



**PHARVARiS**

## **Virtual Investor Day**

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Pioneering science for patient choice

October 23, 2024

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# Agenda



**Michael Manning, M.D., Allergy, Asthma & Immunology, Scottsdale, AZ**



**Raffi Tachdjian, M.D., MPH, David Geffen School of Medicine, UCLA**



**Berndt Modig, CEO Pharvaris**



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



**Wim Souverijns, Ph.D., CCO Pharvaris**

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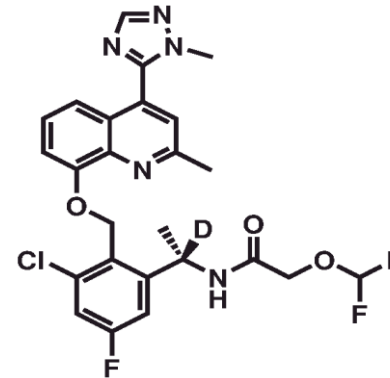
**Wim Souverijns, Ph.D., CCO Pharvaris**

# Deucrictibant has the potential to become a preferred therapy for people living with HAE

## DEUCRICTIBANT extended-release (XR) tablet sustained absorption<sup>1</sup>

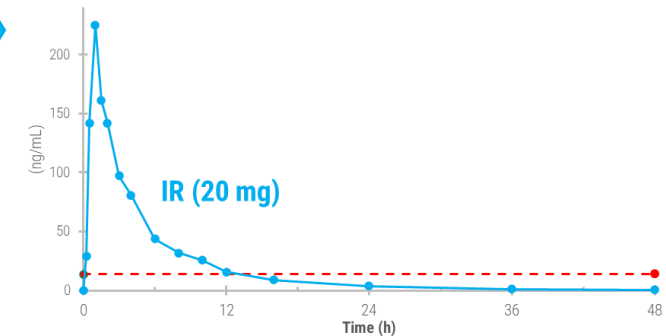


Maintains sustained therapeutic exposure over 24 hours<sup>2</sup> from day one, allowing for once-daily oral treatment to prevent HAE attacks\*



deucrictibant

## DEUCRICTIBANT immediate-release (IR) capsule rapid absorption<sup>3</sup>



Rapidly reaches therapeutic exposure within 15-30 minutes<sup>4</sup>, making it optimal for on-demand oral treatment of HAE attacks\*

Two oral products with the same active ingredient for the prevention and treatment of HAE attacks

\*To be confirmed with clinical data from Phase 3 studies

Source: <sup>1</sup>Company data: single-dose cross-over PK study in healthy volunteers (n=14) under fasting conditions. <sup>2</sup>Lesage A et al. [IDDST 2024](#). <sup>3</sup>Crabbe et al. [AAAAI 2021](#). <sup>4</sup>Maurer M et al. [AAAAI 2023](#).

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# Deucricitbant's differentiated profile for LTP and ODT



**Oral LTP or ODT Formulations**



Deucricitbant is the **only HAE therapy**<sup>1</sup> in development that allows for oral administration **in both prophylaxis and on-demand**<sup>2</sup>



**Single Oral Pill**



**Specific formulations** allow for **once-daily dosing**<sup>3</sup> (XR for LTP) or **rapid, single-dose resolution**<sup>4</sup> of HAE attacks (IR for ODT)



**Rapid to Steady State**



Deucricitbant XR has the potential to achieve steady state within 2-3 days<sup>5</sup>, providing **protection against HAE attacks on the initial day**<sup>3</sup> of LTP initiation



**Rapid Absorption**



Within 15-30 minutes<sup>6</sup>, deucricitbant IR reaches therapeutic exposure resulting in the halt of attack progression within **30 minutes**<sup>7</sup>



**Longer Effective Exposure**



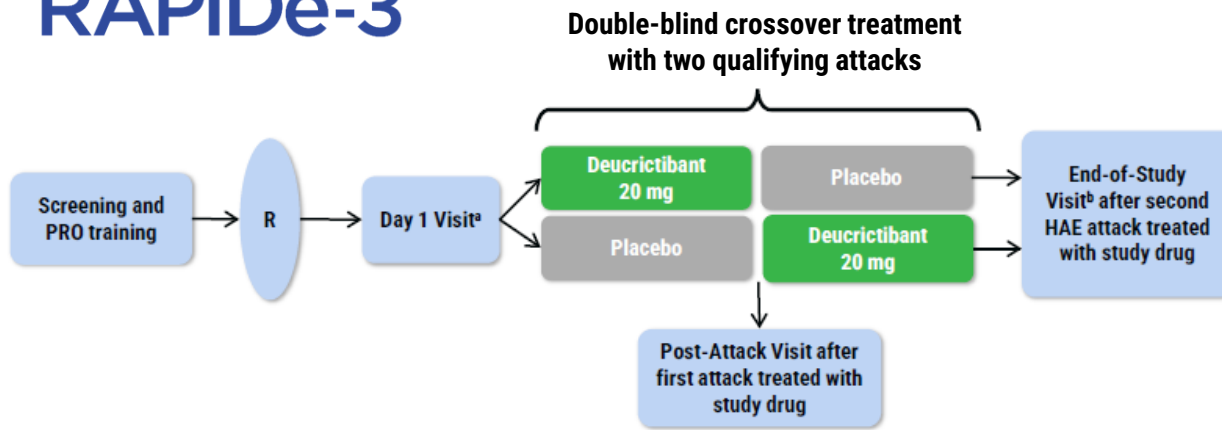
A longer effective exposure results in a **high rate of single-dose attack resolution**<sup>8</sup>



Sources: <sup>1</sup>Company research. <sup>2</sup>Leasge et al. [IDDST 2024](#). <sup>3</sup>Groen K et al. [ACAAI 2022](#). <sup>4</sup>Li H et al. [EAC 2024](#). <sup>5</sup>Maurer M et al. [HAEi Workshop, 2022](#). <sup>6</sup>Maurer M et al. [AAAAI 2023](#). <sup>7</sup>Riedl et al. [WSAAI 2024](#). <sup>8</sup>Maurer M et al. [BKS 2024](#).

# HAE RAPiDe-3<sup>1</sup> study enrolling: A global Phase 3 study of on-demand treatment of angioedema attacks in people with HAE-1/2

