Long-Term Safety and Efficacy of Oral Deucrictibant for Prophylactic and On-Demand Treatment of Hereditary Angioedema Attacks: Results of the Ongoing CHAPTER-1 and RAPIDe-2 Extension Studies

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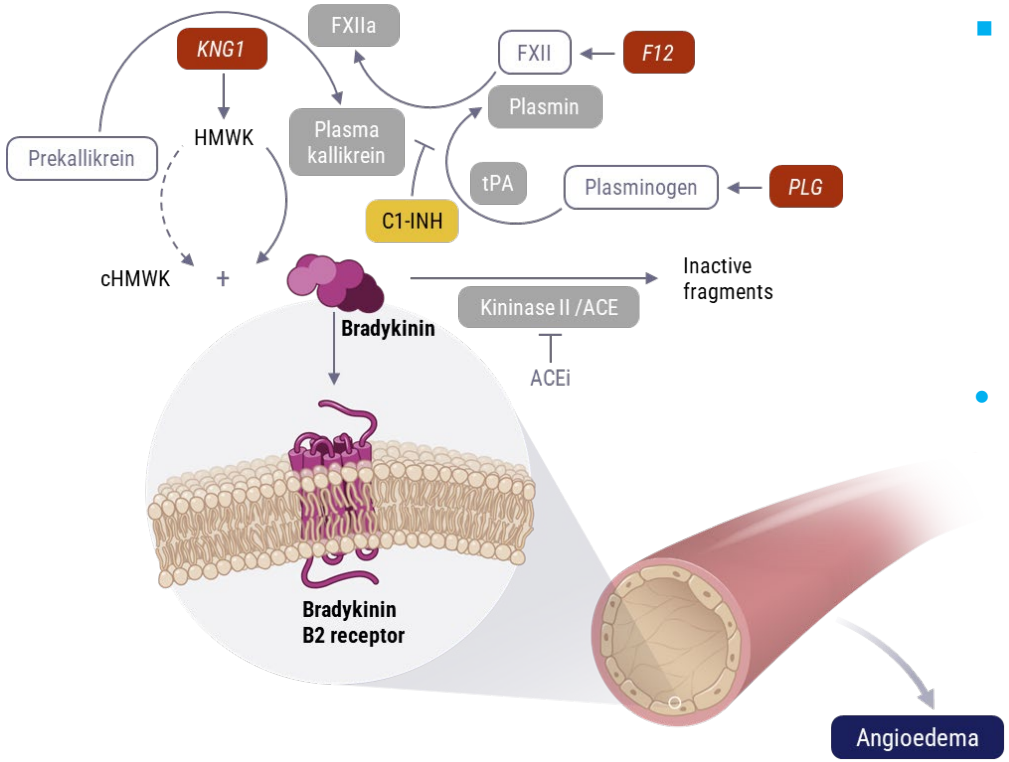
CHAPTER-1 and RAPIDe-2 are Pharvaris-sponsored clinical trials/studies. ClinicalTrials.gov identifiers: NCT05047185, NCT05396105.

HAE is a bradykinin-mediated condition with unmet medical needs



- An unmet need remains for additional prophylactic therapies combining[1-4]:
  - Ease of administration
  - Injectable-like efficacy
  - A well-tolerated profile

- For on-demand treatment, effective and well-tolerated oral therapies may reduce the treatment burden, thus enabling prompt administration.[5]
  - Guidelines recommend treating HAE attacks as early as possible.[6-8]
  - Parenteral administration of currently approved on-demand medications[9-13] can lead to treatment of a number of HAE attacks being delayed or forgone.[4,14,15]

ACE, angiotensin converting enzyme; ACEi, ACE inhibitor; C1-INH, C1 inhibitor; cHMWK, cleaved HMWK; *F12*, gene encoding FXII; FXII, factor XII; FXIIa, factor XIIa; HAE, hereditary angioedema; HMWK, high-molecular-weight kininogen, *KNG1*, gene encoding HMWK; *PLG*, gene encoding plasminogen; tPA, tissue plasminogen activator. **1**. Bouillet L, et al. *Allergy Asthma Proc*. 2022;43:406-12. **2**. Betschel SD, et al. *J Allergy Clin Immunol Pract*. 2023;11:2315-25. **3.** Covella B, et al. *Future Pharmacol*. 2024;4:41-53. **4**. US Food and Drug Administration, Center for Biologics Evaluation and Research. The voice of the patient – hereditary angioedema. May 2018. https://www.fda.gov/media/113509/download. Accessed March 5, 2025. **5**. Mendivil J, et al. Presented at: ACAAI; November 9–13, 2023; Anaheim, CA, USA. **6**. Betschel SD, et al. *Allergy Asthma Clin Immunol.* 2019;15:72. **7**. Busse PJ, et al. *J Allergy Clin Immunol Pract.* 2021;9:132-50. **8**. Maurer M, et al. *Allergy.* 2022;77:1961-90. **9**. Berinert®. Package insert. Accessed March 5, 2024. https://labeling.cslbehring.com/pi/us/berinert/en/berinert-prescribing-information.pdf. **10**. Cinryze®. Summary of product characteristics. Accessed March 5, 2025. https://www.ema.europa.eu/en/documents/product-information/cinryze-epar-product-information_en.pdf. **11**. Firazyr®. Package insert. Accessed March 5, 2025. https://www.shirecontent.com/PI/PDFs/Firazyr_USA_ENG.pdf. **12**. Kalbitor®. Package insert. Accessed March 5, 2025. https://www.shirecontent.com/PI/PDFs/Kalbitor_USA_ENG.pdf. **13**. Ruconest®. Package insert. Accessed March 5, 2025. https://www.ruconest.com/wp-content/uploads/Ruconest_PI_Apr2020.pdf. **14**. Radojicic C, et al. *Allergy Asthma Proc.* 2021;42:S4-10. **15.** Betschel SD et al. *Allergy Asthma Clin Immunol.* 2024;20:43.

