

Long-Term Efficacy and Safety of Oral Deucricitbant, a Bradykinin B2 Receptor Antagonist, in Treatment of Hereditary Angioedema Attacks: Results of the RAPIDe-2 Extension Study

Joshua S. Jacobs¹, Laurence Bouillet², Hugo Chapdelaine³, Henriette Farkas⁴, Delphine Gobert⁵, Roman Hakl⁶, Ramon Lleonart⁷, Avner Reshef⁸, Giuseppe Spadaro⁹, Maria Staevska¹⁰, Marcin Stobiecki¹¹, Anna Valeriewa¹⁰, Justin Sun¹², Li Zhu¹², Ming Yu¹², Giorgio Giannattasio¹³, Peng Lu¹², Marcus Maurer^{14,15}, Emel Aygören-Pürsün¹⁶

¹Allergy and Asthma Clinical Research, Walnut Creek, CA, USA; ²National Reference Center for Angioedema (CREAK), Department of Internal Medicine, Grenoble Alpes University, Laboratoire T-RAIG, UMR 5525 TIMC-IMAG (UGA-CNRS), Grenoble, France; ³CHU de Montréal, Université de Montréal, Montréal, QC, Canada; ⁴Hungarian Angioedema Center of Reference and Excellence, Department of Internal Medicine and Haematology, Semmelweis University, Budapest, Hungary; ⁵Sorbonne Université, Médecine Interne, AP-HP, Centre de référence des angioedèmes à kinines, Hôpital Saint-Antoine, Paris, France; ⁶St. Anne's University Hospital in Brno and Faculty of Medicine Department of Clinical Immunology and Allergology, Masaryk University, Brno, Czech Republic; ⁷Bellvitge University Hospital, Allergology Service, L'Hospitalet de Llobregat, Barcelona, Spain; ⁸Barzilai University Hospital, Allergy, Immunology and Angioedema Center, Ashkelon, Israel; ⁹University of Naples Federico II, Department of Translational Medical Sciences and Center for Basic and Clinical Immunology Research (CIS), Napoli, Italy; ¹⁰Department of Allergology, Medical University of Sofia, Sofia, Bulgaria; ¹¹Jagiellonian University Medical College, Department of Clinical and Environmental Allergology, Krakow, Poland; ¹²Pharvaris Inc., Lexington, MA, USA; ¹³Pharvaris GmbH, Zug, Switzerland; ¹⁴Charité - Universitätsmedizin Berlin, Institute of Allergology, Corporate Member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; ¹⁵Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Immunology and Allergology, Berlin, Germany; ¹⁶University Hospital Frankfurt, Department for Children and Adolescents, Goethe University Frankfurt, Frankfurt, Germany

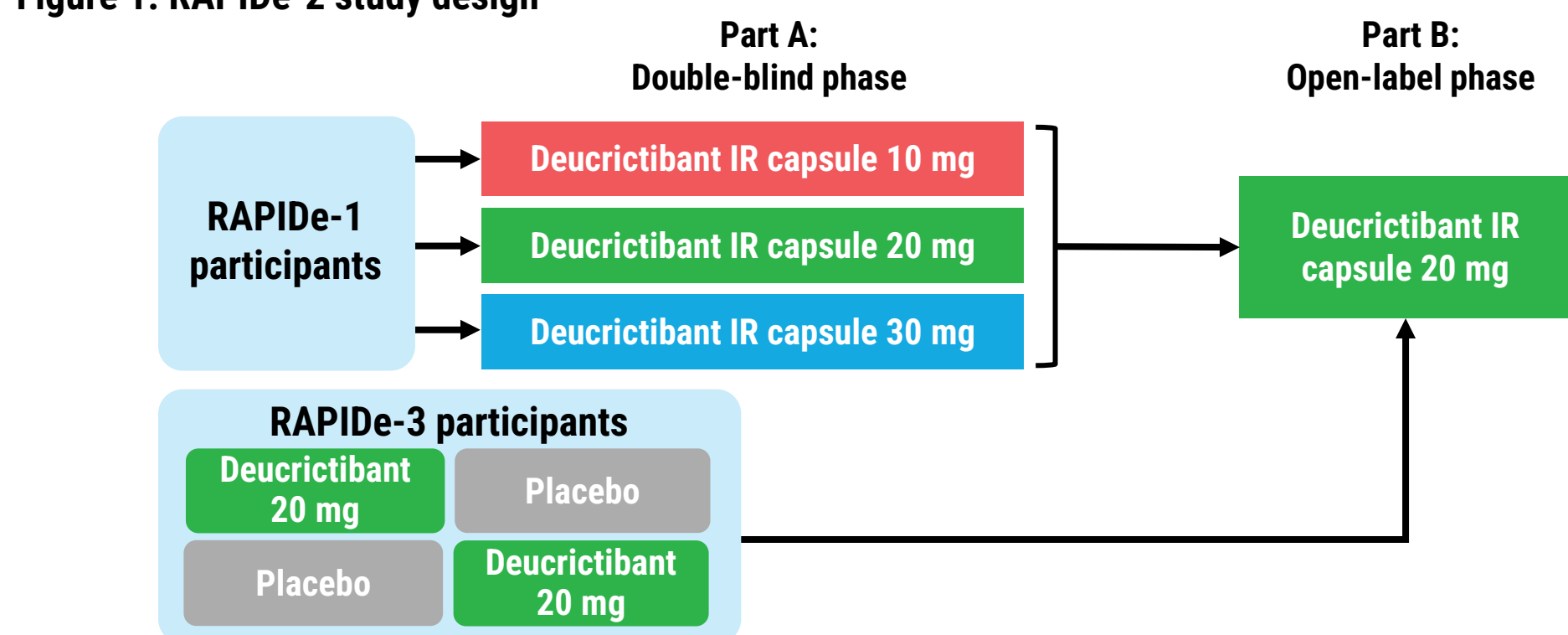
Introduction

- International guidelines recommend that hereditary angioedema (HAE) attacks are treated as early as possible.¹⁻³
- The burden associated with parenteral administration of currently approved on-demand medications⁴⁻⁸ often leads to treatment of HAE attacks being delayed or forgone.⁹⁻¹³
- An unmet need exists for on-demand oral therapies that are effective and well-tolerated, reducing the treatment burden and thus enabling prompt administration.¹³
- Deucricitbant is a selective, orally administered bradykinin B2 receptor antagonist under development for prophylactic and on-demand treatment of HAE attacks.¹⁴⁻¹⁹
- In the RAPIDe-1 Phase 2 trial (NCT04618211),¹⁴ deucricitbant immediate-release (IR) capsule reduced time to onset of symptom relief and to resolution of HAE attacks vs placebo; treatment was well-tolerated.¹⁵