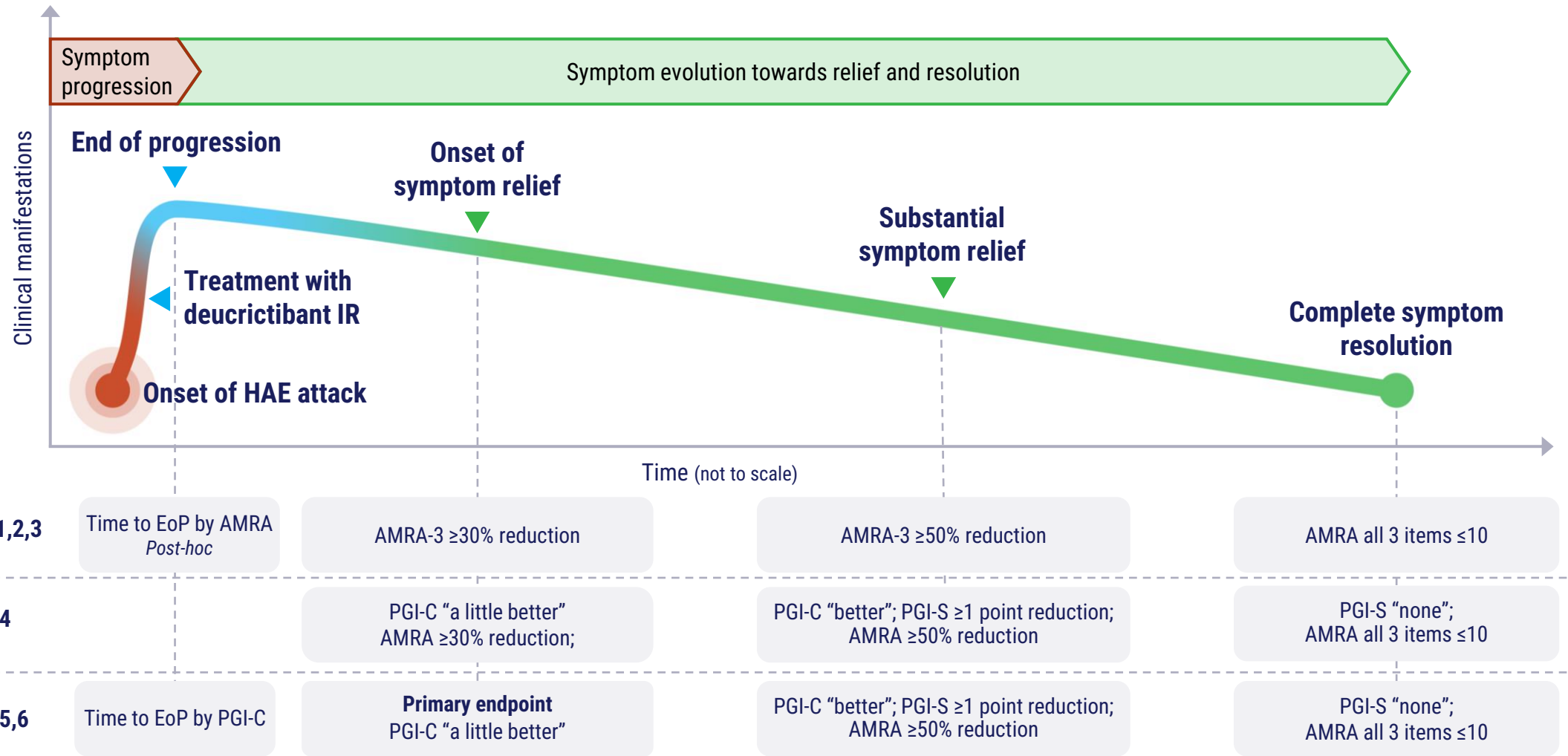
## RAPiDe-3



- Target enrollment of approximately 120 adolescents and adults (between 12 and 75 years old)
- **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

Adolescent patients receive a non-attack dose for PK sampling prior to randomization.  
 Source: <sup>1</sup>Maurer M et al. [EAACI 2024](#).

# Clinical trial endpoints span the entire attack timecourse

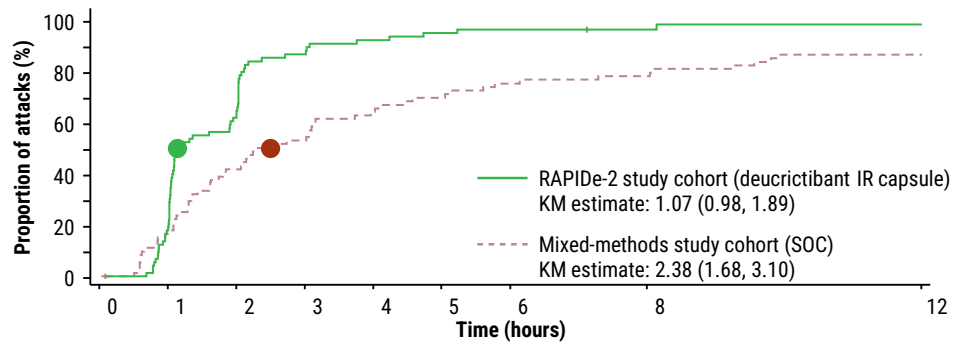


AMRA, Angioedema Symptom Rating Scale; EoP, end of progression; HAE, hereditary angioedema; IR, immediate release; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity.

Source: <sup>1</sup>[NCT04618211](#). <sup>2</sup>Riedl et al. [ACAAI 2023](#). <sup>3</sup>Medivil et al. [GA<sup>2</sup>LEN UCARE 2023](#). <sup>4</sup>[NCT05396105](#). <sup>5</sup>[NCT06343779](#). <sup>6</sup>Maurer et al. [EAACI 2024](#).

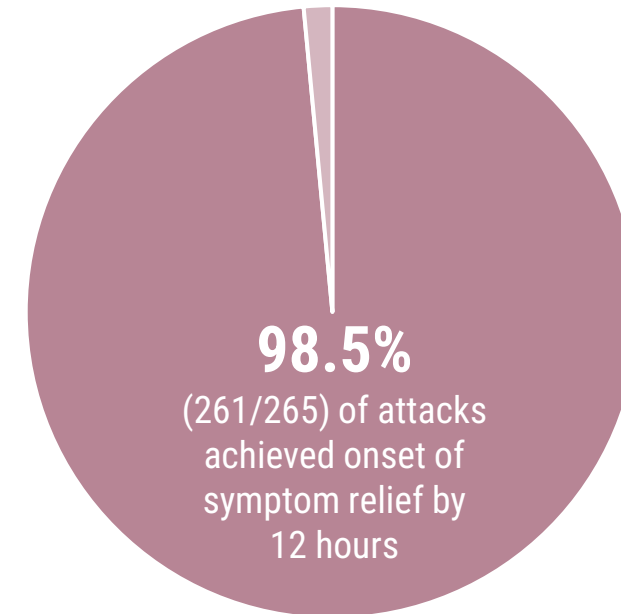
# PGI-C “a little better” is the RAPIDe-3 primary endpoint

## Propensity score-matched analysis findings<sup>1</sup>



Time to symptom relief in hours, median (95% CI)	RAPIDe-2 cohort (deucricitabant; N=73)	Mixed-methods cohort (SOC; N=73)
A PGI-C – “A little better”	1.07 (0.98, 1.89)	2.38 (1.68, 3.10)

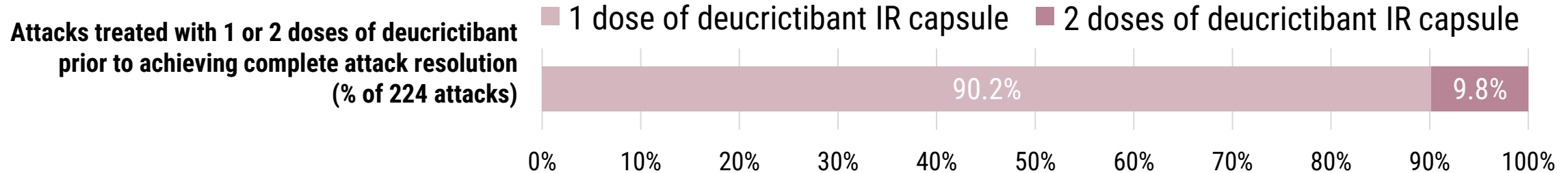
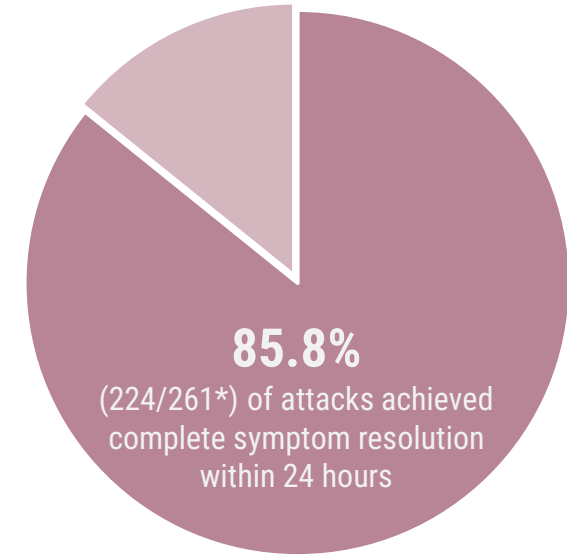
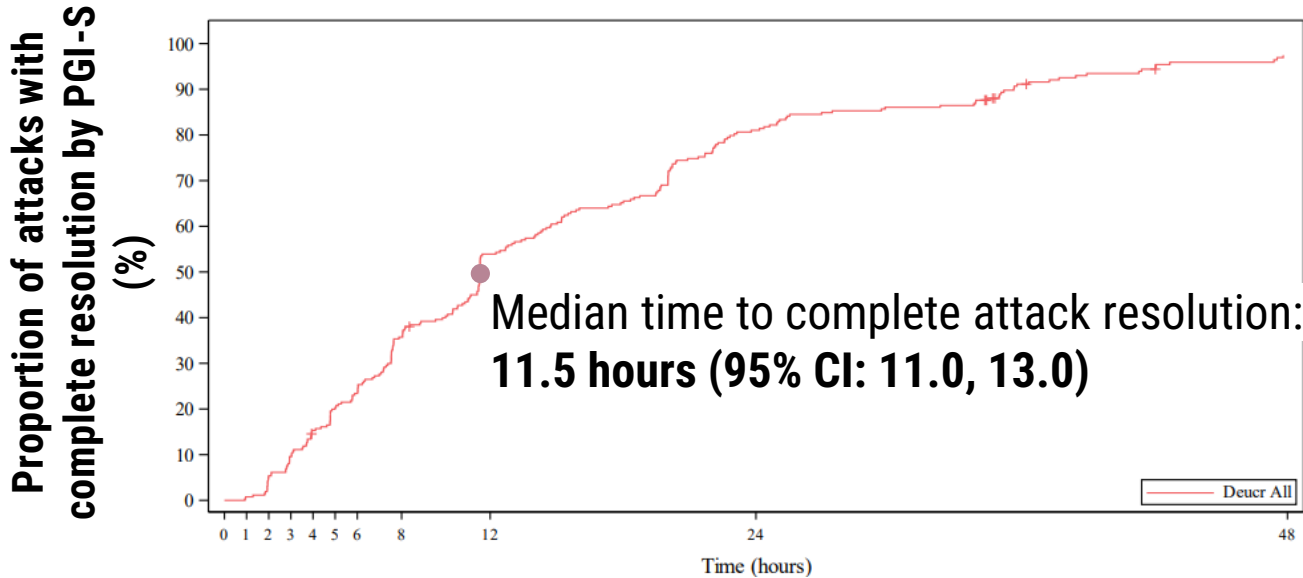
## RAPIDe-2 long-term extension data<sup>2</sup>