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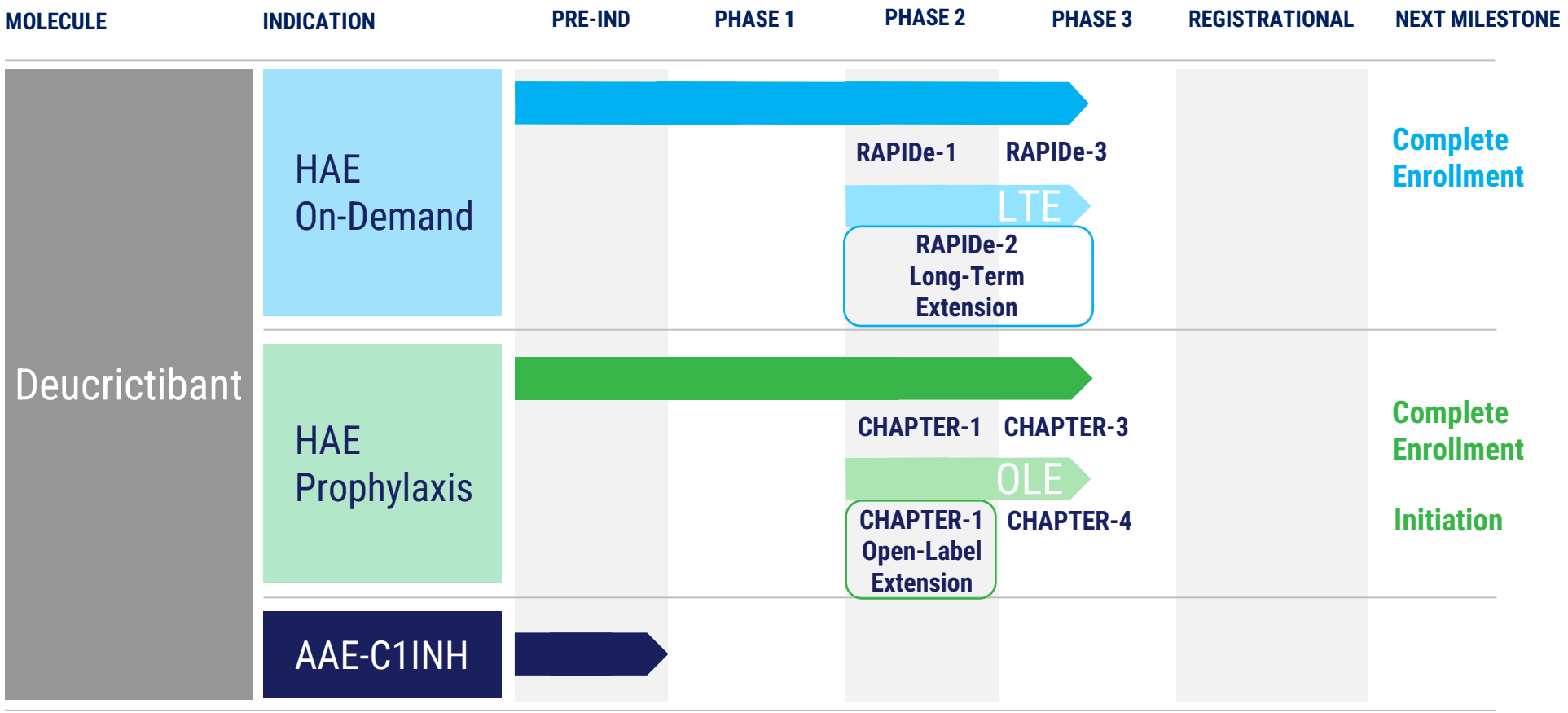
Two oral formulations, same active ingredient for prophylactic and on-demand treatment of bradykinin-mediated angioedema attacks



AAE-C1INH, acquired angioedema due to C1-inhibitor deficiency; HAE, hereditary angioedema; LTE, long-term extension; OLE, open-label extension. RAPIDe-1. ClinicalTrials.gov identifier: NCT04618211. Accessed March 5, 2025. https://www.clinicaltrials.gov/study/NCT04618211. RAPIDe-2. ClinicalTrials.gov identifier: NCT05396105. Accessed March 5, 2025. https://www.clinicaltrials.gov/study/NCT05396105. RAPIDe-3. ClinicalTrials.gov identifier: NCT06343779. Accessed March 5, 2025. https://www.clinicaltrials.gov/study/NCT06343779. CHAPTER-1. ClinicalTrials.gov identifier: NCT05047185. Accessed March 5, 2025. https://www.clinicaltrials.gov/study/NCT05047185. CHAPTER-3. ClinicalTrials.gov identifier: NCT06669754. Accessed March 5, 2025. https://clinicaltrials.gov/study/NCT06669754. CHAPTER-4. ClinicalTrials.gov identifier: NCT06679881. Accessed March 5, 2025. https://clinicaltrials.gov/study/NCT06679881.

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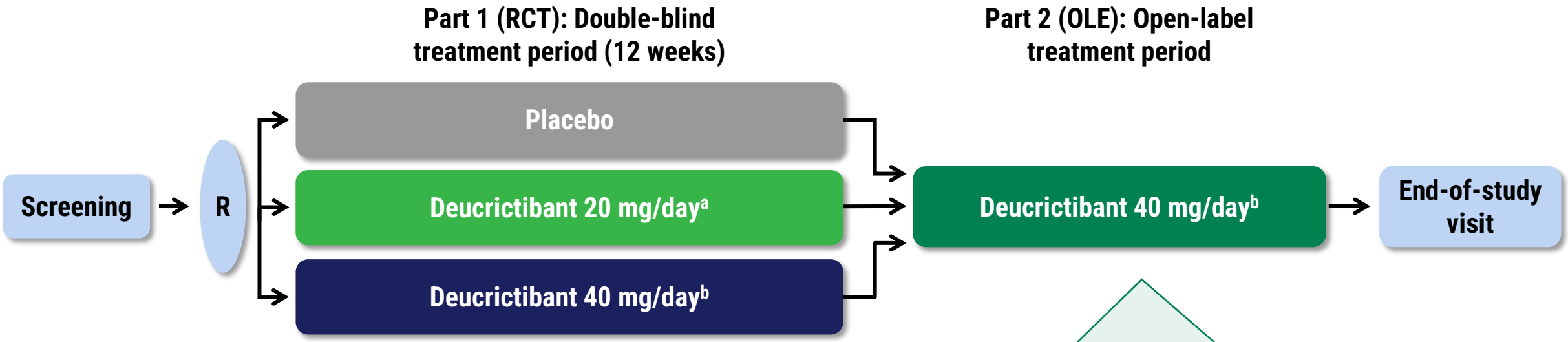
CHAPTER-1: Two-part, Phase 2 trial of deucrictibant for long-term prophylaxis of HAE attacks

Prophylaxis

Key objectives in OLE:

Evaluate safety (primary objective) and efficacy of deucrictibant administered for long-term prophylaxis against HAE attacks.



OLE snapshot analysis (data cutoff: 10 June 2024)

- Participants: All 30 who completed the RCT.
- Mean exposure to deucrictibant 40 mg/day in the OLE: 12.8 months (maximum: ~20 months).

HAE, hereditary angioedema; OLE, open-label extension; IR, immediate-release; R, randomization; RCT, randomized controlled trial. [a]Deucrictibant IR capsule, 10 mg twice daily. [b]Deucrictibant IR capsule, 20 mg twice daily.
CHAPTER-1 is a Pharvaris-sponsored clinical trial. ClinicalTrials.gov identifier: NCT05047185. Accessed March 5, 2025. https://www.clinicaltrials.gov/study/NCT05047185.

Deucrictibant was well tolerated in the OLE with no safety signals

Prophylaxis

- Deucrictibant was generally well tolerated.
  - One treatment-related treatment-emergent adverse event (TEAE) of tooth discoloration.
- No treatment-related serious or severe TEAEs. No treatment-related TEAEs in laboratory parameters, vital signs (including blood pressure), or electrocardiogram findings. No TEAEs leading to treatment discontinuation, study withdrawal, or death.

Adverse events in the OLE	Placebo to 40 mg/day[a] (n=9)		20 mg/day[b] to 40 mg/day[a] (n=11)		40 mg/day[a] to 40 mg/day[a] (n=10)		Total (N=30)	
	Participants, n (%)	Events, n	Participants, n (%)	Events, n	Participants, n (%)	Events, n	Participants, n (%)	Events, n
TEAEs	**5 (55.6)**	**25**	**7 (63.6)**	**31**	**6 (60.0)**	**16**	**18 (60.0)**	**72**
Treatment-related TEAEs	**1 (11.1)**	**1**	**0**	**0**	**0**	**0**	**1 (3.3)**	**1**
Tooth discoloration	1 (11.1)	1	0	0	0	0	1 (3.3)	1
Serious TEAEs	**0**	**0**	**1 (9.1)**	**1**	**1 (10.0)**	**1**	**2 (6.7)**	**2**
Tendon injury	0	0	0	0	1 (10.0)	1	1 (3.3)	1
Hip arthroplasty (arthritis)	0	0	1 (9.1)	1	0	0	1 (3.3)	1
Treatment-related serious TEAEs	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
TEAEs leading to study drug discontinuation, study withdrawal, or death	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

IR, immediate release; OLE, open-label extension; TEAE, treatment emergent adverse event (defined as adverse event occurring during time window from first study drug administration).
n/N= number of participants who received ≥1 dose of study treatment in the OLE by the cutoff date (10 June 2024). [a]Deucrictibant IR capsule, 20 mg twice daily. [b]Deucrictibant IR capsule, 10 mg twice daily.