Methods

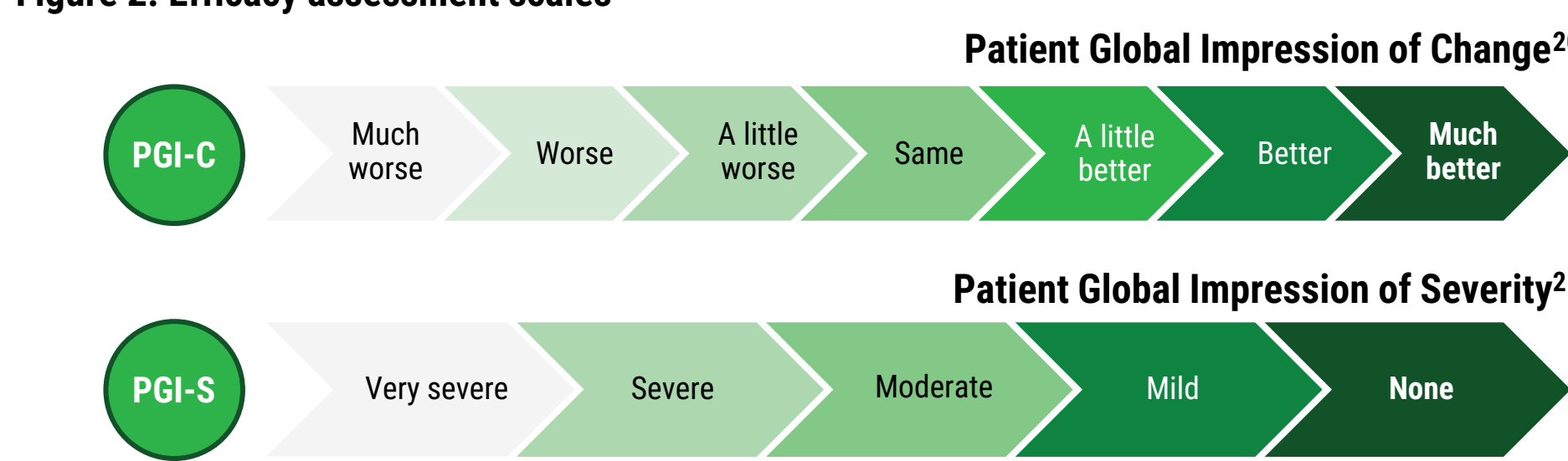
- RAPIDe-2 (NCT05396105)^{16*} is an ongoing two-part Phase 2/3 extension study evaluating long-term safety and efficacy of orally administered deucricitbant IR capsule for the treatment of HAE attacks.
- Part A enrolls adult (≥18 years) participants who completed RAPIDe-1. Participants continue self-administering the same double-blinded dose of deucricitbant IR capsule (10 mg, 20 mg, or 30 mg) received in RAPIDe-1 to treat qualifying non-laryngeal attacks (≥1 symptom with Visual Analogue Scale score ≥30), and laryngeal attacks presenting without breathing difficulties (Figure 1).

Figure 1. RAPIDe-2 study design



- The primary endpoint assesses safety, including treatment-emergent adverse events (TEAEs), clinical laboratory tests, vital signs, and electrocardiogram (ECG) findings.
- Patient-reported outcome (PRO) tools are used to assess efficacy (Figure 2), with data collection pre-specified at pre-treatment, every hour up to 6 hours, and then at 8, 12, 24, and 48 hours, from administration of deucricitbant IR capsule.
- Key efficacy endpoints (Figure 2) include:
 - Onset of symptom relief, defined as Patient Global Impression of Change (PGI-C) rating of at least "a little better" for 2 consecutive timepoints by 12 hours post-treatment.
 - Time to reduction in attack severity, defined as achieving ≥1 level reduction in the Patient Global Impression of Severity (PGI-S) from pre-treatment for 2 consecutive timepoints by 12 hours post-treatment.
 - Proportion of attacks achieving complete attack resolution, defined as achieving PGI-S rating of "none" at 24 hours post-treatment.

Figure 2. Efficacy assessment scales



COI: Grants/research support, honoraria or consultation fees, sponsored speaker bureau - J.S.J.: BioCryst, CSL Behring, Cycle Pharma, Oasis, Pharming, Pharvaris, Takeda; L.B.: BioCryst, Blueprint, CSL Behring, Novartis, Takeda; H.C.: AstraZeneca (Alexion), CSL Behring, KalVista, Merck, Novartis, Pharming, Pharvaris, Roche, Sanofi, Sobi, Takeda; H.F.: BioCryst, CSL Behring, Intellia, KalVista, Ono Pharma, Pharming, Pharvaris, Takeda; D.G.: Pharming, Takeda; R.H.: BioCryst, CSL Behring, KalVista, Pharming, Pharvaris, Takeda; R.L.: BioCryst, CSL Behring, Ionis, KalVista, Novartis, Pharming, Pharvaris, Takeda; A.R.: BioCryst, CSL Behring, Pharming, Pharvaris, Stallergens, Takeda, Teva; G.S.: Pharvaris, Takeda; M.Sta.: No conflicts of interests to disclose relative to this work; M.Sto.: BioCryst, CSL Behring, KalVista, Pharming, Takeda; A.V.: AstraZeneca, Berlin-Chemie/Menarini Group, CSL Behring, KalVista, Novartis, Pharming, Pharvaris, Sobi, Takeda; J.S., L.Z., M.Y., G.G.: Employees of Pharvaris, hold stocks in Pharvaris; P.L.: Employee of Pharvaris, holds stocks/stock options in Pharvaris; M.M.: Adverum, Attune, BioCryst, CSL Behring, KalVista, Pharming, Pharvaris, Takeda; E.A.-P.: Astria, BioCryst, BioMarin, CSL Behring, Intellia, KalVista, Pharming, Pharvaris, Takeda.

Acknowledgments: Medical writing services were provided by Scott Salsman, PhD of Two Labs Pharma Services.

Results

- Data from the RAPIDe-2 Part A combined-dose group at the date of cutoff are reported here.
- A total of 265 attacks from 17 participants were included in the modified intention-to-treat efficacy analysis set (data cutoff: 1 March 2024), defined as all participants who had ≥1 attack treated with deucricitbant and non-missing PGI-C results from ≥1 post-treatment timepoint.
- A total of 337 attacks from 19 participants were included in the safety analysis set (data cutoff: 10 June 2024), defined as all participants who received any dose of deucricitbant in the study.
 - 7 of 337 attacks were laryngeal.
- Baseline characteristics were consistent with the RAPIDe-1 Phase 2 trial (Table 1).

Table 1. Baseline characteristics

	Deucricitbant IR capsule (All doses)
Number of attacks treated ^a	337
Number of participants ^a	19
Age in years, mean (SD)	42.7 (17.6)
Sex: Male/female, n (%)	7 (36.8) / 12 (63.2)
Race: White/other	18 / 1
BMI, mean (SD)	27.0 (3.8)
Years since HAE diagnosis, mean (SD)	21.7 (15.2)
HAE type, n (%)	
HAE-1	17 (89.5)
HAE-2	2 (10.5)

BMI, body mass index; HAE, hereditary angioedema; IR, immediate-release; SD, standard deviation. ^aNumber by the cutoff date of 10 June 2024.

Safety

- Deucricitbant was well-tolerated across all doses, with no treatment-related TEAEs (Table 2).
- No treatment-related serious or severe TEAEs, no treatment-related TEAEs in laboratory parameters, vital signs, or ECG findings, and no TEAEs leading to treatment discontinuation, study withdrawal, or death were reported.

Table 2. TEAEs within 5 days after administration of study drug

Adverse events	Deucricitbant IR capsule (All doses)
Number of attacks treated ^a	337
Number of participants ^a	19
Attacks with any TEAE, n (%)	13 (3.9)
Treatment-related TEAEs, n	0
Serious TEAEs, n	1 ^b
Treatment-related serious TEAEs, n	0
TEAEs leading to study drug discontinuation, study withdrawal, or death, n	0

IR, immediate-release; TEAE, treatment-emergent adverse event (defined as adverse event occurring during time window from first study drug administration). ^aNumber in the safety analysis set (data cutoff: 10 June 2024). ^bTooth caries unrelated to treatment.

Results

Efficacy

- The median time to onset of symptom relief was 1.1 hours (95% CI, 1.0, 1.2) (Figure 3, Table 3).
- 98.5% (261/265) of attacks achieved onset of symptom relief by 12 hours (Table 3, Figure 4).