PGI-C, Patient Global Impression of Change. Time to onset of symptom relief is defined as PGI-C rating of at least “a little better” for two consecutive timepoints post-treatment. Symptom relief is also considered as achieved if PGI-C rating reached at least a “little better” at the last scheduled time point (48 h) provided no rescue medication used within 48h after the last time point. The time is censored at the time of the last post-treatment PGI-C assessment prior to intake of HAE rescue medication, or a medication not allowed for treating an attack.

Source: <sup>1</sup>Riedl MA et al. [BKS 2024](#). <sup>2</sup>Maurer M et al. [BKS 2024](#).

# Median attack resolution time 11.5 hours: 85.8% of attacks completely resolved within 24 hours (90.2% of which with one only dose)<sup>1</sup>



PGI-S, Patient Global Impression of Severity. Time to complete attack resolution is defined as the time to post-treatment PGI-S rating achieving "none". \*261 attacks have non-missing pre-treatment PGI-S. Source: <sup>1</sup>Maurer M et al. [BKS 2024](#).

# Deucricitbant's differentiated profile for LTP and ODT



## Oral LTP or ODT Formulations



Deucricitbant is the **only HAE therapy**<sup>1</sup> in development that allows for oral administration **in both prophylaxis and on-demand**<sup>2</sup>



## Single Oral Pill



**Specific formulations** allow for **once-daily dosing**<sup>3</sup> (XR for LTP) or **rapid, single-dose resolution**<sup>4</sup> of HAE attacks (IR for ODT)



## Rapid to Steady State



Deucricitbant XR has the potential to achieve steady state within 2-3 days<sup>5</sup>, providing **protection against HAE attacks on the initial day**<sup>3</sup> of LTP initiation



## Rapid Absorption



Within 15-30 minutes<sup>6</sup>, deucricitbant IR reaches therapeutic exposure resulting in the halt of attack progression within **30 minutes**<sup>7</sup>



## Longer Effective Exposure

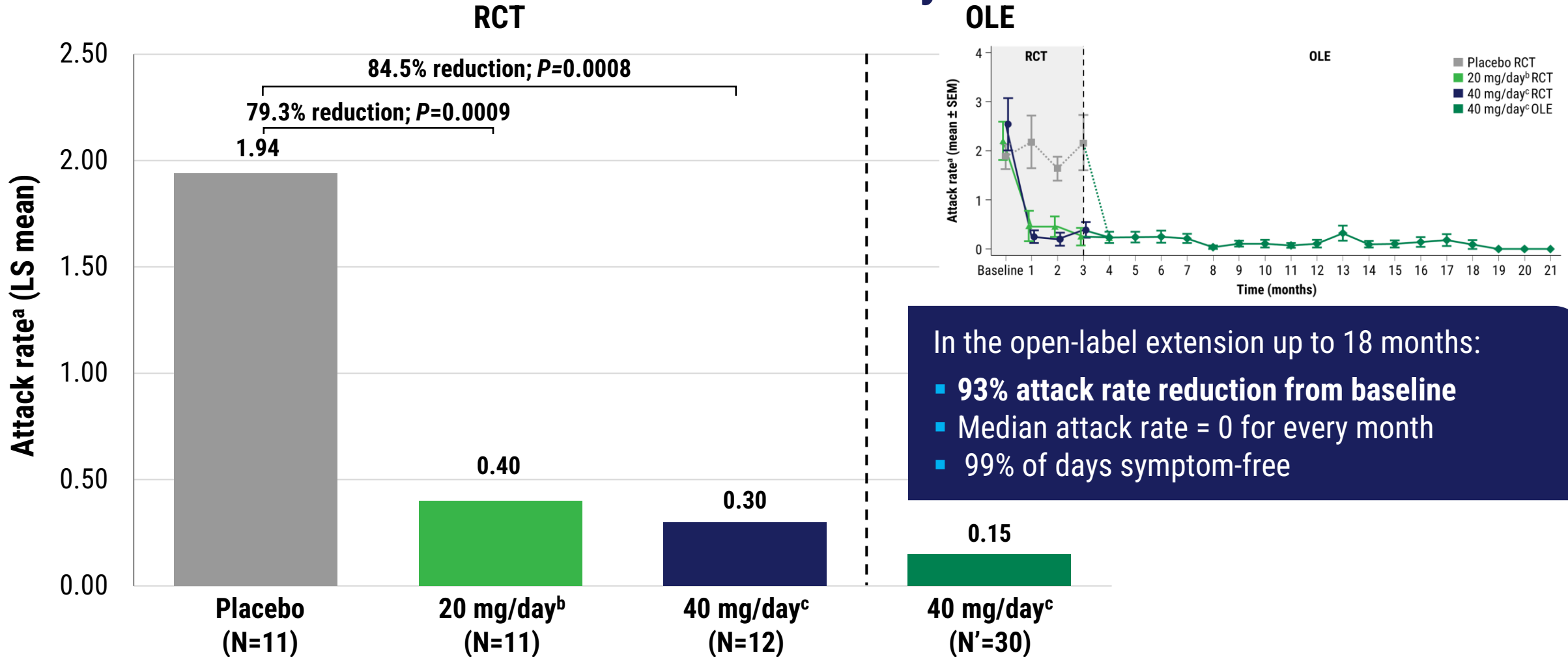


A longer effective exposure results in a **high rate of single-dose attack resolution**<sup>8</sup>