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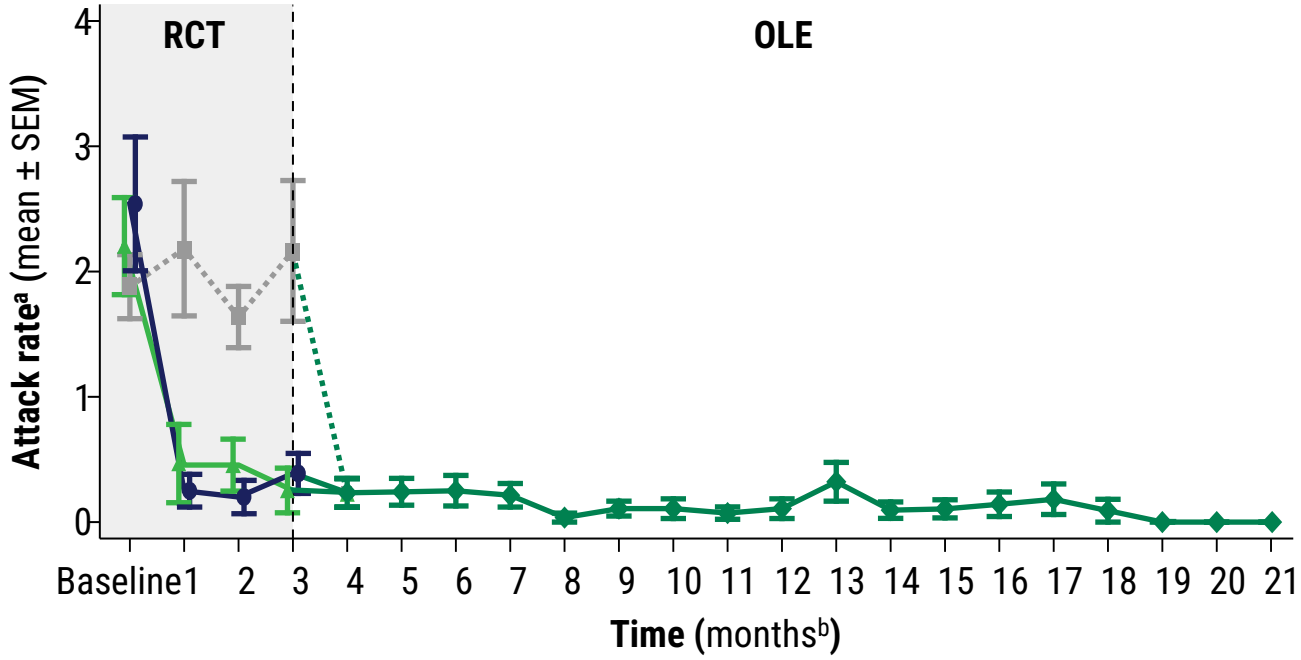
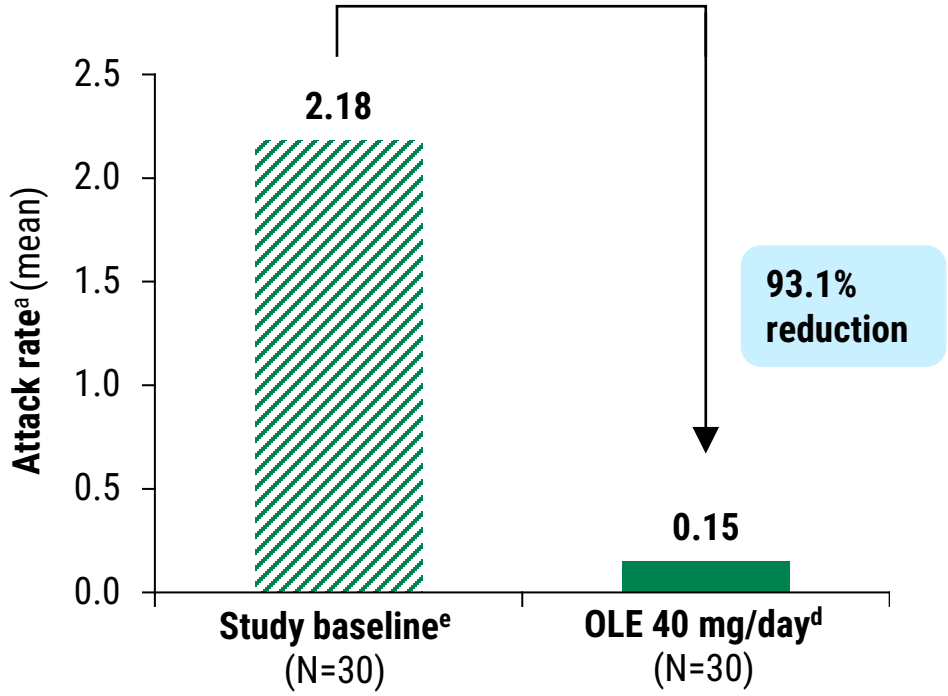
Attack rate reduction in the OLE compared to study baseline

Prophylaxis



Placebo RCT (n)	11	11	11	11																		
20 mg/day[c] RCT (n)	11	11	11	11																		
40 mg/day[d] RCT (n)	12	12	10	10																		
40 mg/day[d] OLE (n)					30	29	28	28	28	28	28	28	28	28	21	19	16	11	11	10	9	7



IR, immediate release; LS, least squares; OLE, open-label extension; RCT, randomized controlled trial; SEM, standard error of the mean. N = number of participants in the OLE. [a]Based on time normalized number of attacks per 4 weeks. [b]1 month = 4 weeks. [c]Deucrictibant IR capsule, 10 mg twice daily. [d]Deucrictibant IR capsule, 20 mg twice daily. [e]Baseline attack rate is raw (unadjusted) mean. OLE attack rate is LS mean. LS mean estimate of attack rate is based on Poisson regression models adjusted for baseline attack rate and time on treatment. No multiplicity adjustment was applied.