Figure 3. Kaplan-Meier plot of time to onset of symptom relief

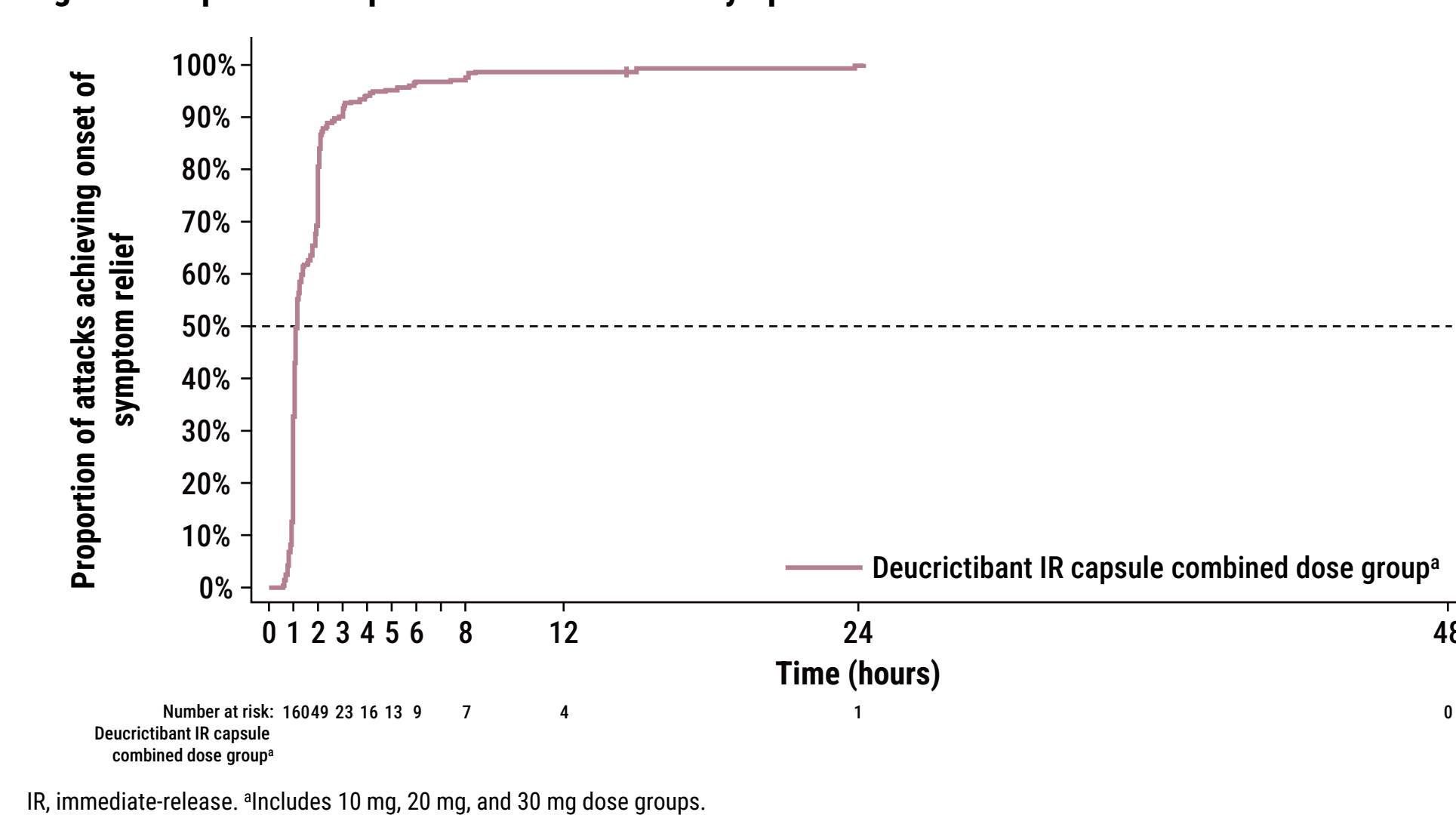


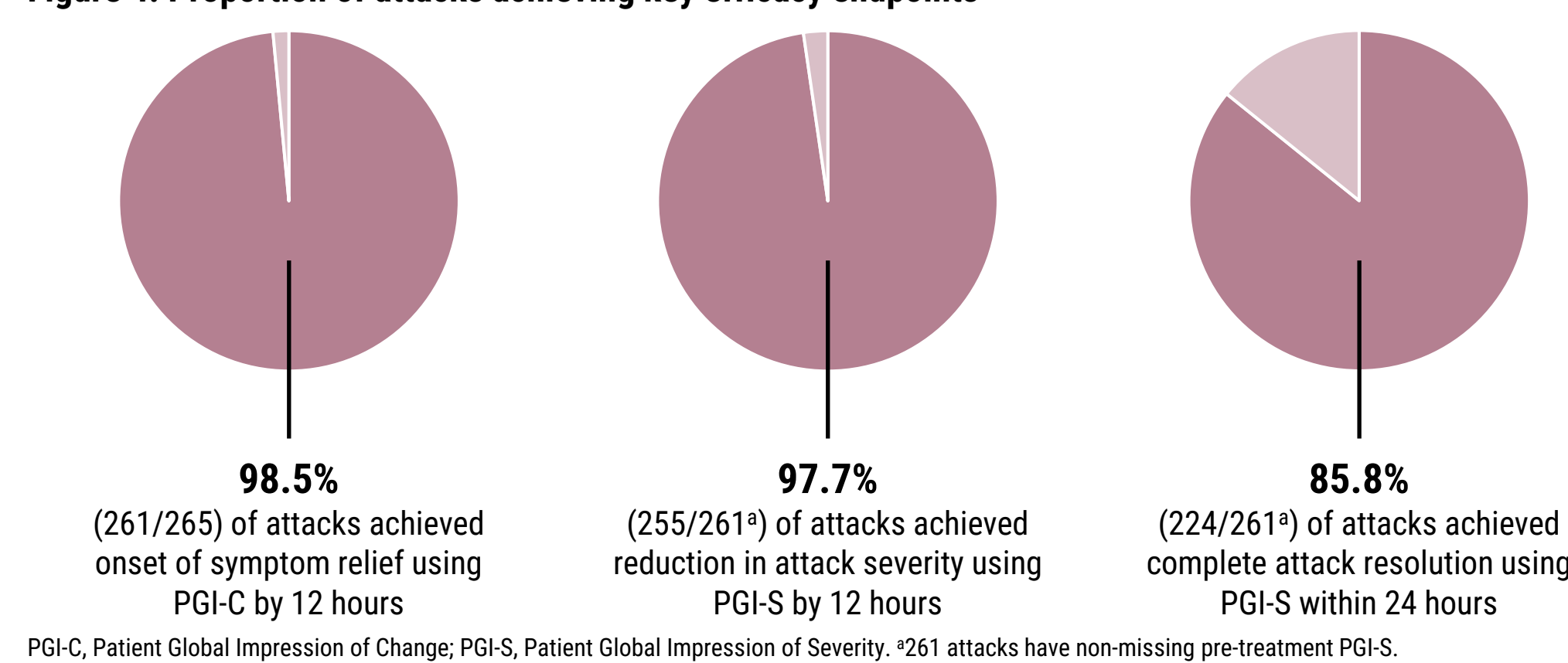
Table 3. Median time to achieving key efficacy endpoints

	Deucricitbant IR capsule (All doses)
Number of attacks treated ^a	265
Number of participants with treated attacks ^a	17
Median time to onset of symptom relief by PGI-C, hours (95% CI)	1.1 (1.0, 1.2)
Median time to reduction in attack severity by PGI-S, ^b hours (95% CI)	2.6 (2.0, 2.9)
Median time to complete attack resolution by PGI-S, ^b hours (95% CI)	11.5 (11.0, 13.0)

IR, immediate-release; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity. ^aNumber in the modified intention-to-treat efficacy analysis set (data cutoff: 01 March 2024). ^b261 attacks have non-missing pre-treatment PGI-S.