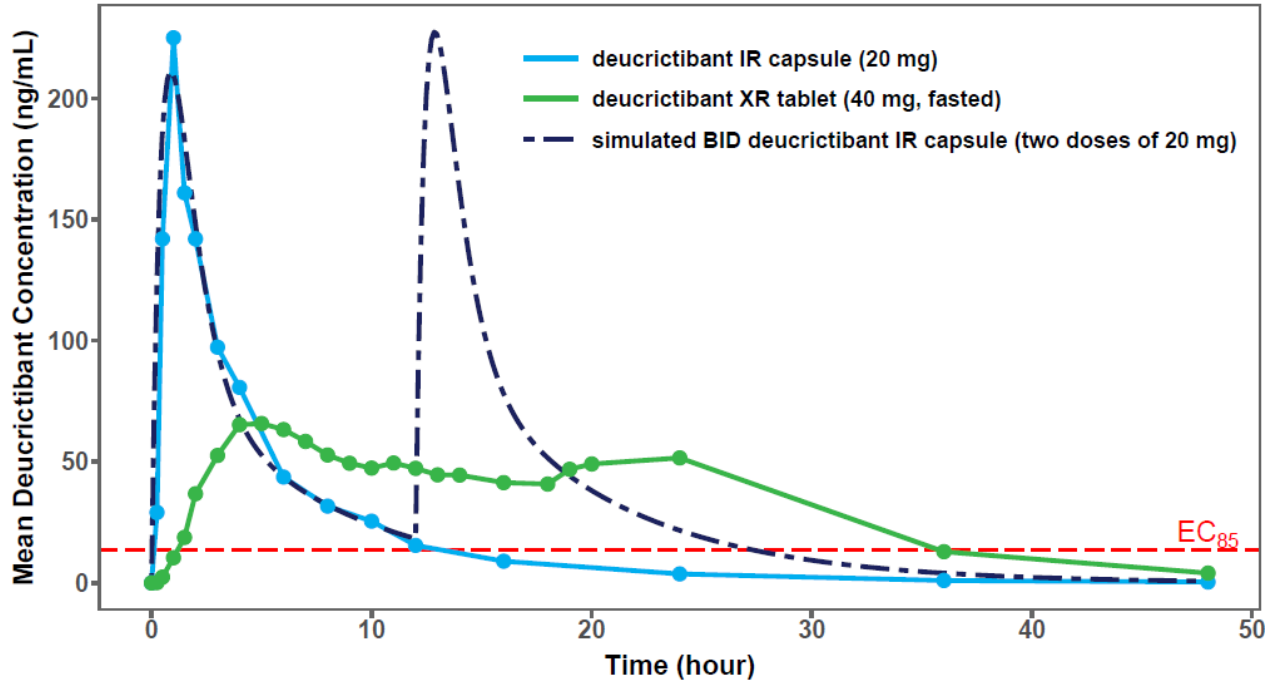
Sources: <sup>1</sup>Company research. <sup>2</sup>Leasge et al. [IDDST 2024](#). <sup>3</sup>Groen K et al. [ACAAI 2022](#). <sup>4</sup>Li H et al. [EAC 2024](#). <sup>5</sup>Maurer M et al. [HAEi Workshop, 2022](#). <sup>6</sup>Maurer M et al. [AAAAI 2023](#). <sup>7</sup>Riedl et al. [WSAAI 2024](#). <sup>8</sup>Maurer M et al. [BKS 2024](#).

# Continuing deucricitbant treatment sustained the early-onset attack reduction for over one and a half years



IR, immediate release; OLE, open label extension; RCT, randomized controlled trial. N = number of participants randomized in each treatment group in Part 1 of the study. N' = number of participants in the OLE. <sup>a</sup>1 month = 4 weeks. <sup>b</sup>Deucricitbant IR capsule, 10 mg twice daily. <sup>c</sup>Deucricitbant IR capsule, 20 mg twice daily. Source: Riedl MA et al. [BKS 2024](#).

# Commercial XR formulation maintains exposure above therapeutic level for at least 24 hours

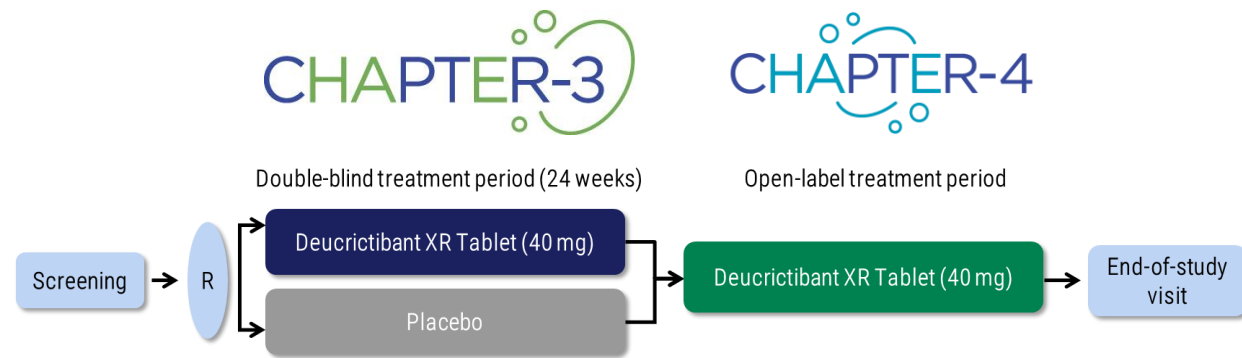


- **Extended-release** matrix controls release and absorption of compound in small intestine as well as in colon
- Supports **once-daily** dosing while maintaining exposure more consistently versus twice-daily IR (used in proof-of-concept Phase 2 CHAPTER-1 study)
- **Formulation patent** applications filed with broad coverage of worldwide pharmaceutical markets

Source: Company data: single-dose cross-over PK study in healthy volunteers (n=14) under fasting conditions



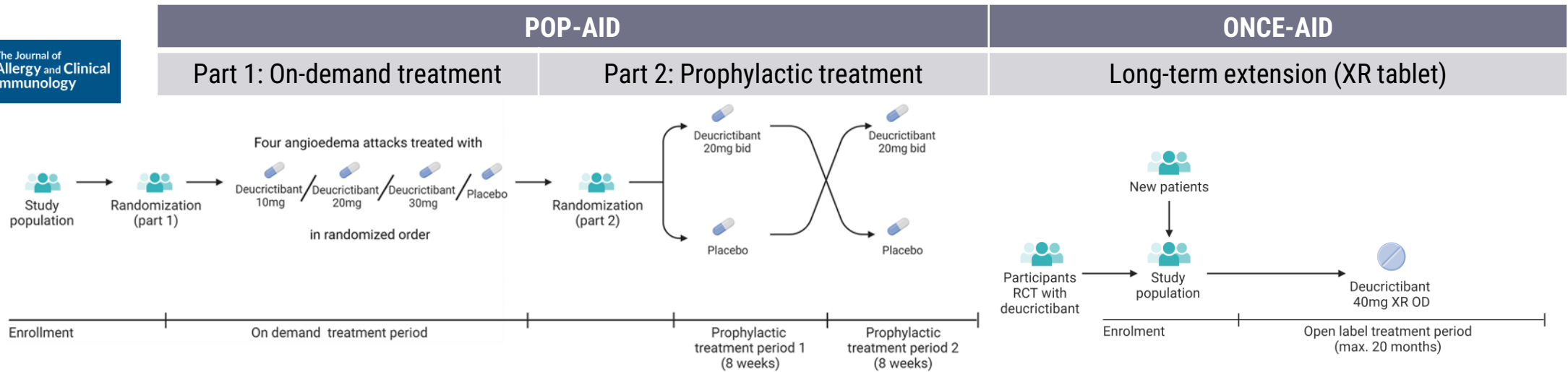
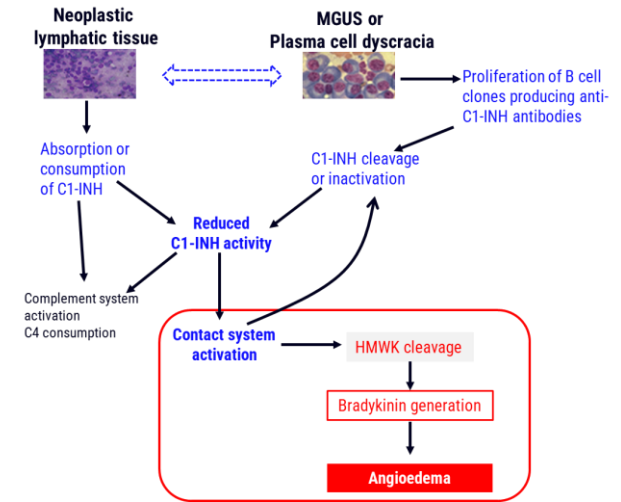
# CHAPTER-3 study: A global Phase 3 study of prophylactic treatment of angioedema attacks in people with HAE