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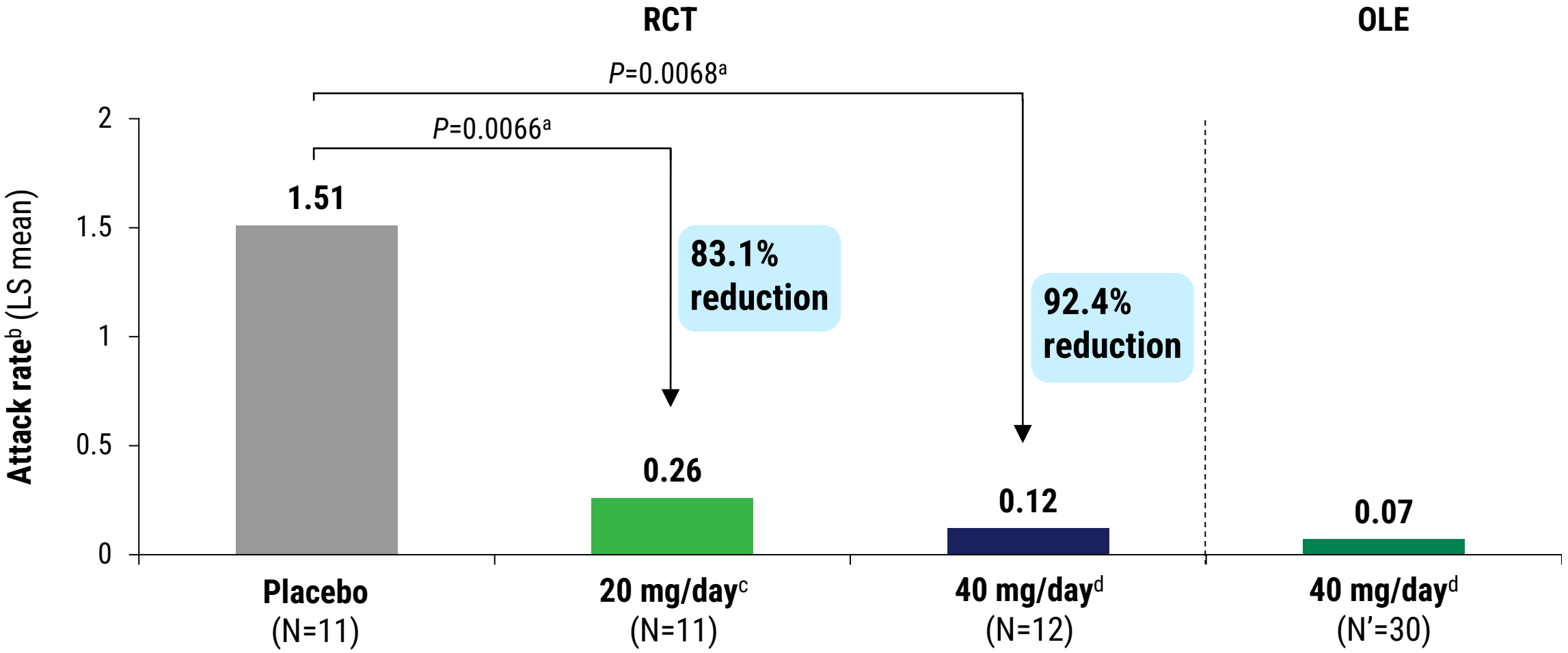
Reduced rate of “moderate and severe” attacks in the RCT remained low in the OLE

Prophylaxis



IR, immediate release; LS, least squares; OLE, open-label extension; RCT, randomized controlled trial. N = number of participants randomized in each treatment group in the RCT. N’ = number of participants in the OLE. LS mean estimates of attack rate are based on Poisson regression models adjusted for baseline attack rate and time on treatment. No multiplicity adjustment was applied. [a]The *P*-values in this figure are nominal. [b]Based on time normalized number of attacks per 4 weeks. [c]Deucrictibant IR capsule, 10 mg twice daily. [d]Deucrictibant IR capsule, 20 mg twice daily.

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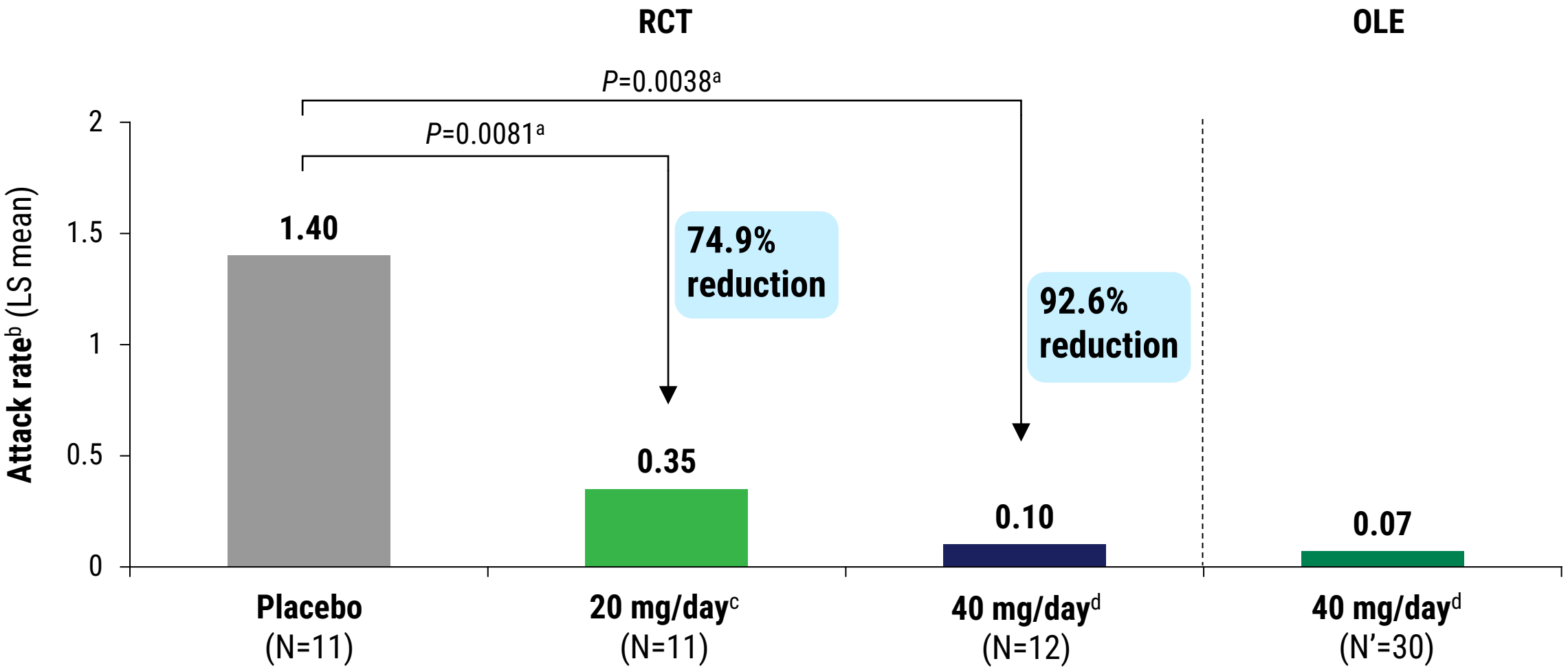
Reduced rate of on-demand–treated attacks in the RCT remained low in the OLE

Prophylaxis



IR, immediate release; LS, least squares; OLE, open-label extension; RCT, randomized controlled trial. N = number of participants randomized in each treatment group in the RCT. N' = number of participants in the OLE. LS mean estimates of attack rate are based on Poisson regression models adjusted for baseline attack rate and time on treatment. No multiplicity adjustment was applied. [a]The *P*-values in this figure are nominal. [b]Based on time normalized number of attacks per 4 weeks. [c]Deucrictibant IR capsule, 10 mg twice daily. [d]Deucrictibant IR capsule, 20 mg twice daily.

