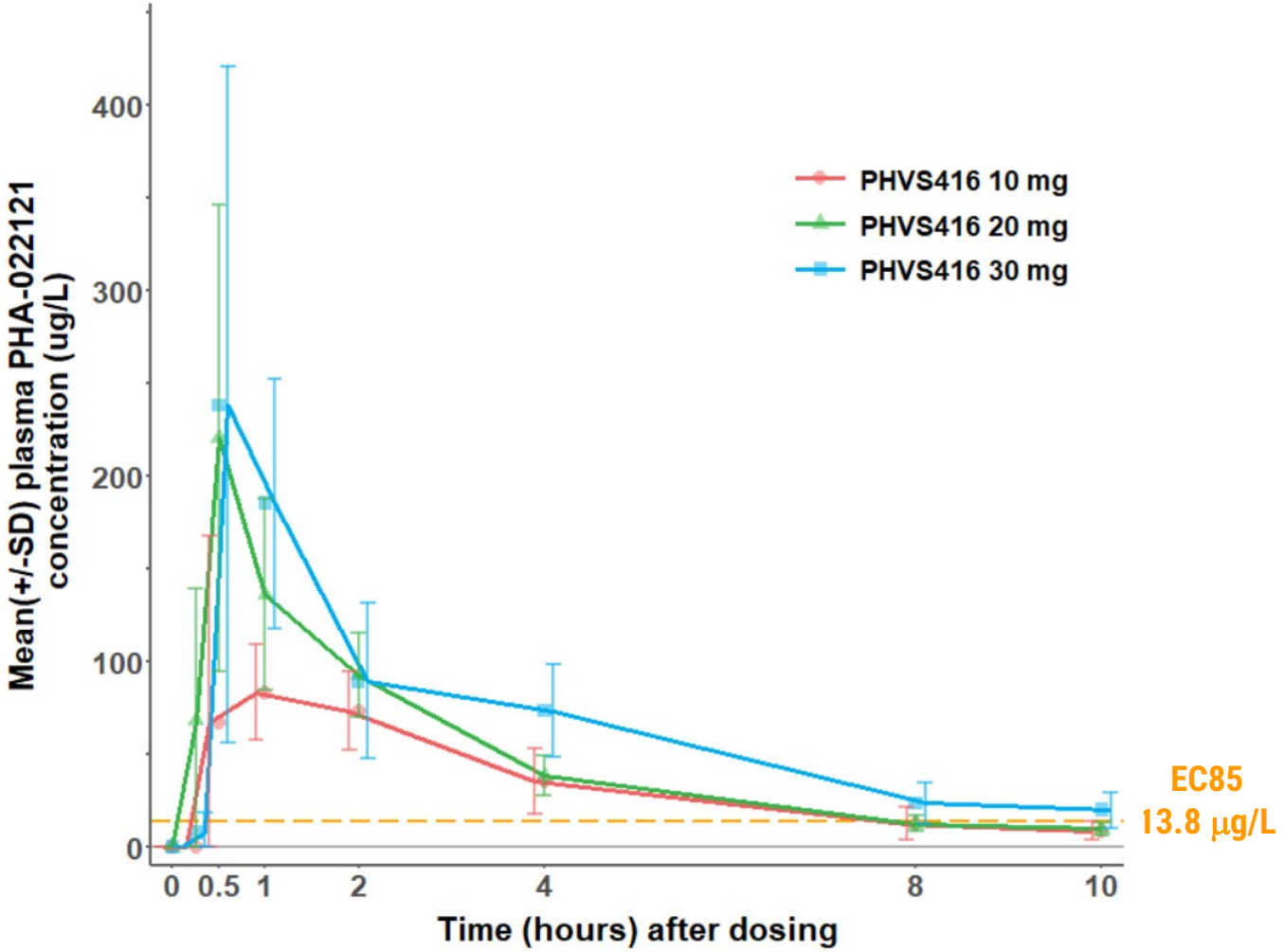
Demographics and baseline characteristics are generally balanced (mITT Analysis Set)

- 156 attacks from 73 patients were included in the safety analysis set
- 147 attacks from 62 patients were included in the mITT analysis set for efficacy

	PHVS416 10 mg	PHVS416 20 mg	PHVS416 30 mg	Total
N	22	18	22	62
Age in yrs (mean)	42.5	44.5	41.9	42.9
Sex - M/F	7/15	5/13	8/14	20/42
Race - White/Other	20/2	18/0	22/0	60/2
Height in cm (mean)	169	167	170	169
BMI (mean)	27.5	27.6	27.9	27.7
Years since HAE diagnosis (mean)	21.11	21.64	23.98	22.28
HAE				
Type 1	18	15	22	55
Type 2	4	2	0	6
Type 1 or Type 2	0	1	0	1