- Target enrollment of approximately 81 adolescents and adults living with HAE; 2:1 randomization
- Initiating by year-end 2024
- **Study objectives**
  - Evaluation and characterization of investigator-confirmed HAE attacks during 24-week treatment period
  - Incidence of treatment-emergent adverse events
  - Evaluation of deucricitibant XR pharmacokinetics
  - Measure of change in participant-reported health-related quality of life
- Rollover to open-label extension

# Deucricitbant proof-of-concept in acquired angioedema due to C1-INH deficiency (AAE-C1INH)<sup>1,2</sup>

- Estimated prevalence of 1:100,000 to 1:500,000
  - ~ 10% of HAE type 1/2
- Currently, no therapies approved for AAE
- Investigator-initiated trial (IIT) by the Amsterdam UMC

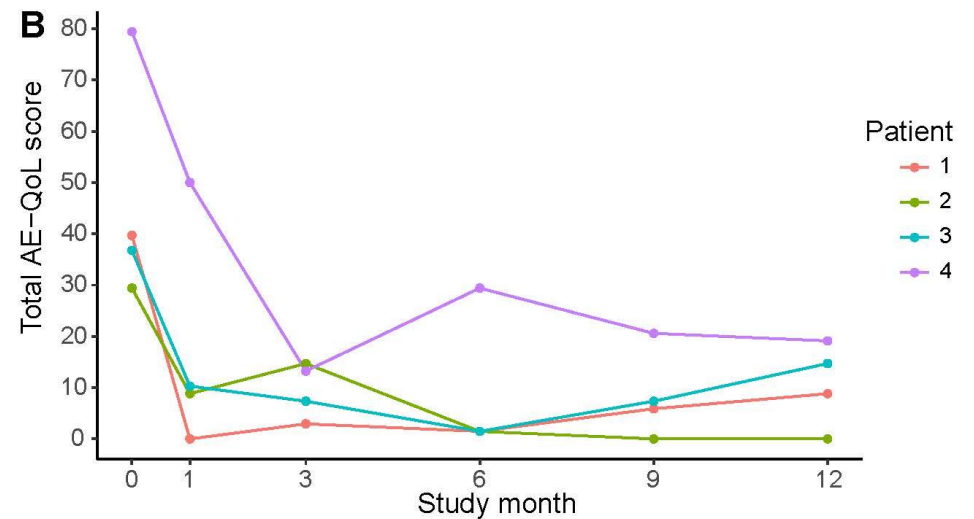
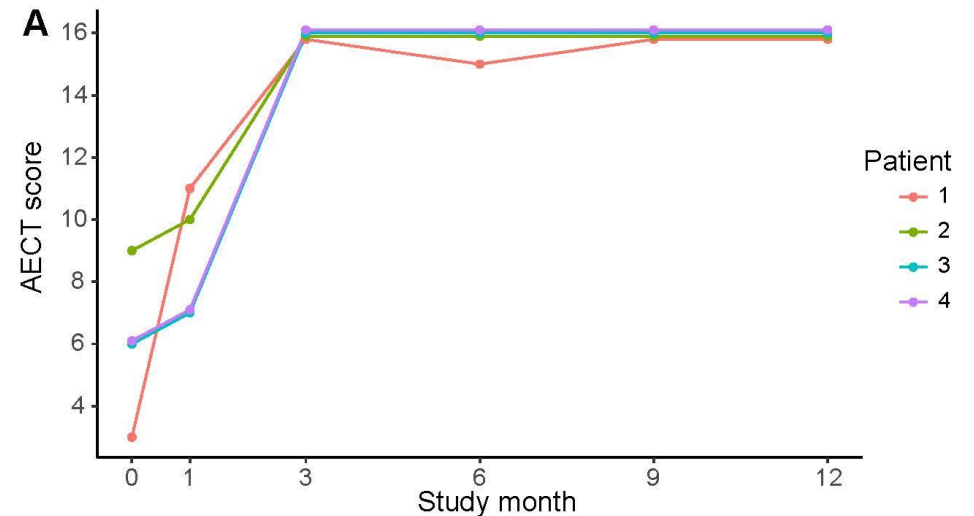
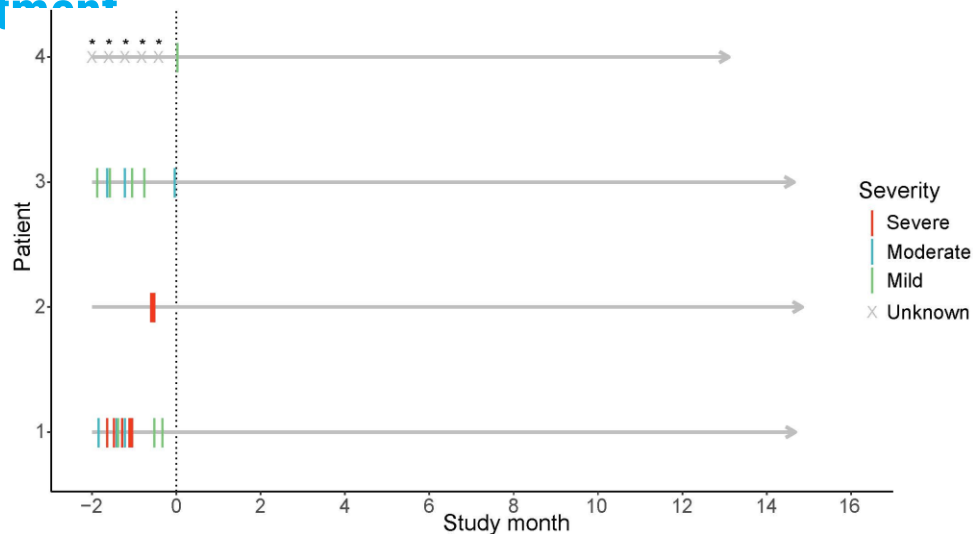


Source: <sup>1</sup>Petersen RS et al. *J Allergy Clin Immunol*. 2024. <sup>2</sup>Petersen RS et al. *BKS* 2024.