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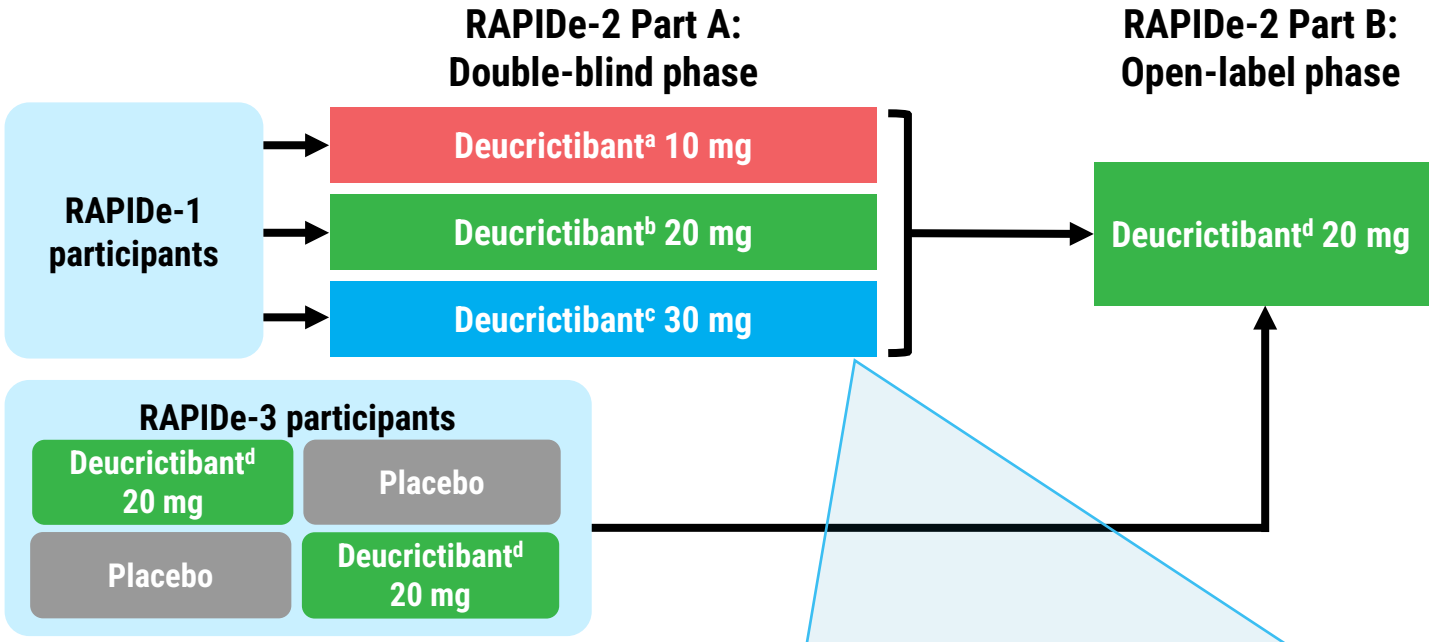
On-demand

RAPIDe-2: Two-part, Phase 2/3 extension study of deucrictibant for on-demand treatment of repeat HAE attacks

Key objectives: Evaluate long-term safety and efficacy of deucrictibant for on-demand treatment of repeat HAE attacks.



Part A snapshot analysis

- Participants: Those who had completed RAPIDe-1 continue self-administering the same double-blinded dose received in RAPIDe-1 to treat qualifying attacks including non-severe laryngeal attacks presenting without breathing difficulties.
- Data: Results shown for combined dose group due to dose blinding.

HAE, hereditary angioedema; IR, immediate-release. [a]1x deucrictibant IR capsule 10 mg + 2x placebo capsule. [b]2x deucrictibant IR capsule 10 mg + 1x placebo capsule. [c]3x deucrictibant IR capsule 10 mg. [d]1x deucrictibant IR capsule 20 mg. RAPIDe-1. ClinicalTrials.gov identifier: NCT04618211. Accessed March 5, 2025. https://www.clinicaltrials.gov/study/NCT04618211. RAPIDe-2. ClinicalTrial.org identifier: NCT05396105. Accessed March 5, 2025. https://clinicaltrials.gov/study/NCT053961052. RAPIDe-3. ClinicalTrial.org identifier: NCT06343779. Accessed March 5, 2025. https://clinicaltrials.gov/study/NCT06343779. RAPIDe-2 is a Pharvaris-sponsored clinical study.

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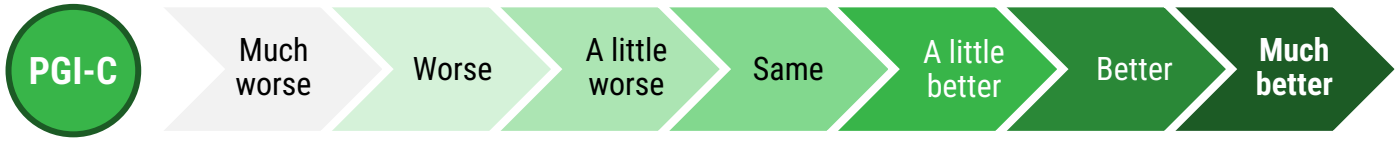
Study endpoints

- **Primary endpoint:** Safety, including TEAEs, clinical laboratory tests, vital signs, and ECG findings.
- **Efficacy:** Assessed using patient-reported outcome tools.
- **Efficacy endpoints included**:
  - **Time to onset of symptom relief**:
    PGI-C rating of at least “a little better” for
    2 consecutive timepoints by 12 hours post-treatment
  - **Time to reduction in attack severity**:
    ≥1-level reduction in PGI-S from pre-treatment for
    2 consecutive timepoints by 12 hours post-treatment
  - **Time to substantial symptom relief:**
    PGI-C rating of at least “better” for
    2 consecutive timepoints by 12 hours post-treatment
  - **Proportion of attacks achieving complete attack resolution**:
    PGI-S rating of “none” at 24 hours post-treatment

Patient Global Impression of Change[1]



Patient Global Impression of Severity[1]

ECG, electrocardiogram; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity; TEAE, treatment-emergent adverse events. **1.** Cohn DM, et al. *Clin Transl Allergy*. 2023;e12288.

Deucrictibant was well tolerated across all doses

On-demand

337 attacks[a] from 19 participants:

- No treatment-related TEAEs.
- No treatment-related serious or severe TEAEs, no treatment-related TEAEs in laboratory parameters, vital signs (including blood pressure), or ECG findings.
- No TEAEs leading to treatment discontinuation, study withdrawal, or death.

TEAEs within 5 days after administration of study drug

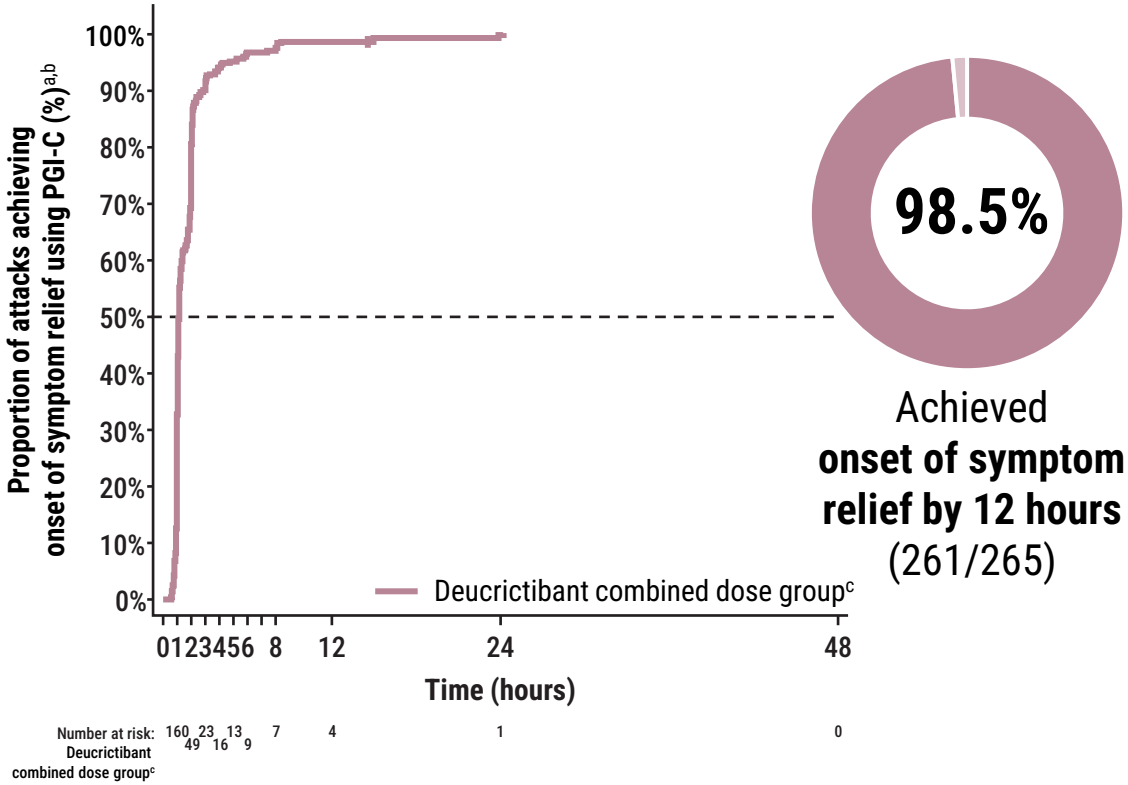
Adverse events	Deucrictibant (combined dose group[b])
Attacks with any TEAE, n (%)	13 (3.9)
Treatment-related TEAEs, n	0
Serious TEAEs, n	1[c]
Treatment-related serious TEAEs, n	0
TEAEs leading to study drug discontinuation, study withdrawal, or death, n	0