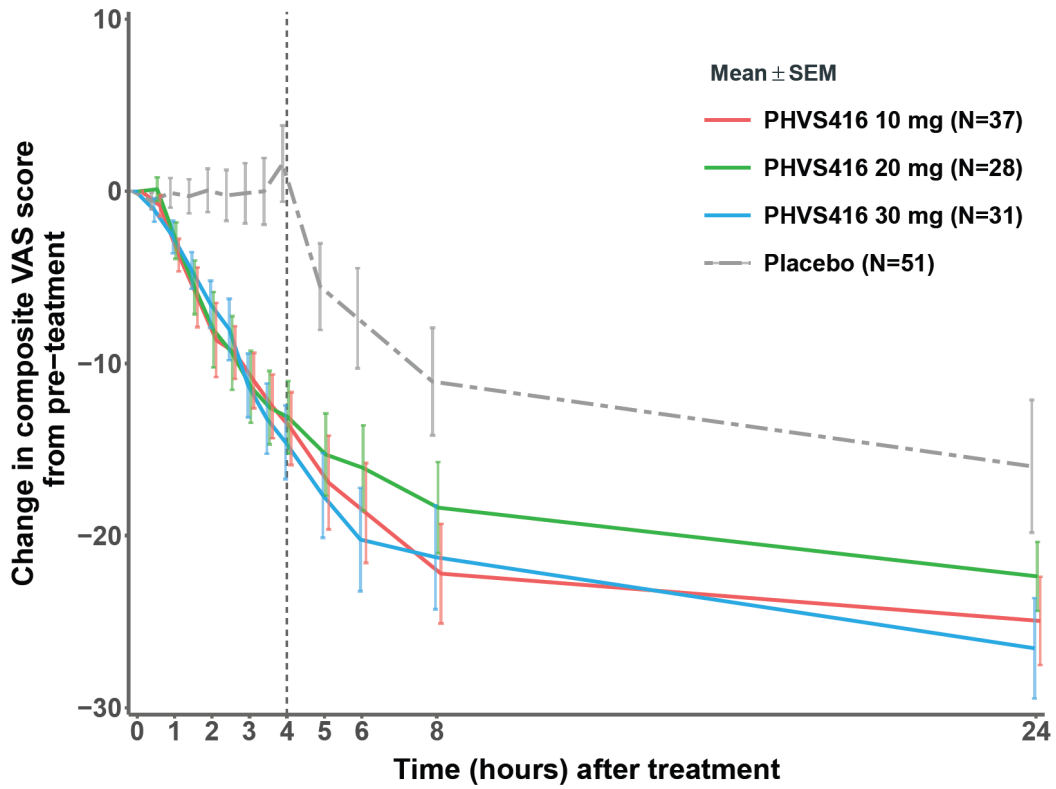
mITT = modified intent-to-treat. The mITT Analysis Set includes all randomized patients who had at least one treated HAE attack and who had non-missing VAS results at both pre-treatment and at least 1 post-treatment time point of that attack

PK profile in HAE patients: Rapid absorption confirmed, consistent with Phase 1 healthy volunteer studies



- Rapid absorption with mean plasma levels >EC_{85} (13.8 ng/mL) reached 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