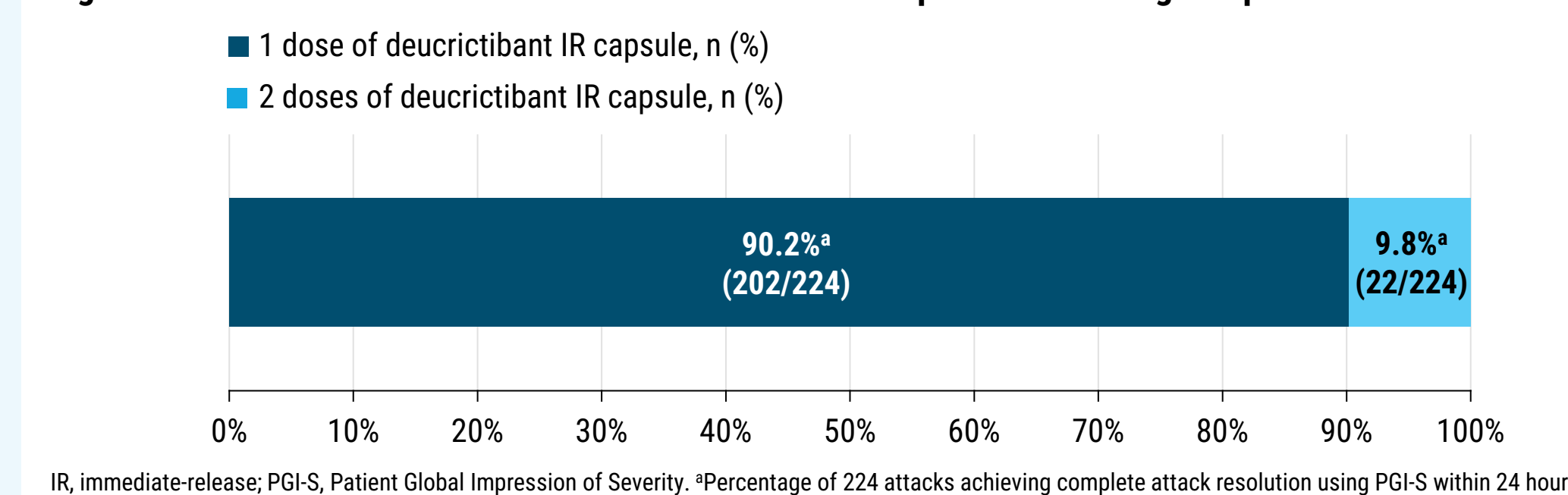
- 85.8% (224/261) of attacks achieved complete attack resolution within 24 hours (Figure 4). 90.2% (202/224) of attacks achieved this milestone with a single dose of deucricitbant IR capsule (Figure 5).

Figure 4. Proportion of attacks achieving key efficacy endpoints



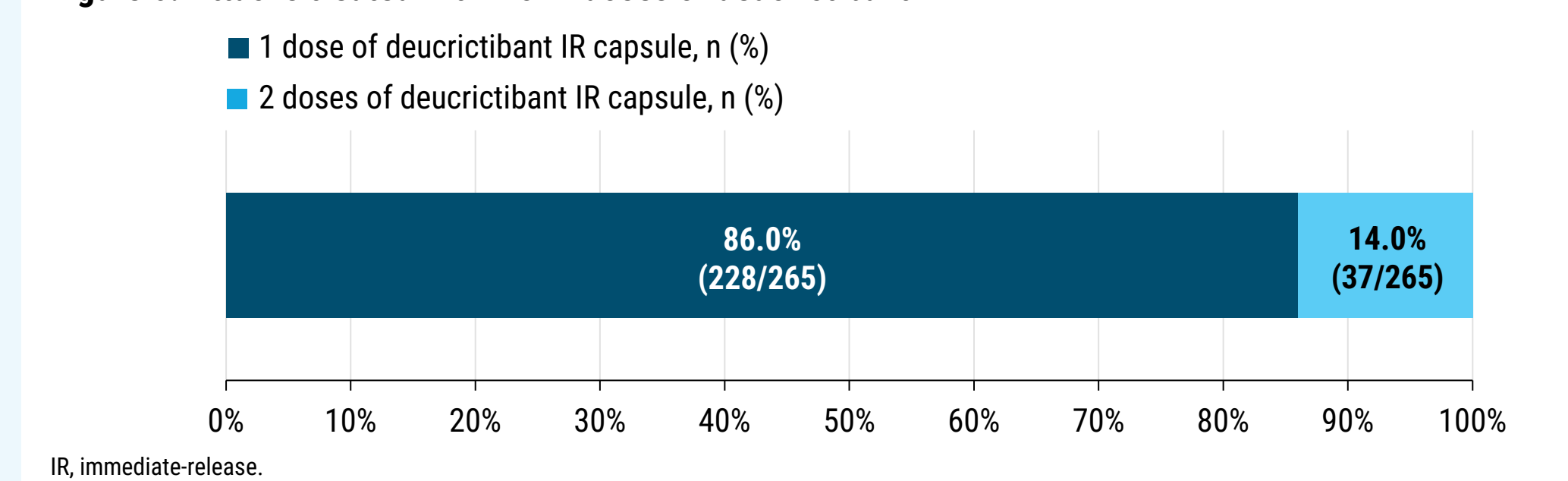
Results

Figure 5. Attacks treated with 1 or 2 doses of deucricitbant prior to achieving complete attack resolution



- A total of 86.0% (228/265) of all attacks were treated with a single dose of deucricitbant IR capsule (Figure 6).

Figure 6. Attacks treated with 1 or 2 doses of deucricitbant



Conclusions

- In the current analysis of the ongoing RAPIDe-2 Phase 2/3 extension study, deucricitbant IR capsule was well-tolerated for all studied doses with no new safety signals observed.
- Efficacy analysis showed:
 - 1.1 hours median time to onset of symptom relief by PGI-C – 98.5% of attacks by 12 hours.
 - 2.6 hours median time to reduction in attack severity by PGI-S – 97.7% of attacks by 12 hours.
 - 11.5 hours median time to complete attack resolution by PGI-S – 85.8% of attacks within 24 hours.
 - 86.0% of attacks were treated with a single dose of deucricitbant IR capsule.
- Results from the ongoing RAPIDe-2 extension are consistent with the Phase 2 RAPIDe-1 study and provide evidence on the long-term safety and efficacy of deucricitbant IR capsule for repeat treatment of HAE attacks.

References

- Betschel S, et al. *Allergy Asthma Clin Immunol*. 2019;15:72. 2. Busse PJ, et al. *J Allergy Clin Immunol Pract*. 2021;9:132-150. 3. Maurer M, et al. *Allergy*. 2022;77:1961-1990.
- Bierment® [package insert]. <https://labeling.csibehring.com/pi/us/beriner/en/beriner-prescribing-information.pdf>. Accessed August 5, 2024. 5. Cinyz® [summary of product characteristics]. https://www.ema.europa.eu/en/documents/product-information/cinyzepar-product-information_en.pdf. Accessed August 5, 2024. 6. Firazy® [package insert]. https://www.shirecontent.com/PI/PDFs/Firazy_USA_ENG.pdf. Accessed August 5, 2024. 7. Kalibitor® [package insert]. https://www.shirecontent.com/PI/PDFs/Kalibitor_USA_ENG.pdf. Accessed August 5, 2024. 8. Ruconest® [package insert]. https://www.ruconest.com/wp-content/uploads/Ruconest_PL_Apr2020.pdf. Accessed August 5, 2024. 9. Burnette A, et al. *AAAAI* 2023. 10. Tuong LA, et al. *Allergy Asthma Proc*. 2014;35:250-254. 11. 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 August 5, 2024. 12. Radjicic C, et al. Presented at AAAAI 2023, Feb 24-27, San Antonio, TX, USA. 13. Mendivil J, et al. Presented at ACAAI 2023, Nov 9-13, Anaheim, CA, USA. 14. <https://www.clinicaltrials.gov/study/NCT04618211>. Accessed August 5, 2024. 15. Maurer M, et al. Presented at AAAAI 2022, Feb 25-28, San Antonio, TX, USA. 16. <https://clinicaltrials.gov/study/NCT05396105>. Accessed August 19, 2024. 17. <https://www.clinicaltrials.gov/study/NCT06343779>. Accessed August 15, 2024. 18. E. Aygören-Pürsün, et al. Presented at EAAAI 2024, May 31-June 3, Valencia, Spain. 19. <https://clinicaltrials.gov/study/NCT05047185>. Accessed August 26, 2024. 20. Guy W (ed). *ECDEU Assessment Manual for Psychopharmacology*. Rockville, MD: US Department of Health, Education, and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, 1976. 21. Cohn DM, et al. *Clin Transl Allergy*. 2023;e1228.