# Deucricitbant XR tablet for the prevention of acquired angioedema (AAE-C1INH) attacks<sup>1,2</sup>

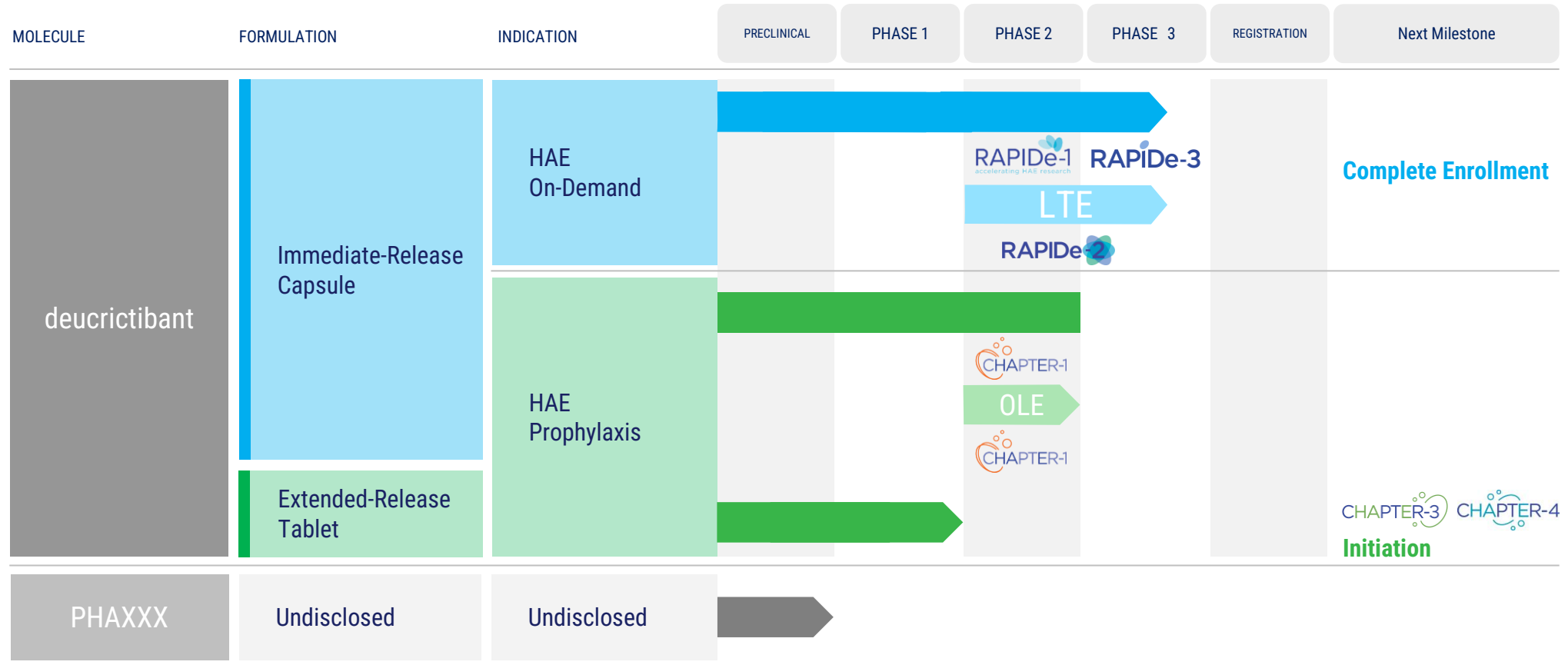
Attacks per month	Patient 1	Patient 2	Patient 3	Patient 4
Baseline	1.2	1.2	0.9	2.2
Placebo	2.0	0.6	1.0	N/A
Deucricitbant	0	0	0	0.1

## Attacks before and during deucricitbant XR treatment



Notes: the baseline attack rate covers 90 days prior to randomization for prophylactic treatment in the randomized controlled trial for Patients 1, 2, and 3, and 90 days prior to enrollment in the open-label portion for Patient 4. \*Patient 4 reported five angioedema attacks in the two months prior to enrollment, but did not recall the exact dates on which these attacks occurred. Graph A: Angioedema Control Test (AECT) score during prophylactic treatment with deucricitbant XR tablet. Graph B: Angioedema Quality of Life (AE-QoL) score during prophylactic treatment with deucricitbant XR tablet. Source: <sup>1</sup>Petersen RS et al. *J Allergy Clin Immunol*. <sup>2</sup>Petersen RS et al. *BKS 2024*.

# Wholly-owned pipeline focused on bradykinin B2 receptor mechanism



LTE: long-term extension, OLE: open-label extension

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# Our strategy is to become a market leader in HAE

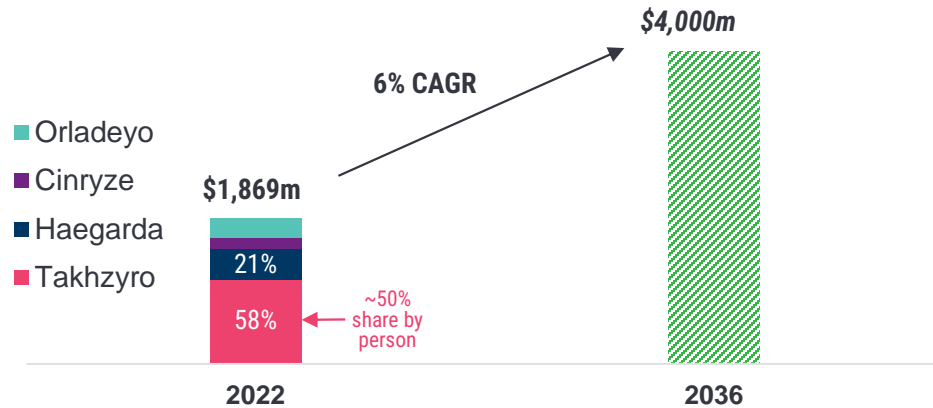
Rooted in a deep commitment to engage with the HAE community



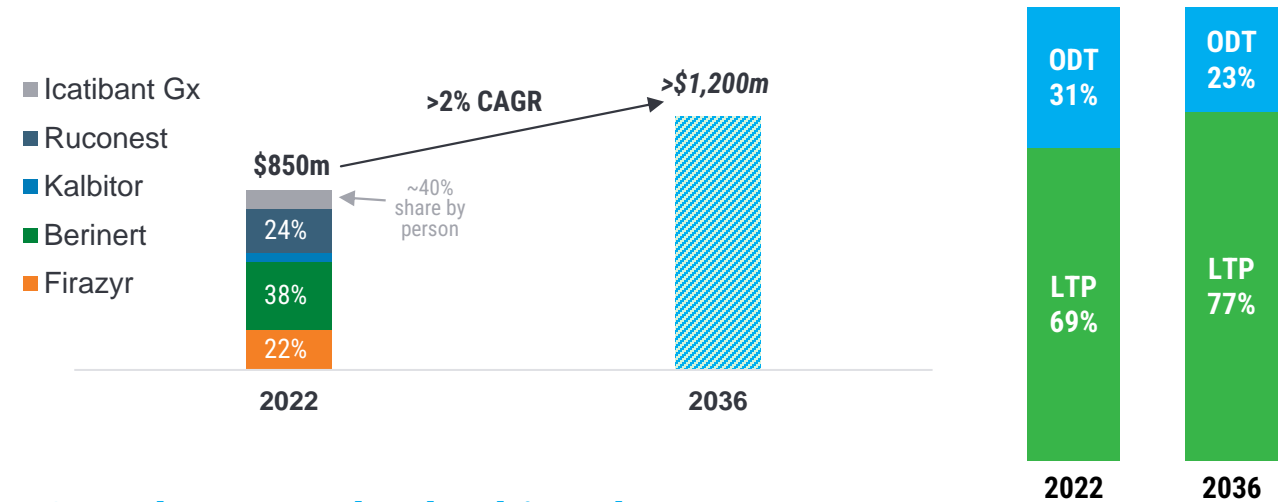
Notes: Aspirational, to be confirmed with Phase 3 clinical data

# In the U.S., significant growth in the long-term prophylaxis (LTP) and on-demand therapy (ODT) market is expected over the next decade<sup>1</sup>

## Value of prophylaxis<sup>1-3</sup>



## Value of on-demand<sup>1-3</sup>



### Growth expected to be driven by:

- New options
- Increased convenience
- Continued paradigm shift from ODT to LTP

### Growth expected to be driven by:

- New options
- Increased convenience
- Increased treatment rate

LTP to further grow as the dominant treatment paradigm in the US market through to 2036<sup>1</sup>