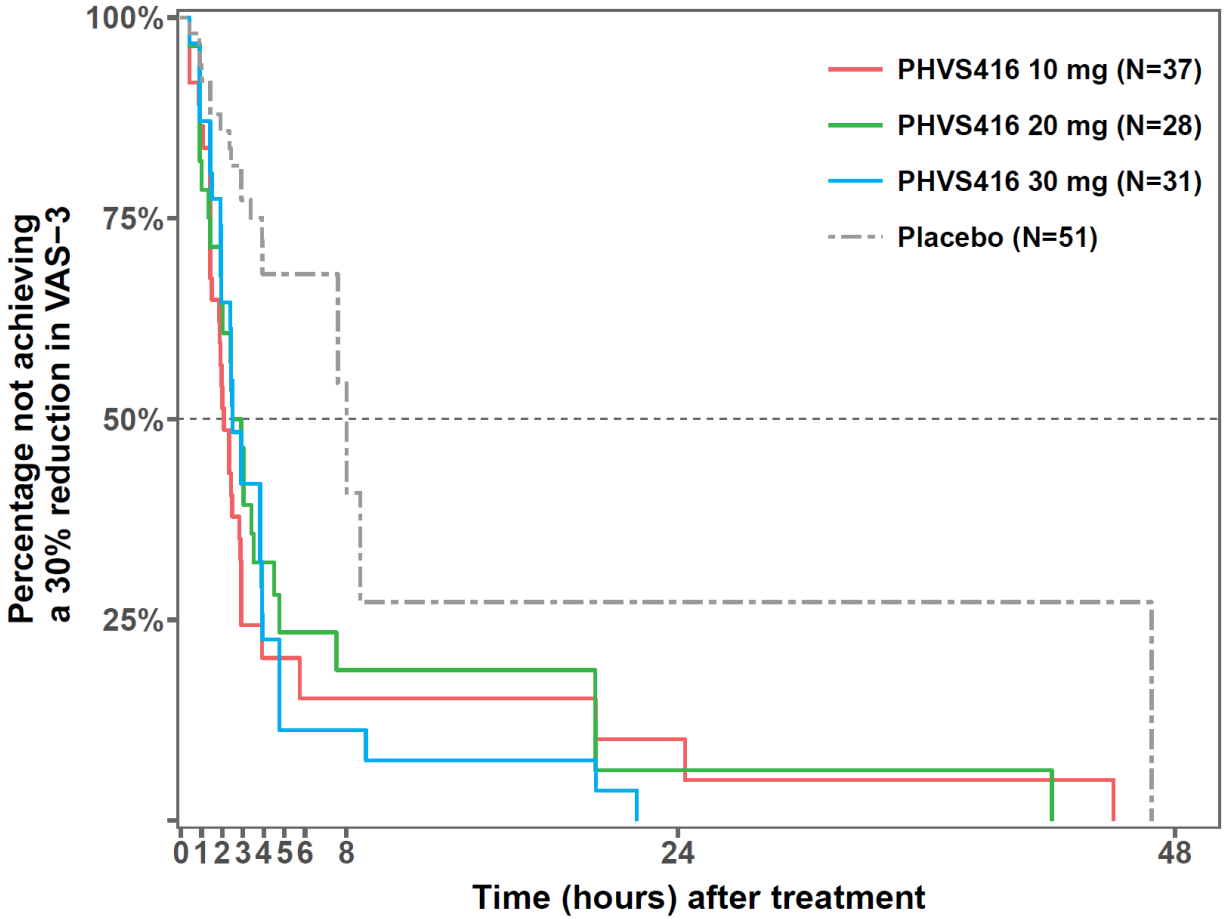


Difference from placebo in change from pre-treatment to 4 h post-treatment, least-squares mean (95% CI)		
PHVS416 10 mg	-16.75 (-21.52, -11.97)	p < 0.0001†
PHVS416 20 mg	-15.02 (-20.22, -9.81)	p < 0.0001
PHVS416 30 mg	-16.28 (-21.27, -11.29)	p < 0.0001
Combined PHVS416	-16.08 (-19.87, -12.29)	

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

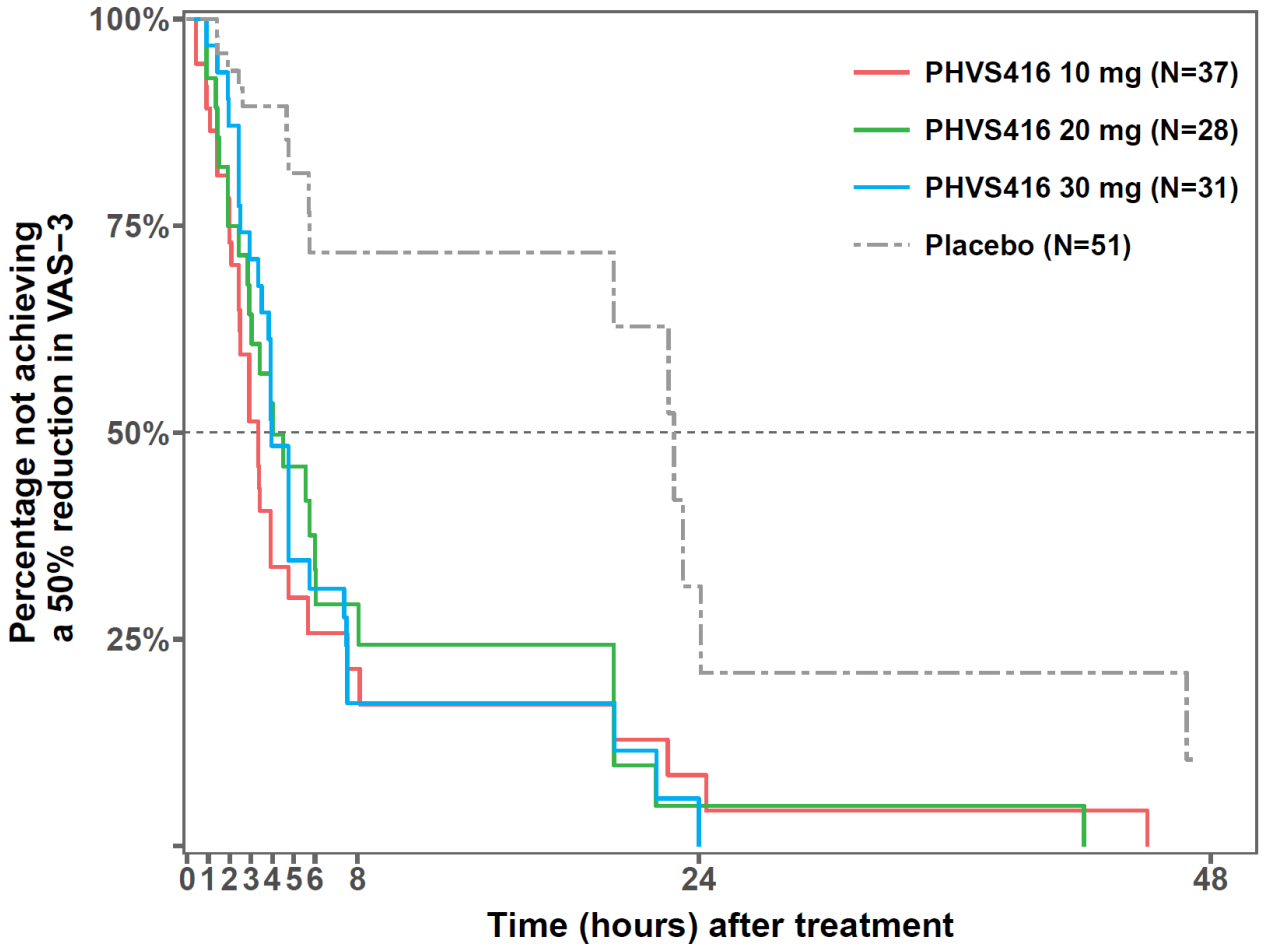
PHVS416 significantly shortened time to onset of symptom relief (30% reduction in VAS-3)



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)	

†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.