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

Author disclosures

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Acknowledgments: Medical writing services were provided by Andrea Cifelli, BSc, and Scott Salsman, PhD, of Two Labs Pharma Services.

RAPIDe-2 is a Pharvaris-sponsored clinical trial. ClinicalTrials.gov identifier: NCT05396105

Introduction

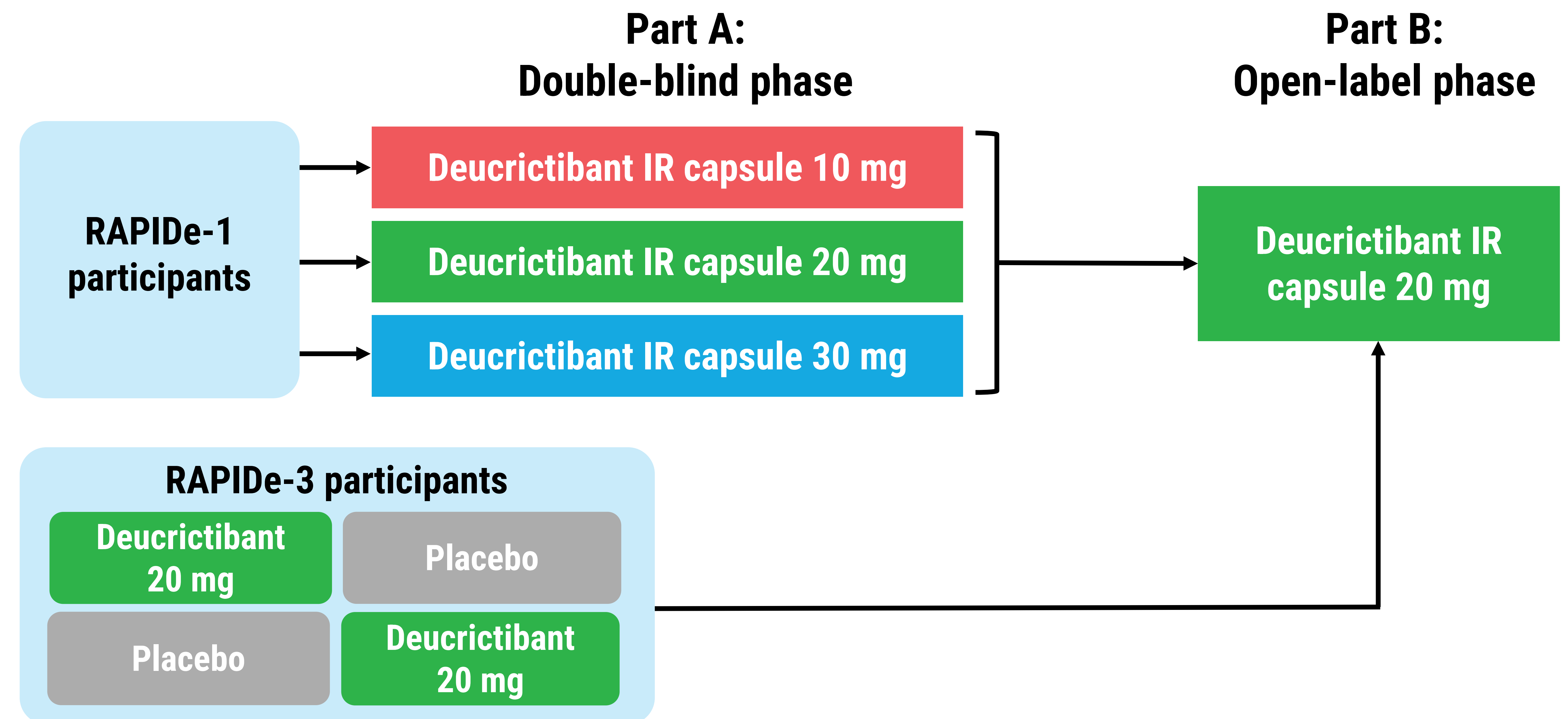
- International guidelines recommend that hereditary angioedema (HAE) attacks are treated as early as possible.¹⁻³
- The burden associated with parenteral administration of currently approved on-demand medications⁴⁻⁸ often leads to treatment of HAE attacks being delayed or forgone.⁹⁻¹³
- An unmet need exists for on-demand oral therapies that are effective and well-tolerated, reducing the treatment burden and thus enabling prompt administration.¹³
- Deucricitibant is a selective, orally administered bradykinin B2 receptor antagonist under development for prophylactic and on-demand treatment of HAE attacks.¹⁴⁻¹⁹
- In the RAPIDe-1 Phase 2 trial (NCT04618211),¹⁴ deucricitibant immediate-release (IR) capsule reduced time to onset of symptom relief and to resolution of HAE attacks vs placebo; treatment was well-tolerated.¹⁵

1. Betschel S, et al. *Allergy Asthma Clin Immunol*. 2019;15:72. 2. Busse PJ, et al. *J Allergy Clin Immunol Pract*. 2021;9:132-150. 3. Maurer M, et al. *Allergy*. 2022;77:1961-1990. 4. Berinert® [package insert], <https://labeling.cslbehring.com/pi/us/berinert/en/berinert-prescribing-information.pdf>. Accessed August 5, 2024. 5. Cinryze® [summary of product characteristics], https://www.ema.europa.eu/en/documents/product-information/cinryze-epar-productinformation_en.pdf. Accessed August 5, 2024. 6. Firazyr® [package insert], https://www.shirecontent.com/PI/PDFs/Firazyr_USA_ENG.pdf. Accessed August 5, 2024. 7. Kalbitor® [package insert], https://www.shirecontent.com/PI/PDFs/Kalbitor_USA_ENG.pdf. Accessed August 5, 2024. 8. Ruconest® [package insert], https://www.ruconest.com/wp-content/uploads/Ruconest_PI_Apr2020.pdf. Accessed August 5, 2024. 9. Burnette A, et al. AAAAI 2023. 10. Tuong LA, et al. *Allergy Asthma Proc*. 2014;35:250-254. 11. 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 August 5, 2024. 12. Radojicic C, et al. Presented at AAAAI 2023, Feb 24-27, San Antonio, TX, USA. 13. Mendevil J, et al. Presented at ACAAI 2023, Nov 9-13, Anaheim, CA, USA. 14. <https://www.clinicaltrials.gov/study/NCT04618211>. Accessed August 5, 2024. 15. Maurer M, et al. Presented at AAAAI 2022, Feb 25-28, San Antonio, TX, USA. 16. <https://clinicaltrials.gov/study/NCT05396105>. Accessed August 19, 2024. 17. <https://www.clinicaltrials.gov/study/NCT06343779>. Accessed August 15, 2024. 18. E. Aygören-Pürsün, et al. Presented at EAACI 2024, May 31-June 3, Valencia, Spain. 19. <https://clinicaltrials.gov/study/NCT05047185>. Accessed August 26, 2024.

RAPIDe-2 objectives and study design

- RAPIDe-2 (NCT05396105)¹ is an ongoing two-part Phase 2/3 extension study evaluating long-term safety and efficacy of orally administered deucricitibant IR capsule for the treatment of HAE attacks.
 - Part A enrolls adult (≥ 18 years) participants who completed RAPIDe-1.
 - Participants continue self-administering the same double-blinded dose of deucricitibant IR capsule (10 mg, 20 mg, or 30 mg) received in RAPIDe-1 to treat qualifying non-laryngeal attacks^a (≥ 1 symptom with Visual Analogue Scale score ≥ 30), and laryngeal attacks presenting without breathing difficulties.
 - Data from the RAPIDe-2 Part A combined-dose group at the date of cutoff reported in this publication.