**HAE market growth will be driven by increased efficacy and convenience of new therapies**

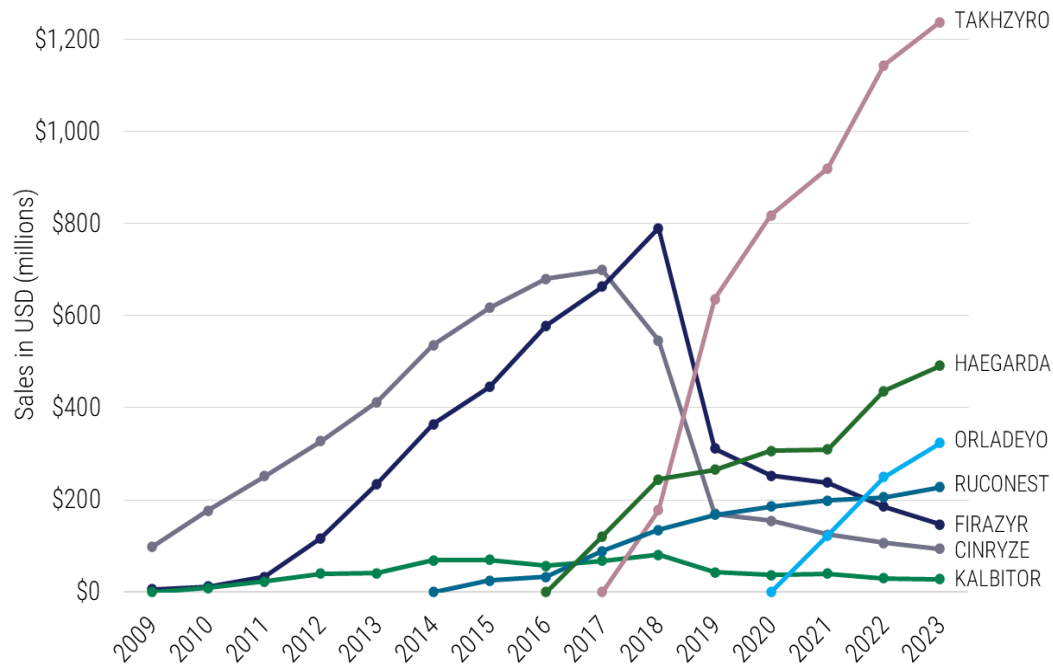
Source: <sup>1</sup>IQVIA market evolution and company data. <sup>2</sup>Evaluate Pharma uptake curves 2008-2023. <sup>3</sup>SEC filings (BioCryst, CSL Behring, Pharming, Takeda).

# Despite treatment satisfaction, the U.S. HAE market is dynamic, with people actively seeking a better<sup>1</sup> product

People actively switch therapies<sup>2,3</sup>: first-to-market is no guarantee for long-term market leadership

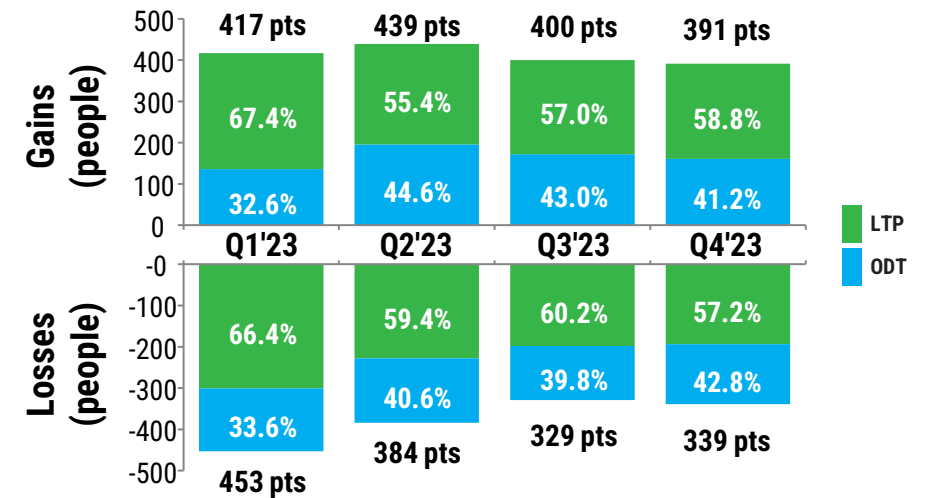
Across ~7,000 people with HAE, there were over >1,500 unique counts of treatment initiation in 2023<sup>4</sup>

Evolution of HAE product sales<sup>1,2</sup>



- Preference for convenient administration
- ODT-only to LTP switches dominate
- Most LTP gains went to Takhzyro and Orladeyo

U.S. HAE switches, gains ↑ and losses ↓<sup>3</sup>



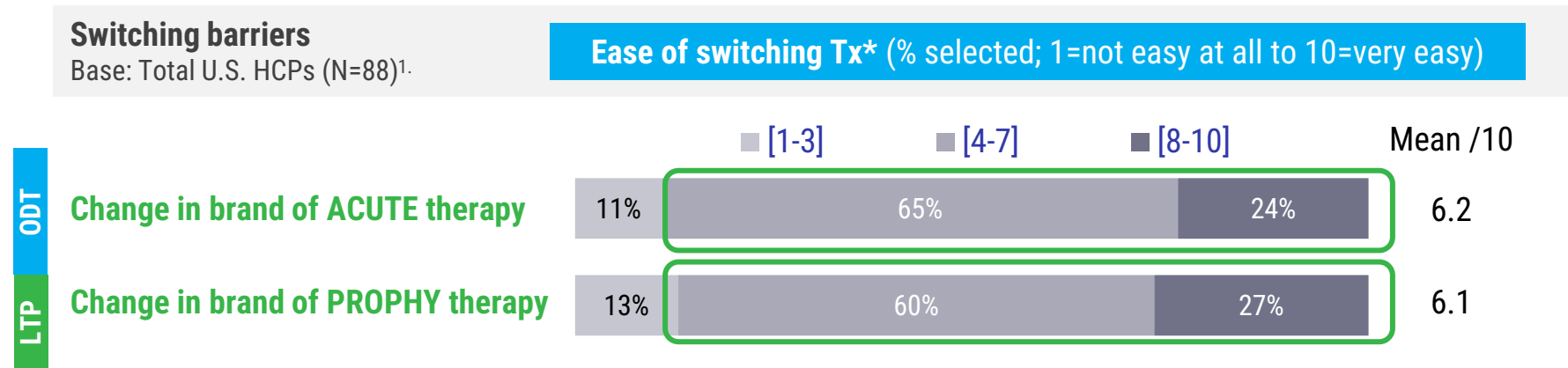
# of new Rx    -36    +55    +70    +52

<sup>1</sup>Treatment selection is driven by physicians and patient preference.

Source: <sup>2</sup>Evaluate Pharma uptake curves 2008-2023 <sup>3</sup>SEC filings (BioCryst, CSL Behring, Pharming, Takeda). <sup>4</sup>U.S. Chart Audit 2023.



# For both patients on prophylaxis or on-demand therapy, switching treatment is moderately easy for HCPs<sup>1</sup>



**HCPs would feel comfortable switching therapy after at least 6 months on current treatment**

\*Based on HCPs experience, considering all the barriers there may be from an access/coverage and clinical perspective. Source: <sup>1</sup>Company Research (October 2024).

# Efficacy is prime for HCPs, but patient preference drives choice for oral administration<sup>1</sup>

## HCPs top reasons for selecting a therapy (current users, n = 216)

Efficacy	44%
Convenience of dosing frequency	30%
Convenience of administration	28%
Insurance coverage/cost	27%
Patient's preference	27%

- **Efficacy** remains the first driver for HCP preference
- **Dosing frequency** and **route of administration** play less of decisive role in HCP preference and are at par with **patients' preference**

## Patient preference or request for prophylactic route of administration based on HCPs experience (current users, n = 216)

Oral (preferred over injection)	38%
Subcutaneous injection (preferred over oral)	18%
No preference/request	46%

- **Nearly 40% of patients** actively **request or prefer an oral LTP**
- Less than 20% would prefer or request an injection

Source: <sup>1</sup>Company Research (October 2024).

# But people with HAE are not willing to trade off efficacy for the convenience of an oral therapy<sup>1</sup>

## Efficacy vs. Convenience trade-off

Base: Total U.S. Patients (N=94); excluding those not on prophylaxis and unlikely to start (N=87)<sup>1</sup>.