ECG, electrocardiogram; IR, immediate-release; TEAE, treatment-emergent adverse event (defined as adverse event occurring during time window from first study drug administration). [a]Number in the safety analysis set (data cutoff: 10 June 2024). [b]Deucrictibant IR capsule 10, 20 and 30 mg. [c]Tooth caries unrelated to treatment.

On-demand

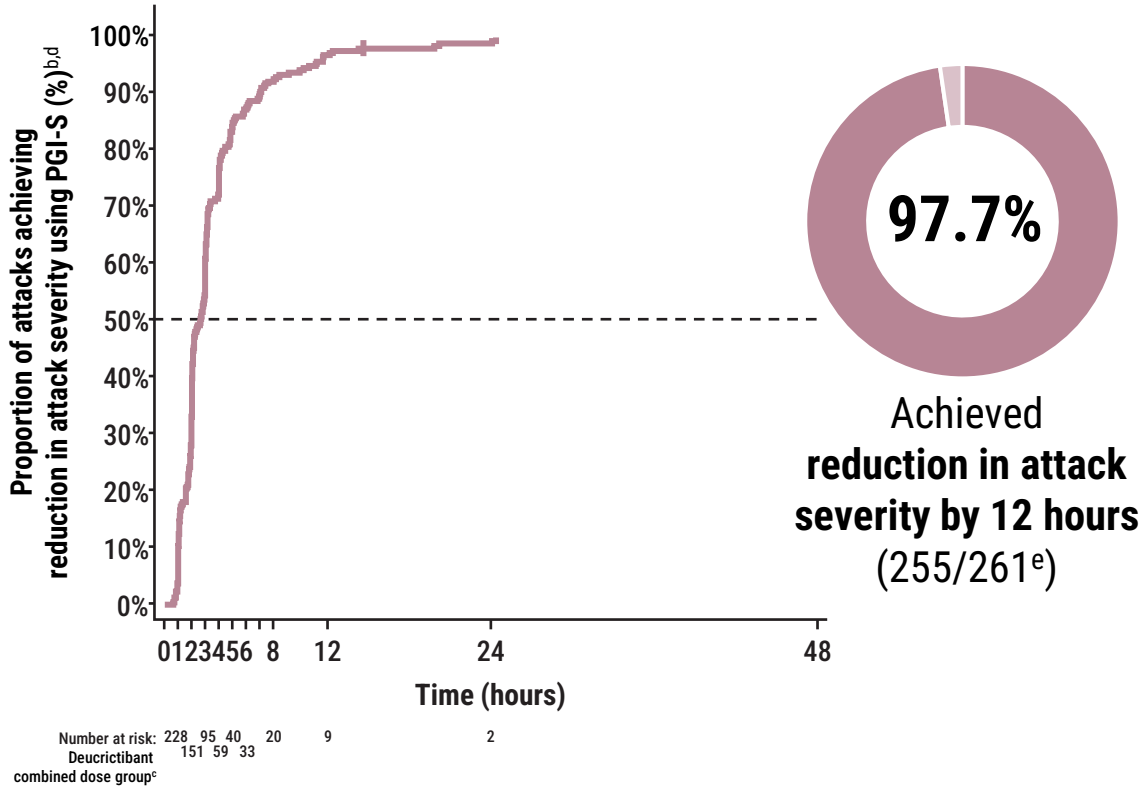
1.1 hours to onset of symptom relief and 2.6 hours to reduction in attack severity with deucrictibant

Median time to onset of symptom relief by PGI-C
1.1 hours
(95% CI, 1.0, 1.2)



Achieved **onset of symptom relief by 12 hours** (261/265)

Median time to reduction in attack severity by PGI-S
2.6 hours
(95% CI, 2.0, 2.9)



Achieved **reduction in attack severity by 12 hours** (255/261[e])

CI, confidence interval; IR, immediate-release; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity. [a]PGI-C rating of at least "a little better" for 2 consecutive timepoints by 12 hours post-treatment regardless of any missing intervening assessments. [b]Within-participant correlation was not accounted for in all Kaplan-Meier estimates. [c]Includes deucrictibant IR capsule 10 mg, 20 mg, and 30 mg dose groups. [d]≥1 point reduction in PGI-S from pre-treatment for 2 consecutive timepoints by 12 hours post-treatment. [e]261 attacks had non-missing pre-treatment PGI-S. Results are shown for the modified intent-to-treat efficacy analysis set (265 attacks in 17 participants; data cutoff: 01 March 2024).

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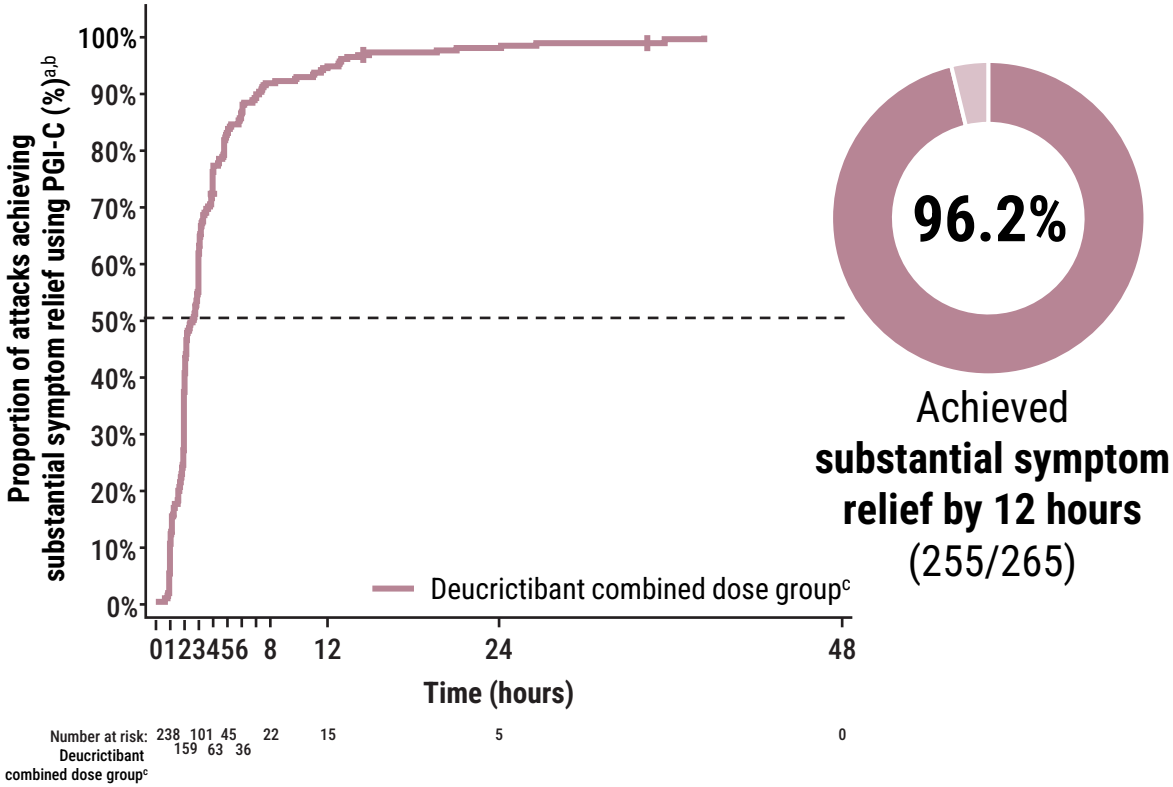
On-demand