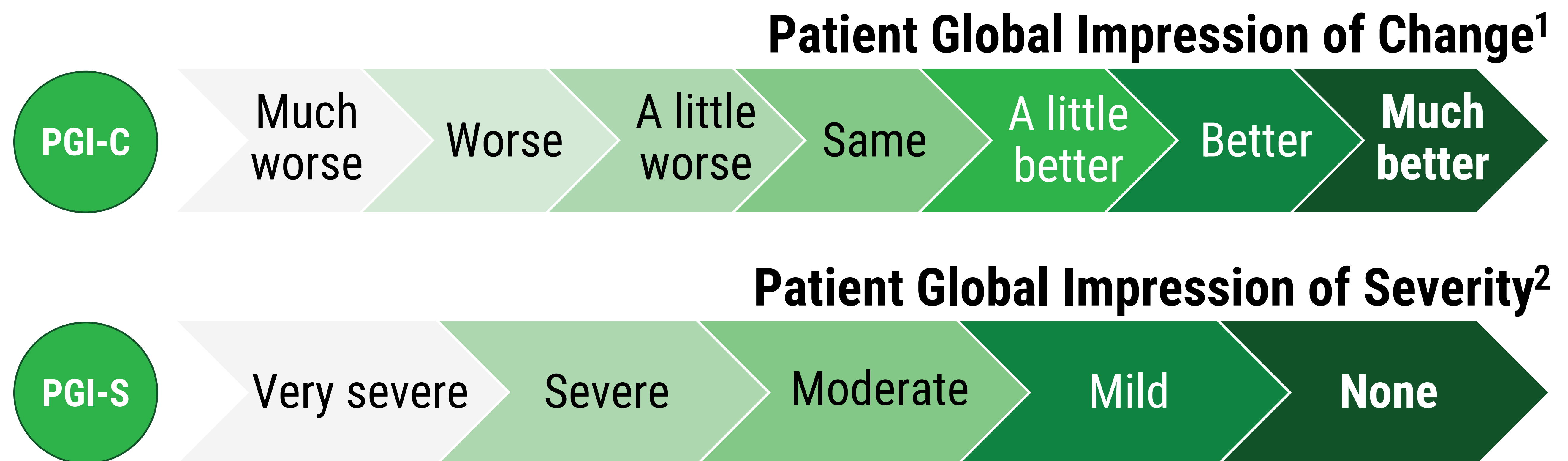
RAPIDe-2 study design



Study endpoints

- **Primary endpoint:** Safety, including TEAEs, clinical laboratory tests, vital signs, and ECG findings.
- **Efficacy:** Assessed using PRO tools.
- **Key efficacy endpoints:**
 - **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.
 - **Proportion of attacks achieving complete attack resolution:** PGI-S rating of “none” at 24 hours post-treatment.

Efficacy (PRO) assessment scales



ECG, electrocardiogram; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity; PRO, patient-reported outcome; TEAE, treatment-emergent adverse event.

1. Guy W (ed). ECDEU Assessment Manual for Psychopharmacology. Rockville, MD: US Department of Health, Education, and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, 1976.

2. Cohn DM, et al. *Clin Transl Allergy*. 2023;e12288.

Baseline characteristics

- 265 attacks from 17 participants included in the mITT efficacy analysis set (data cutoff: 01 March 2024).^a
- 337 attacks from 19 participants included in the safety analysis set (data cutoff: 10 June 2024).^b
 - 7 of 337 attacks were laryngeal.
- Baseline characteristics consistent with the RAPIDe-1 Phase 2 trial.

Baseline characteristics

	Deucricitibant IR capsule (All doses)
Number of attacks treated^c	337
Number of participants^c	19
Age in years, mean (SD)	42.7 (17.6)
Sex: Male/female, n (%)	7 (36.8) / 12 (63.2)
Race: White/other	18 / 1
BMI, mean (SD)	27.0 (3.8)
Years since HAE diagnosis, mean (SD)	21.7 (15.2)
HAE type, n (%)	
HAE-1	17 (89.5)
HAE-2	2 (10.5)

BMI, body mass index; HAE, hereditary angioedema; IR, immediate-release; mITT, modified intention-to-treat; SD, standard deviation. ^aAll participants who had ≥1 attack treated with deucricitibant and non-missing PGI-C results from ≥1 post-treatment timepoint. ^bAll participants who received any dose of deucricitibant in the study. ^cNumber by the cutoff date of 10 June 2024.

Deucrictibant was well-tolerated across all doses

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

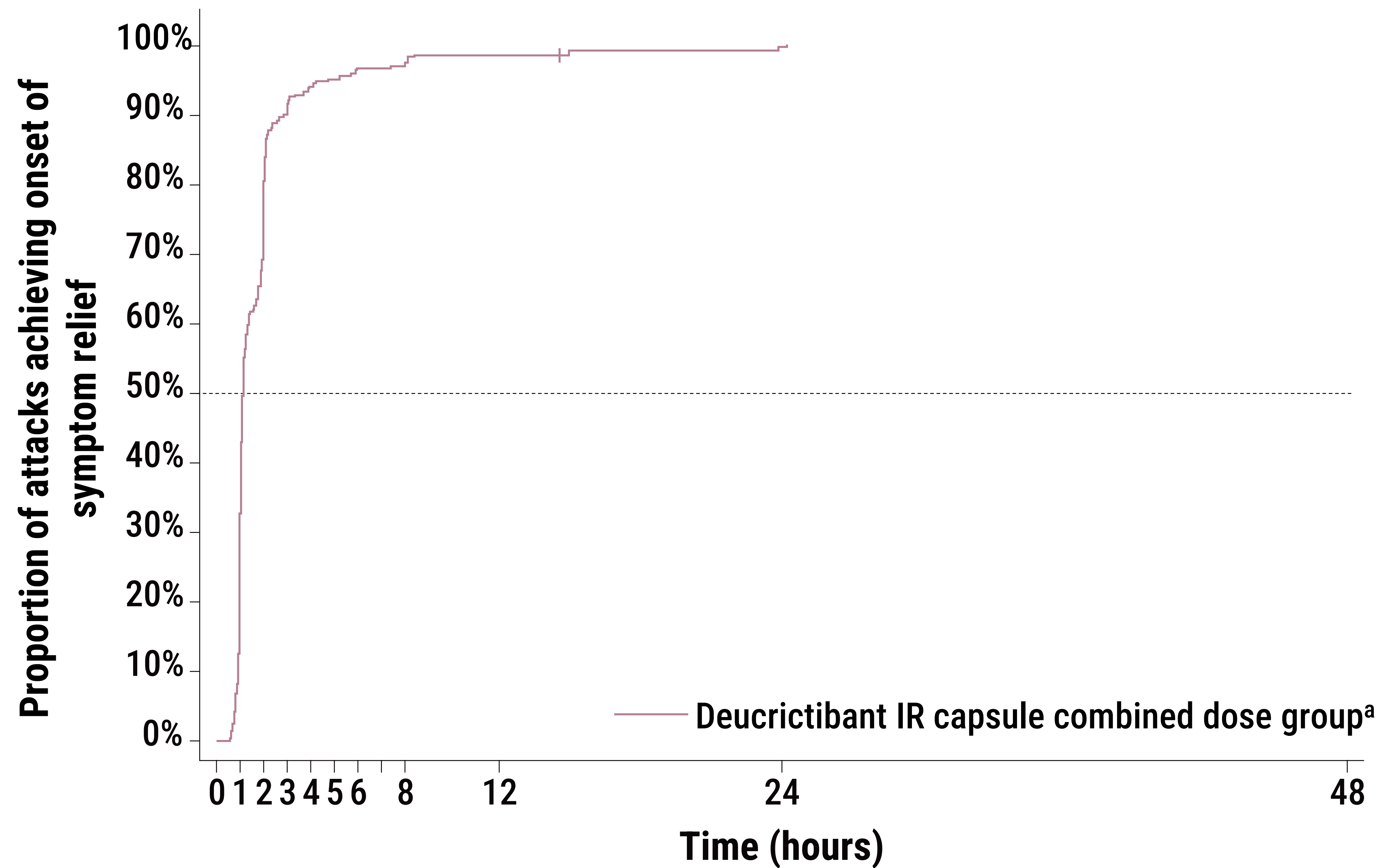
TEAEs within 5 days after administration of study drug

Adverse events	Deucrictibant IR capsule (All doses)
Number of attacks treated^a	337
Number of participants^a	19
Attacks with any TEAE, n (%)	13 (3.9)
Treatment-related TEAEs, n	0
Serious TEAEs, n	1 ^b
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). ^aNumber in the safety analysis set (data cutoff: 10 June 2024). ^bTooth caries unrelated to treatment.