■ Strongly agree (L)  
 ■ Somewhat Agree (L)  
 ■ Agree with Neither more  
 ■ Somewhat agree (R)  
 ■ Strongly agree (R)

ODT

I prefer the **CONVENIENCE of an ORAL ON-DEMAND** therapy, even if EFFICACY IS LOWER than injectable routes of administration (IV or subcutaneous)



I prefer the **MOST EFFECTIVE ON-DEMAND** therapy available, even if the route of administration is an INJECTABLE

LTP

I prefer the **CONVENIENCE of an ORAL PROPHYLACTIC** therapy, even if EFFICACY IS LOWER than injectable routes of administration (IV or subcutaneous)



I prefer the **MOST EFFECTIVE PROPHYLACTIC** therapy available, even if the route of administration is an INJECTABLE

**An oral therapy with injectable-like efficacy has the potential to become the preferred option for patients**

Notes: ODT: on-demand therapy. LTP: long-term prophylaxis. Source: <sup>1</sup>Company Research (October 2024).

# Despite high compliance on novel therapies, including Orladeyo<sup>®</sup>, breakthrough attacks are still common with nearly 3 attacks per year<sup>1</sup>

Base: Total U.S. HCPs (N=88) <sup>1</sup>		Total	TAKHZYRO <sup>®</sup>	CINRYZE <sup>®</sup>	ORLADEYO <sup>®</sup>	HAEGARDA <sup>®</sup>	DANOCRINE <sup>®</sup>
Base: current users		216	83	22	55	46	*10
<b>Compliance</b>							
	High	65%	64%	50%	71%	70%	60%
	Medium	33%	35%	50%	27%	28%	30%
	Low	2%	1%	0%	2%	2%	10%
<b>Number of attacks in the past 6 months</b>							
	Average # attacks (total treated or not)	1.4	1.6	1.6	1.7	1.4	0.9
	% pts with 1+ attack (total treated or not)	66%	64%	77%	79%	59%	60%
	Average # attacks resulting in ER visit	0.4	0.4	0.8	0.3	0.7	0.3
	% pts with 1+ attack resulting in ER visit	34%	27%	59%	26%	58%	33%

Notes: \*small base size for DANOCRINE. Source: <sup>1</sup>Company Research (October 2024).

# People living with HAE are seeking a life not defined by their condition nor burdened by its management<sup>1</sup>



**Efficacy** is a prime driver...



but **safety and tolerability** cause exploration of alternatives...

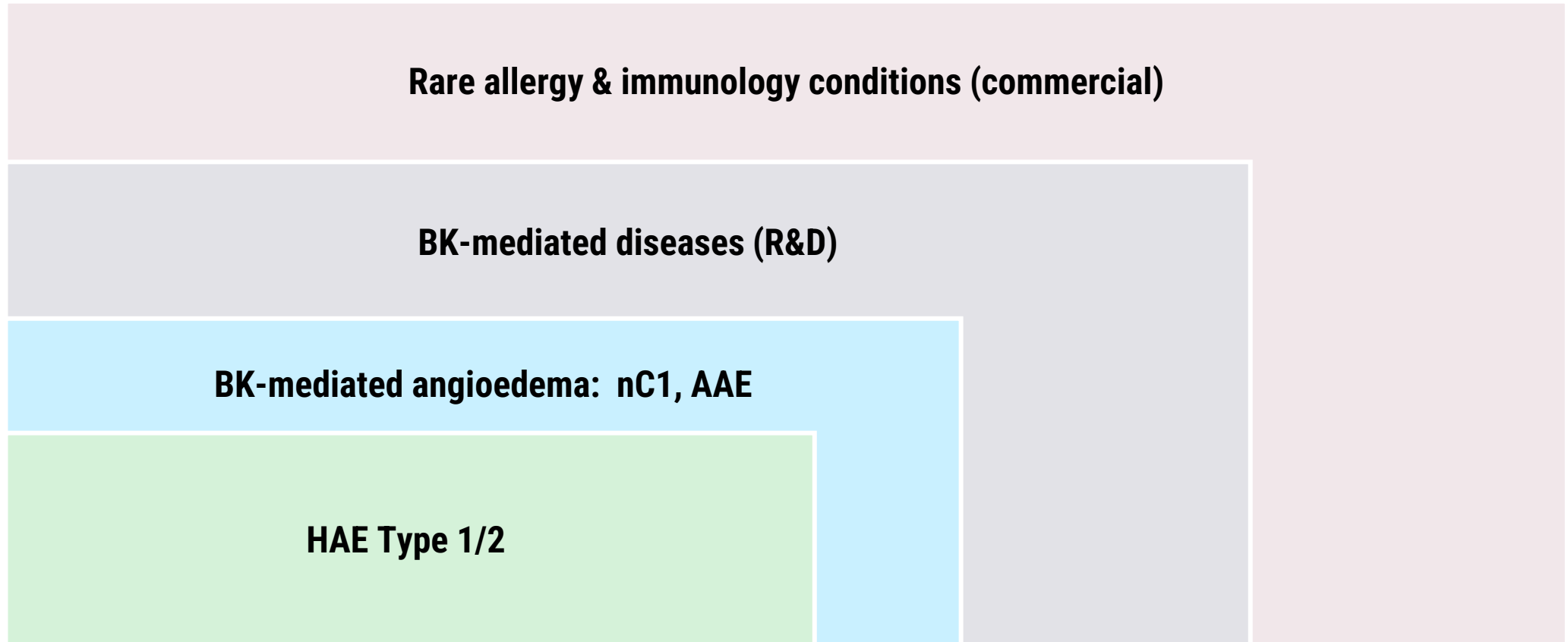


...while **convenience** is a key driver for overall preference<sup>2</sup>

People living with HAE actively switch between products<sup>3</sup>, seeking improvement in efficacy, safety/tolerability, and convenience

Source: <sup>1</sup>Lumry WR et al. *Allergy Asthma Proc.* 2020. <sup>2</sup>Geba et al, *J Drug Access*, 2021. <sup>3</sup>U.S. Chart Audit 2023

# Pharvaris aspires to leverage its foundational B2R expertise to develop therapies for conditions beyond HAE



# Agenda



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# Pioneering science for patient choice for hereditary angioedema (HAE)

## DEUCRICTIBANT

FDA orphan drug designation<sup>1</sup>

Robust IP on CoM (granted in multiple territories, initial term to 2038) and formulations<sup>2,3</sup>



### TWO LATE-STAGE PROGRAMS

- Deucricitbant is an orally available small molecule targeting the **validated bradykinin B2 receptor**<sup>4</sup>
- Results from randomized Phase 2 trials<sup>5,6</sup> and their ongoing extensions<sup>7,8</sup> **demonstrate a differentiated profile** for both **preventing** and **treating** HAE attacks with **injectable-like efficacy, rapid onset of action, a favorable tolerability profile, and oral convenience** over current standard of care<sup>9</sup> for people living with HAE



### LARGE GLOBAL HAE MARKET

- Predicted **\$5.2B market** in 2036<sup>10</sup>
- While people living with HAE appear satisfied with their treatment, history has shown that the availability of a **more efficacious, better-tolerated** and/or **more convenient** alternative drives a **dynamic switch to the better product**<sup>11</sup>
- Internationally, the **long-term prevention** market is likely to **grow significantly**<sup>10</sup>



### STRONG FUNDAMENTALS

- Two pivotal **Phase 3** studies **designed to differentiate** current standard of care in both prophylaxis and on-demand treatments
- Accomplished team with **track record in HAE drug development and commercialization**
- Approximately **€344M** cash and cash equivalents as of June 30, 2024

Source: <sup>1</sup>U.S. FDA OOPD listing. <sup>2</sup>World Intellectual Property Organization. <sup>3</sup>European Patent Office. <sup>4</sup>Lesage et al. *Int. Immunopharmacology*. 2022. <sup>5</sup>Riedl MA et al. *AAAAI 2024*. <sup>6</sup>Maurer M et al. *AAAAI 2023*. <sup>7</sup>Riedl MA et al. *BKS 2024*. <sup>8</sup>Maurer M et al. *BKS 2024*. <sup>9</sup>Riedl MA et al. *BKS 2024*. <sup>10</sup>IQVIA predictions. <sup>11</sup>Evaluate Pharma Uptake Curves 2008-2023.