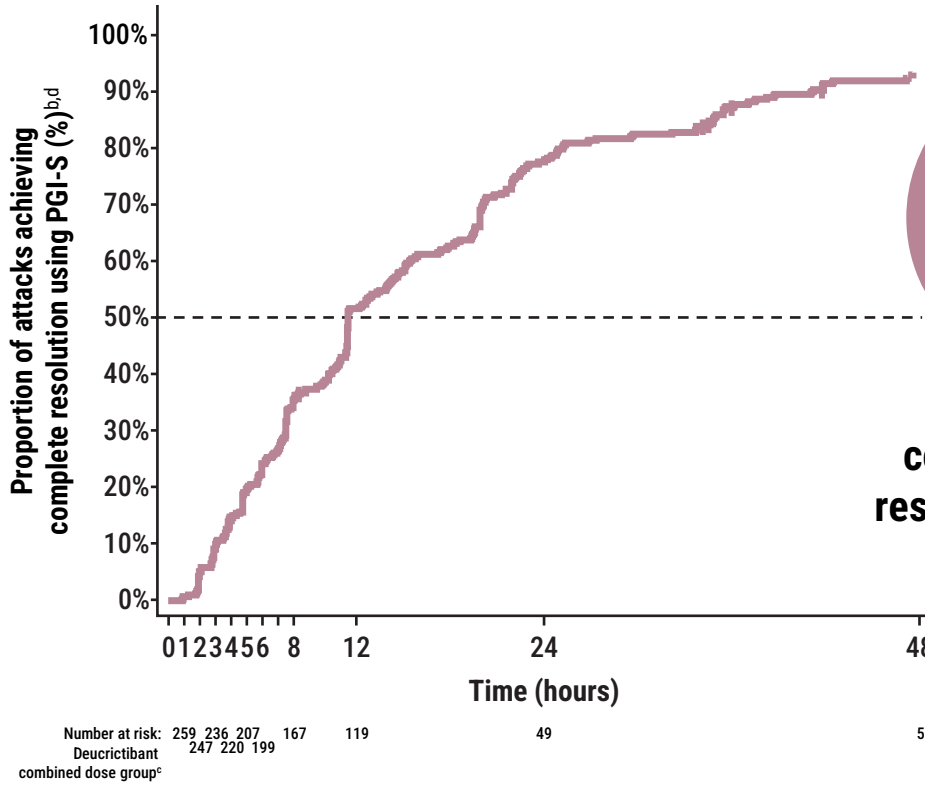
2.7 hours to substantial symptom relief and 11.5 hours to complete attack resolution with deucrictibant

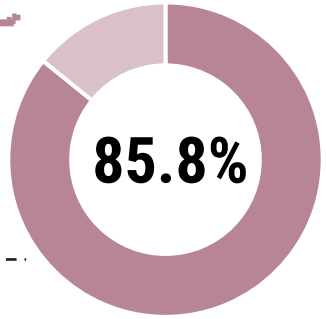
Median time to substantial symptom relief by PGI-C
2.7 hours
(95% CI, 2.1, 2.9)



Achieved **substantial symptom relief by 12 hours** (255/265)

Median time to complete attack resolution by PGI-S
11.5 hours
(95% CI, 11.0, 13.0)





Achieved **complete symptom resolution by 24 hours** (224/261e)

CI, confidence interval; IR, immediate-release; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity. [a]PGI-C rating of at least "better" for 2 consecutive timepoints by 12 hours post-treatment regardless of any missing intervening assessments. [b]Within-participant correlation was not accounted for in all Kaplan-Meier estimates. [c]Includes deucrictibant IR capsule 10 mg, 20 mg, and 30 mg dose groups. [d]PGI-S rating of "none" at 24 hours post-treatment. [e]261 attacks had non-missing pre-treatment PGI-S. Results are shown for the modified intent-to-treat efficacy analysis set (265 attacks in 17 participants; data cutoff: 01 March 2024).

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Conclusions

Prophylaxis: CHAPTER-1 OLE	On-demand: RAPIDe-2
Overall results: – Evidence on the long-term safety and efficacy of deucrictibant for prevention and treatment of HAE attacks. – Support further development of deucrictibant as a potential prophylactic and on-demand therapy for HAE.	
Safety: All studied doses of deucrictibant were well tolerated, with no safety signals observed.	
Efficacy: Deucrictibant 40 mg treatment: – Reduced attack rate in the OLE vs RCT baseline by 93.1%. – "Moderate and severe" attack rate was 0.07. – On-demand-treated attack rate was 0.07.	**Efficacy:** Combined dose group (deucrictibant 10, 20 and 30 mg): Median times to – Onset of symptom relief: 1.1 hours 98.5% of attacks by 12 hours. – Reduction in attack severity: 2.6 hours 97.7% of attacks by 12 hours. – Substantial symptom relief: 2.7 hours 96.2% of attacks by 12 hours. – Complete attack resolution: 11.5 hours 85.8% of attacks by 24 hours.

The Authors and the Sponsor would like to thank all the people with HAE
as well as all study site staff who have been participating in the CHAPTER-1 trial and RAPIDe-2 study.

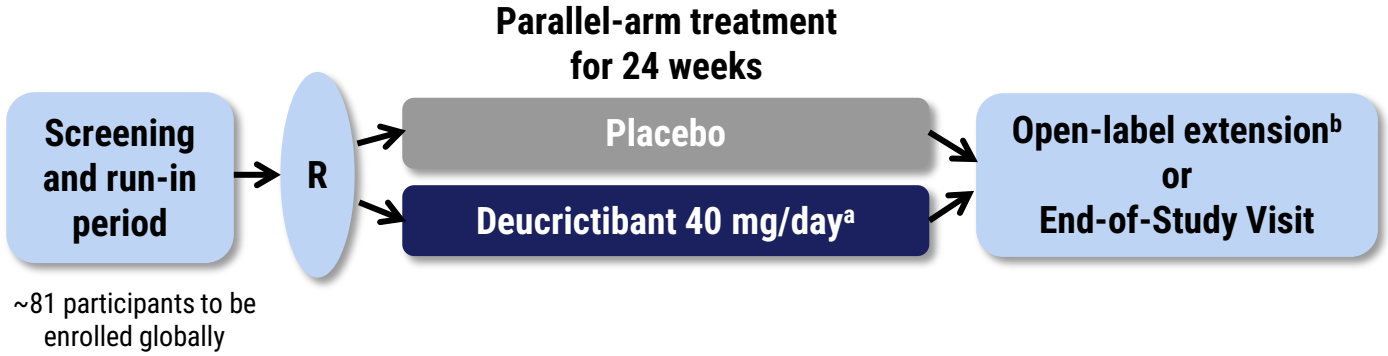
HAE, hereditary angioedema; OLE, open-label extension; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity; RCT, randomized controlled trial.