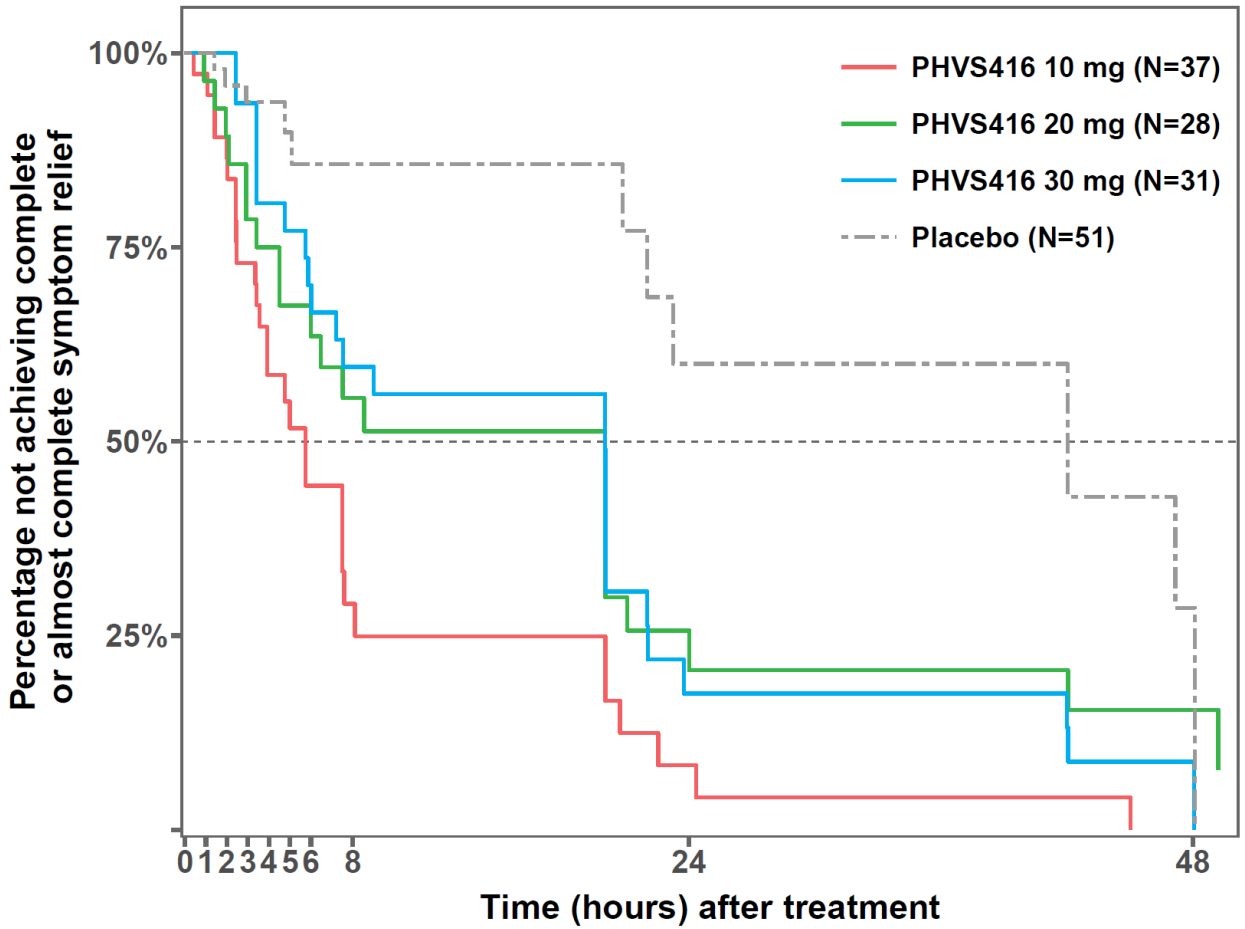
PHVS416 significantly reduces time to 50% reduction in VAS-3



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.

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)	

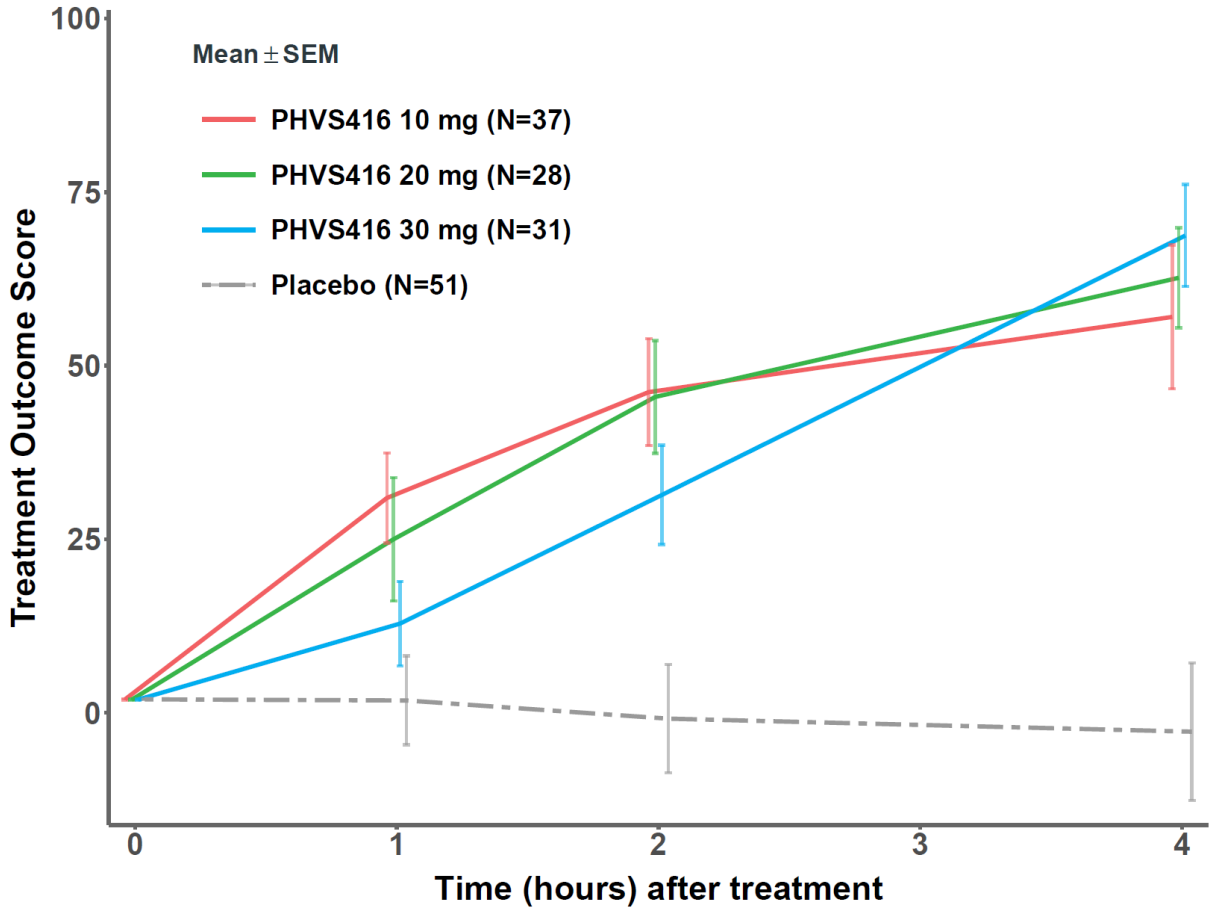
†Nominal p-value; VAS assessed every 30 minutes up to 4 hours post-treatment, then at 5, 6, 8, 24, 48 hours; N = The number of attacks in the mITT Analysis Set. Median time based on Kaplan-Meier estimates. p-values based on a marginal Cox proportional hazards model. The combined PHVS416 results are based on post-hoc analyses to provide a reference of the result by pooling all three active doses.