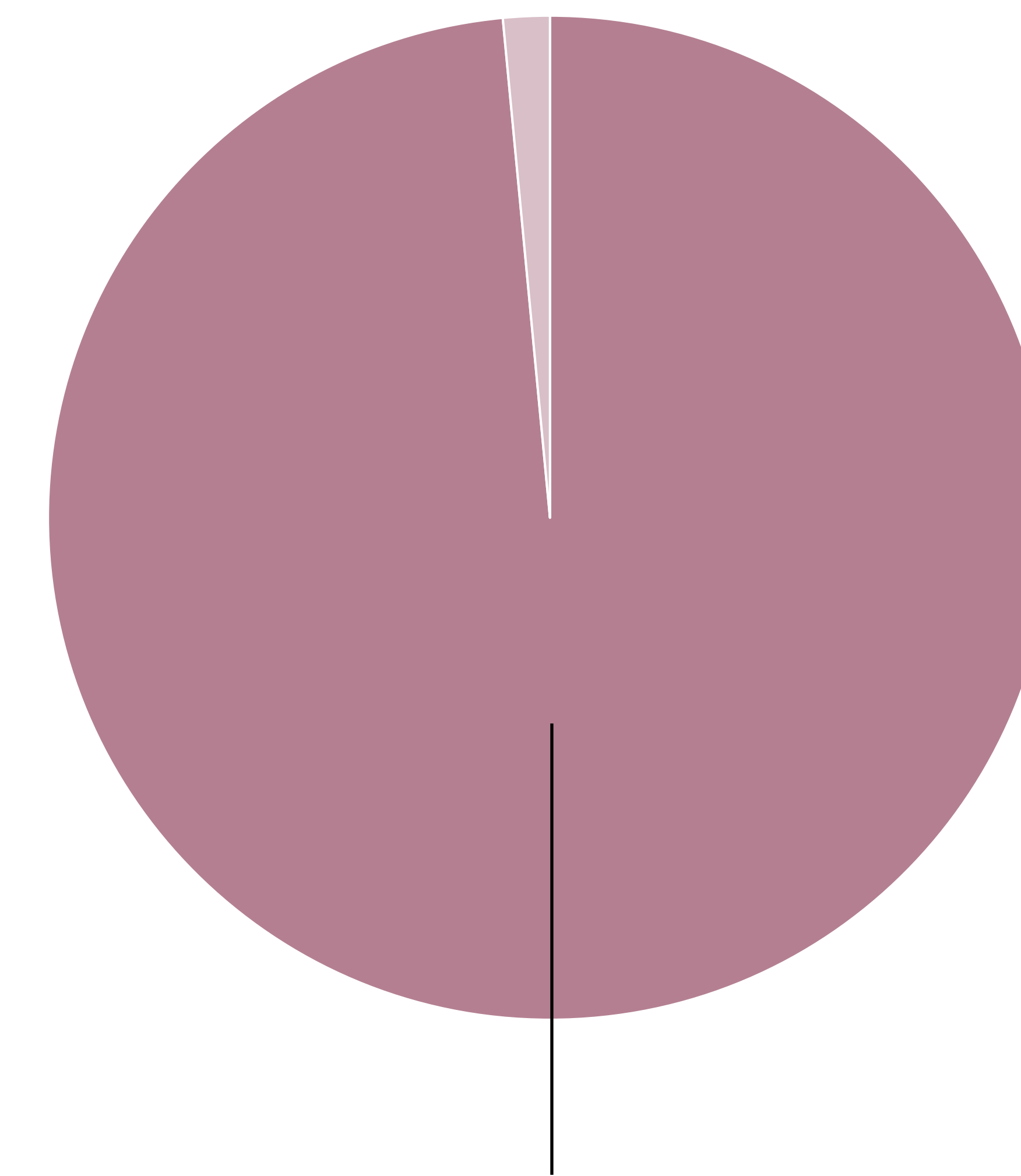
1.1 hours median time to onset of symptom relief by PGI-C

Kaplan-Meier plot of time to onset of symptom relief



Number at risk: 160 23 13 7 4
 Deucricitabant IR capsule 49 16 9
 combined dose group^a

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

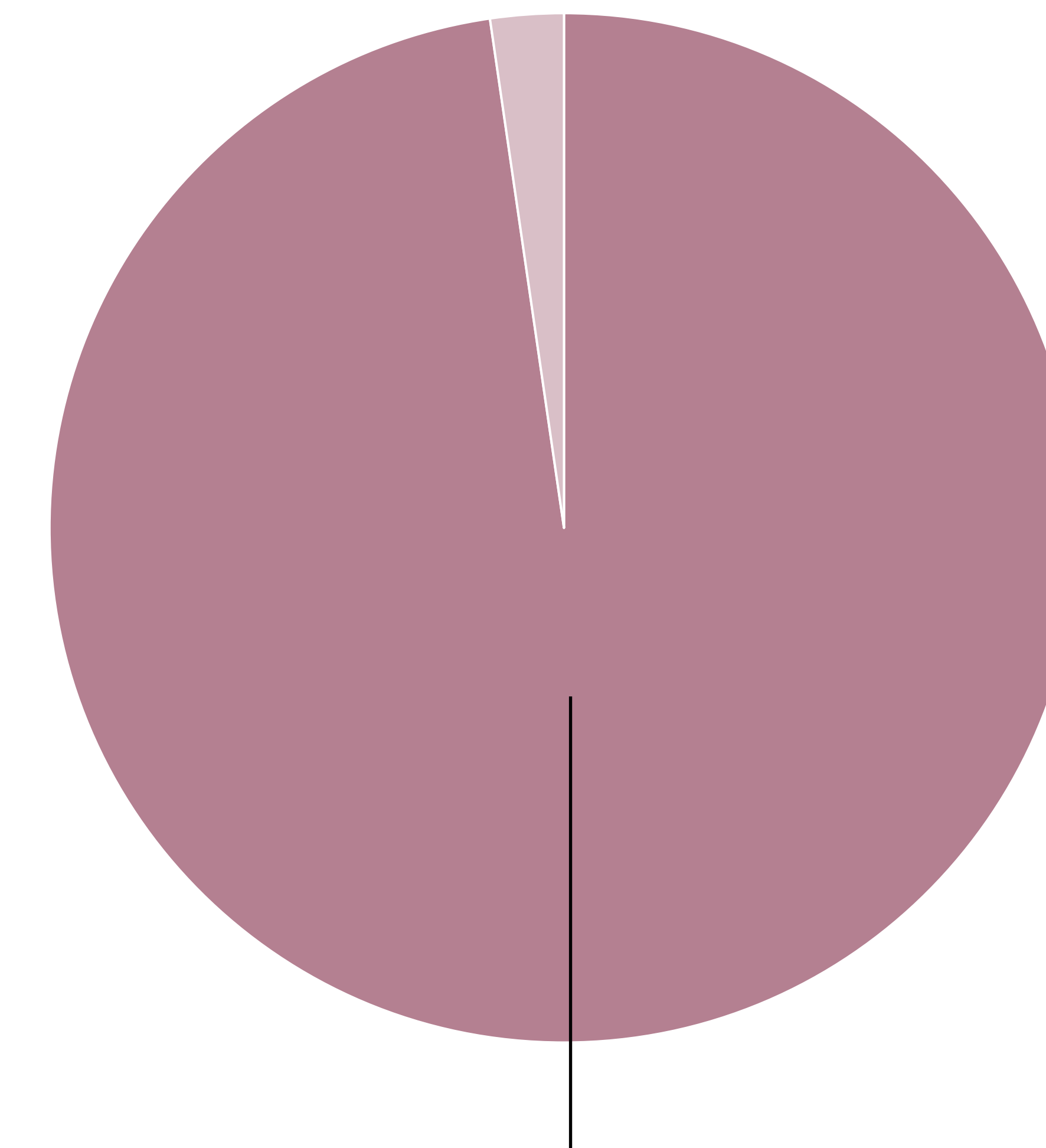


98.5%
 (261/265) of attacks achieved onset of
 symptom relief using PGI-C^b by 12 hours

IR, immediate-release; PGI-C, Patient Global Impression of Change. ^aIncludes 10 mg, 20 mg, and 30 mg dose groups. ^bPGI-C rating of at least “a little better” for 2 consecutive timepoints by 12 hours post-treatment.