Phase 3 trials investigating efficacy and safety of deucrictibant for prophylactic and on-demand treatment of HAE attacks

Prophylaxis

CHAPTER-3

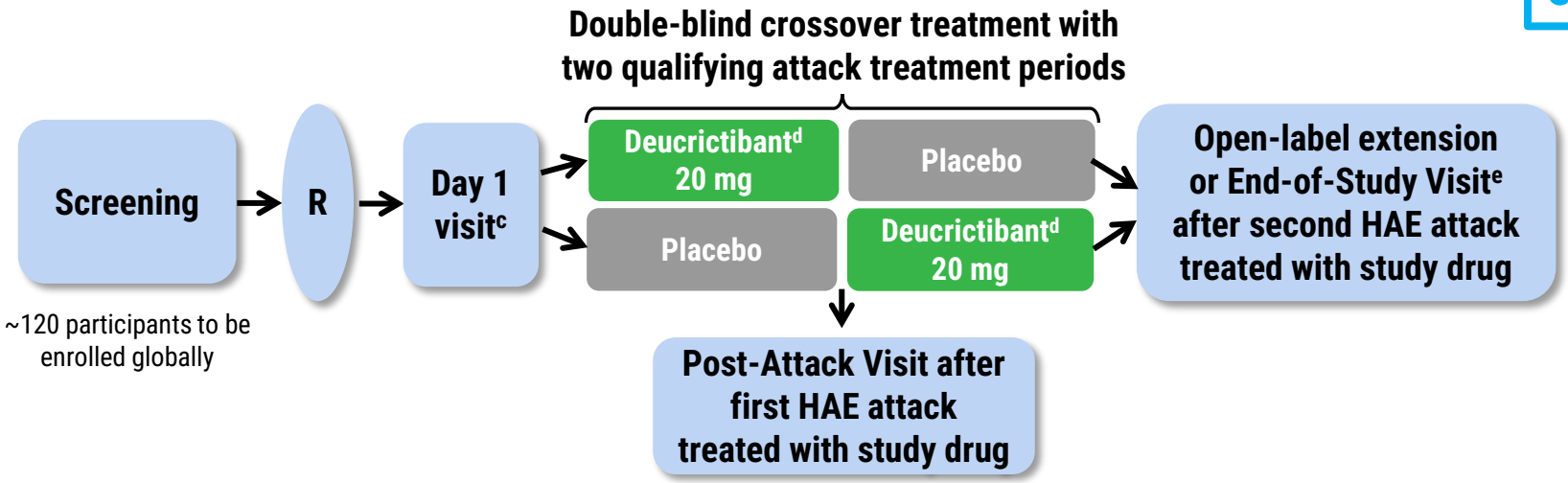
Deucrictibant extended-release (XR) tablet



On-demand

RAPIDe-3

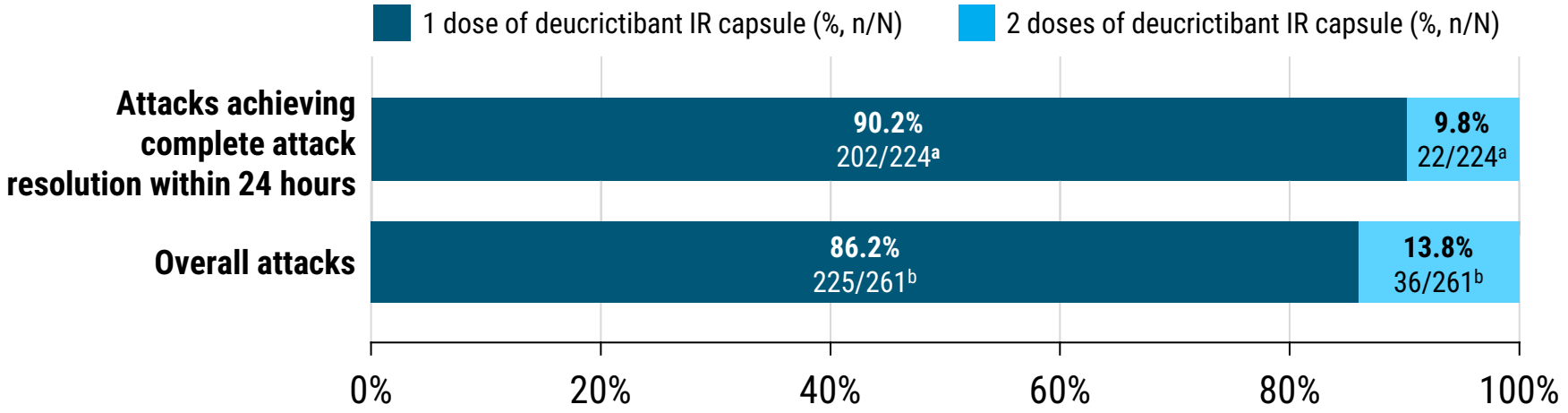
Deucrictibant immediate-release (IR) capsule

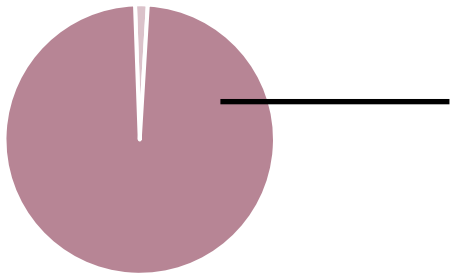


HAE, hereditary angioedema; R, randomization. [a]Deucrictibant XR tablet 40 mg once daily. [b]All participants who complete the parallel-arm treatment period are eligible for the open-label extension. [c]Adolescent participants receive a non-attack dose for pharmacokinetic sampling at Day 1 Visit prior to randomization. [d]Deucrictibant IR capsule 20 mg. [e]Data from the End-of-Study Visit may be used to qualify the participant for an open-label extension study with deucrictibant. Pharmacokinetics of deucrictibant 40 mg XR tablet will be assessed in CHAPTER-3. CHAPTER-3. ClinicalTrials.gov identifier: NCT06669754. Accessed March 5, 2025. https://clinicaltrials.gov/study/NCT06669754. RAPIDe-3. ClinicalTrials.gov identifier: NCT06343779. Accessed March 5, 2025. https://www.clinicaltrials.gov/study/NCT06343779.

This presentation includes data for an investigational product not yet approved by regulatory authorities.

Majority of attacks treated with a single dose of deucrictibant and did not use rescue medication





98.5%
of attacks treated with deucrictibant IR capsule did not use rescue medication
(261/265)

IR, immediate-release; PGI-S, Patient Global Impression of Severity. [a]Number of 224 attacks achieving complete attack resolution, defined as PGI-S score of 'none' by 24 hours. [b]Number of attacks that were not treated with rescue medication. Rescue medication was used for four attacks: three after 1 dose of deucrictibant and one after 2 doses of deucrictibant.

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