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

PHVS416 significantly improves TOS score at 4h

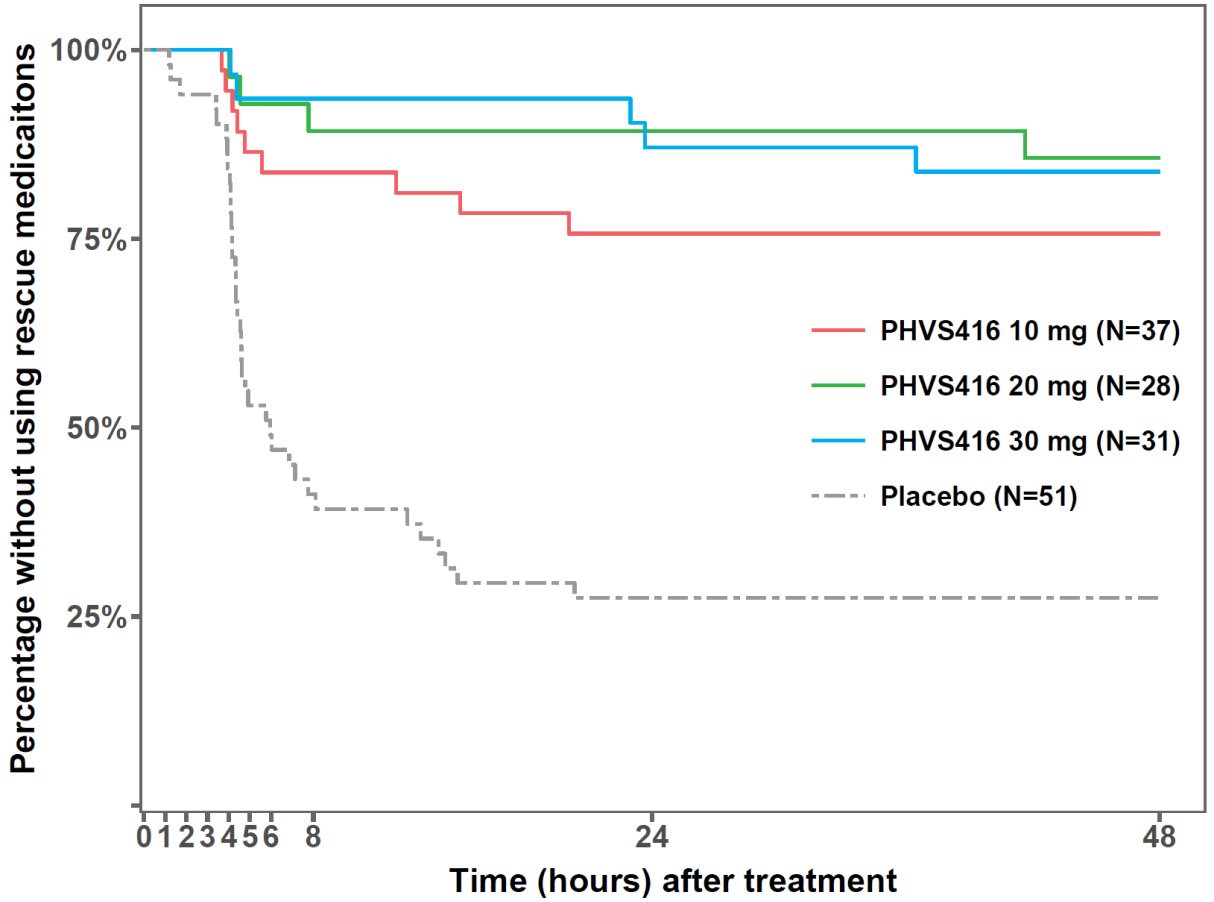


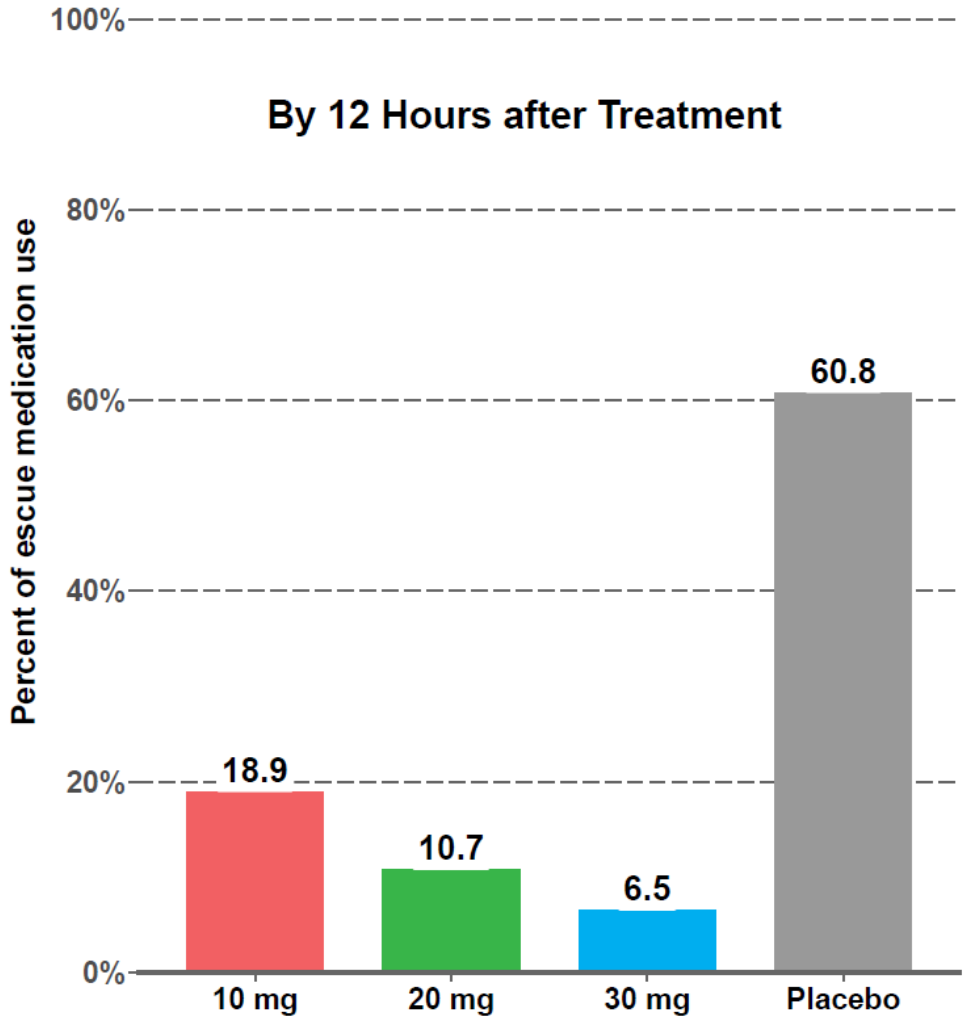
Difference from placebo in 4 h post-treatment least-squares mean (95% CI)		
PHVS416 10 mg	64.13 (40.35, 87.91)	$p < 0.0001^{\dagger}$
PHVS416 20 mg	62.69 (36.71, 88.67)	$p < 0.0001$
PHVS416 30 mg	71.06 (46.09, 96.03)	$p < 0.0001$
Combined PHVS416	66.05 (47.42, 84.69)	

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*

Patients treating with PHVS416 used substantially less rescue medication





N = The number of attacks in the mITT Analysis Set

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

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

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

Recap of RAPIDe-1 top-line results

- 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

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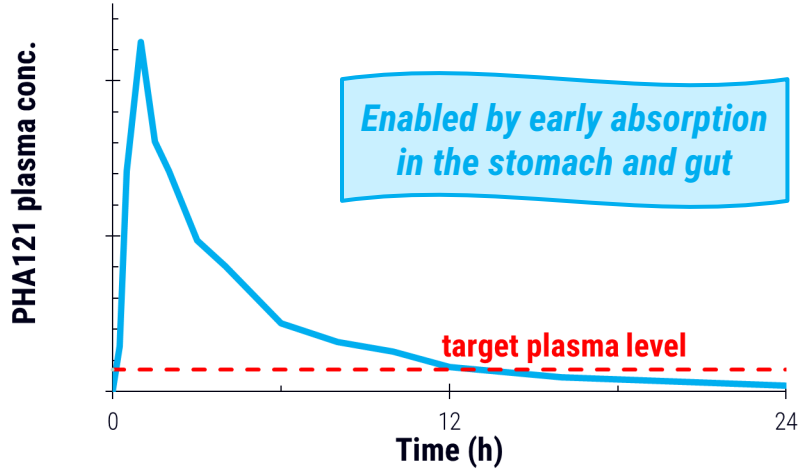
On-demand and prophylaxis: Developing two oral products utilizing the same active ingredient

PHA121

PHVS416

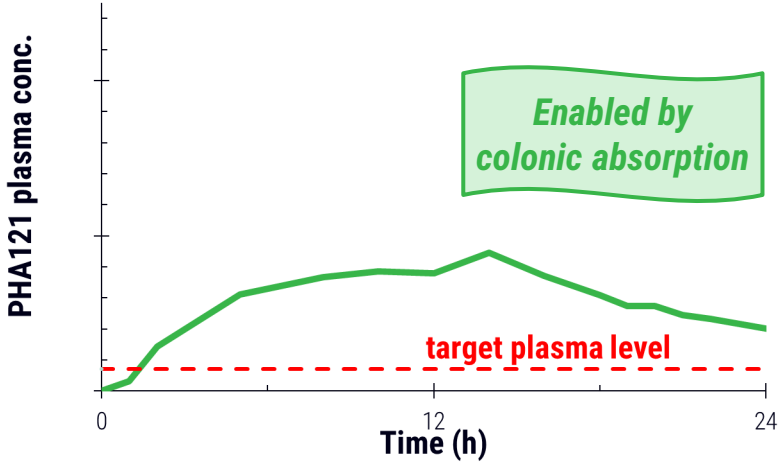
Softgel capsule formulation



Potential to provide rapid, easy, and reliable symptom relief for all attacks*

PHVS719

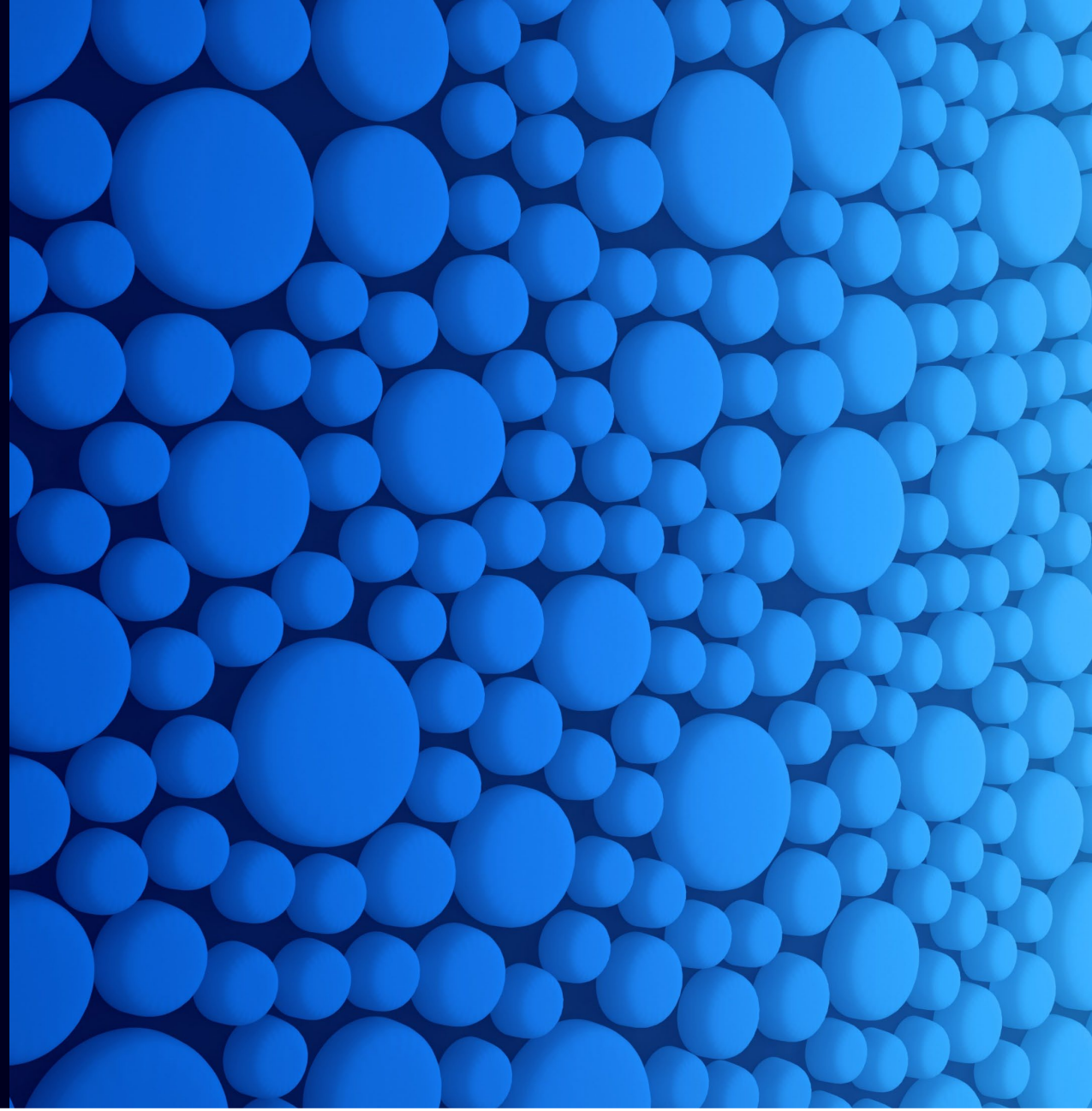
Extended-release tablet formulation



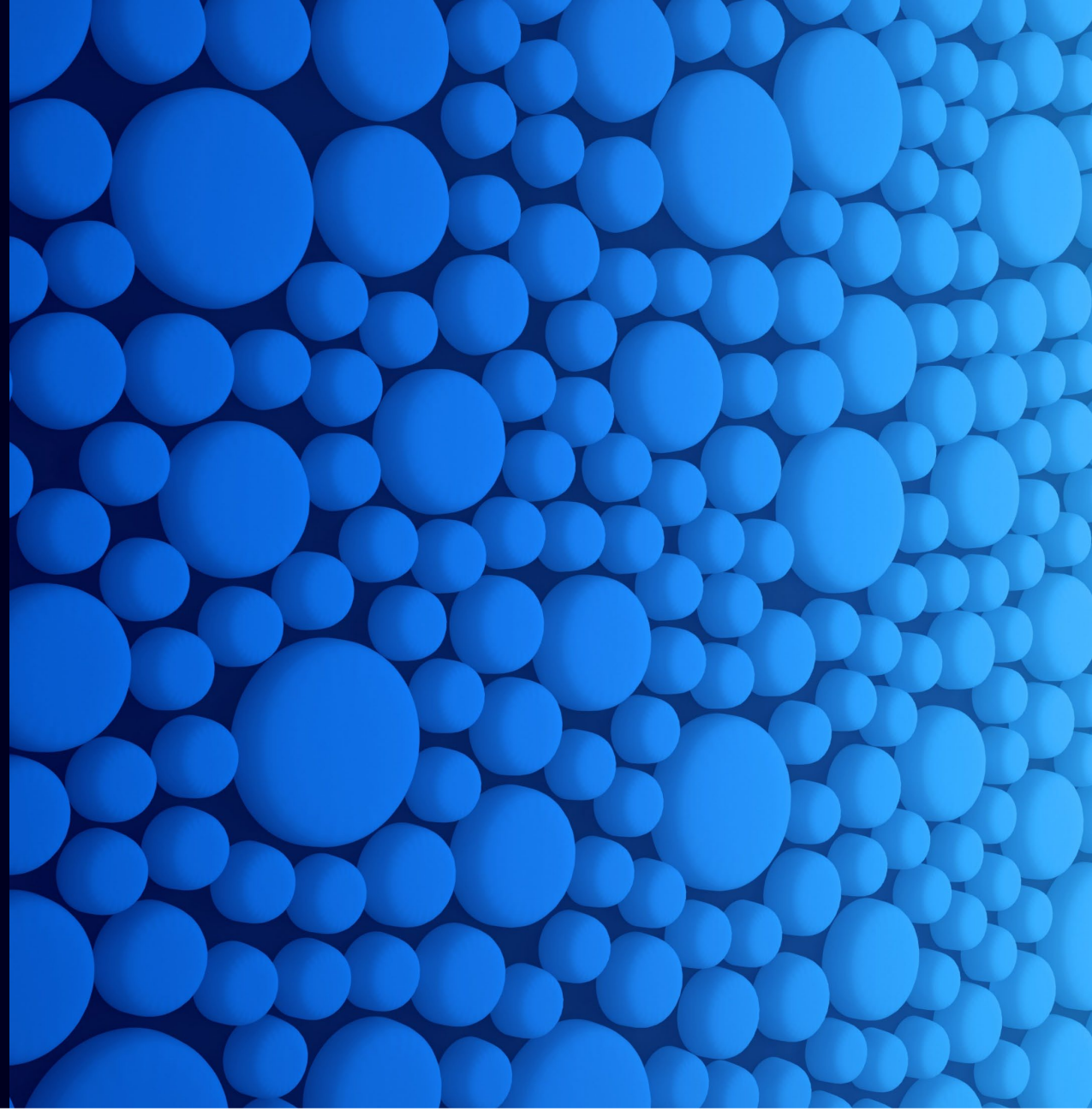
Aim to maintain compound exposure to prevent attacks, for convenient and effective control*

*Aspirational; to be confirmed with clinical data

Q&A



Appendix



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	

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

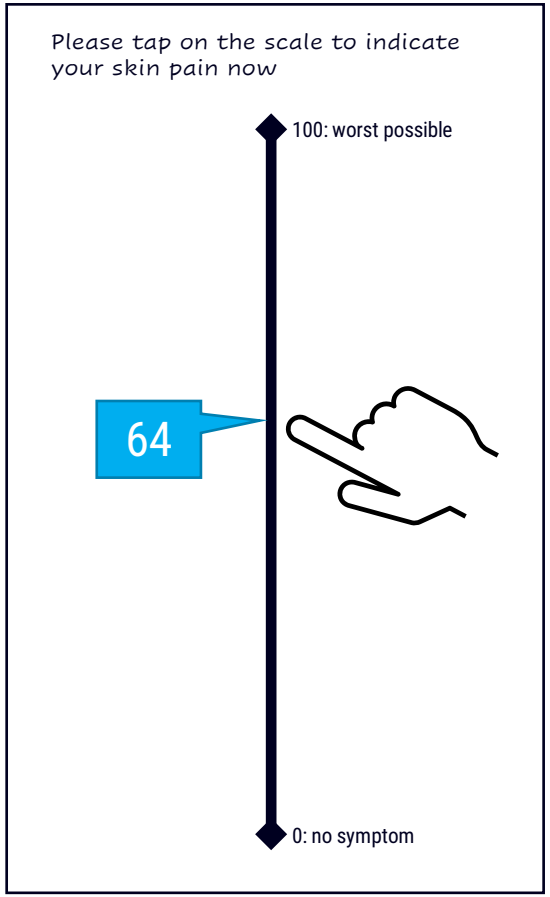
	Placebo N=51	PHVS416 10 mg N=37	PHVS416 20 mg N=28	PHVS416 30 mg N=31	Combined PHVS416* N=96
Time to onset of symptom relief by VAS-3 30% reduction[a]					
Median time in hours (95% CI)	8.0 (7.6, 46.9)	2.1 (1.5, 2.9)	2.7 (1.9, 3.5)	2.5 (1.9, 3.8)	2.4 (2.0, 2.9)
Hazard ratio		3.81	3.08	3.61	
p-value		<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	

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

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

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

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