97.7% of attacks achieved reduction in attack severity using PGI-S by 12 hours

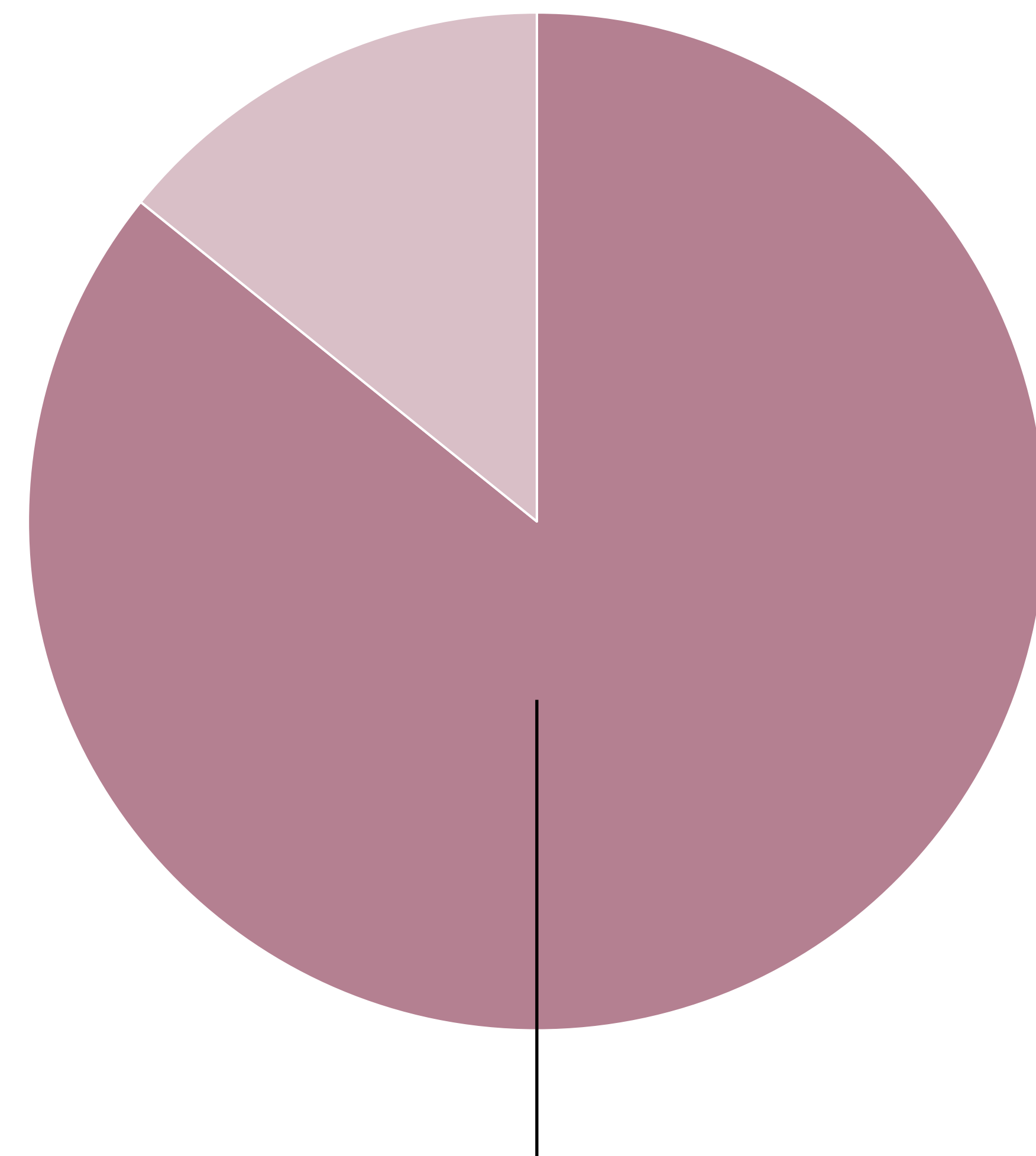
2.6 (95% CI, 2.0, 2.9) hours
median time to reduction in attack severity
by PGI-S^a



97.7%
(255/261^b) of attacks achieved reduction in
attack severity using PGI-S^a by 12 hours

85.8% of attacks achieved complete attack resolution within 24 hours

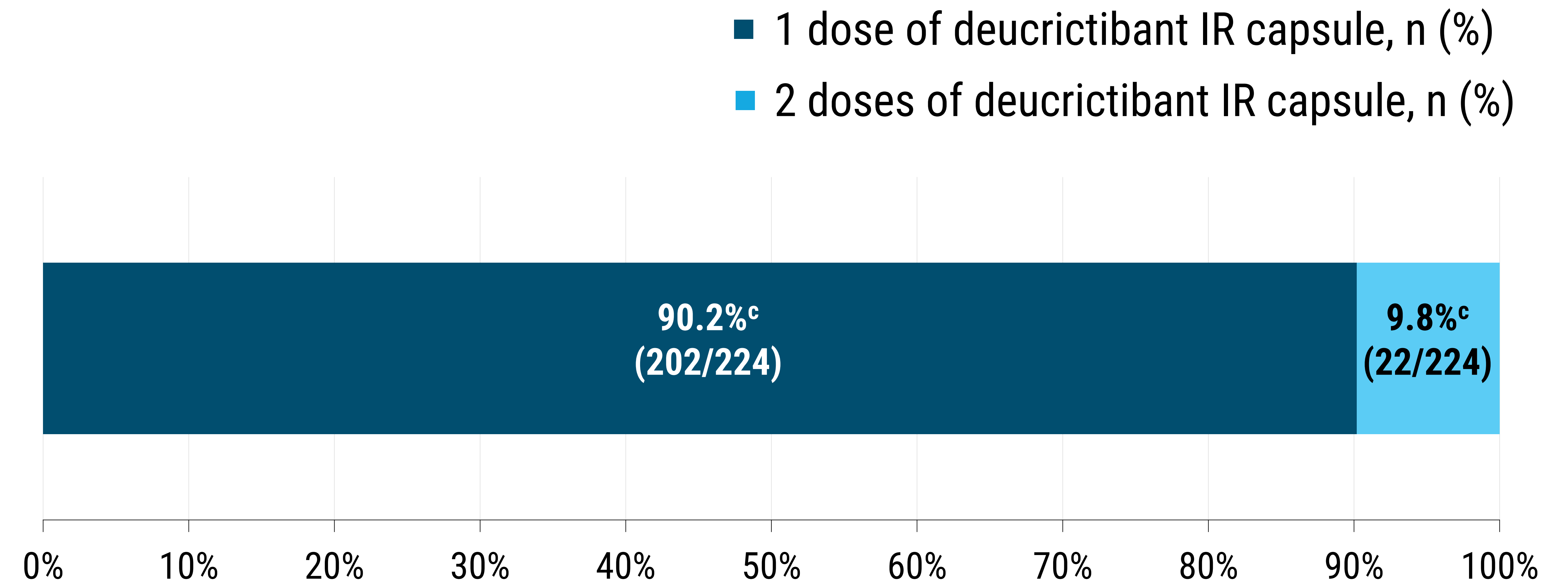
11.5 (95% CI, 11.0, 13.0) hours
median time to complete attack resolution
by PGI-S^a



85.8%
(224/261^b) of attacks achieved complete
attack resolution using PGI-S^a within 24 hours

90.2% (202/224) of attacks achieved this milestone
with a single dose of deucricitabant IR capsule.

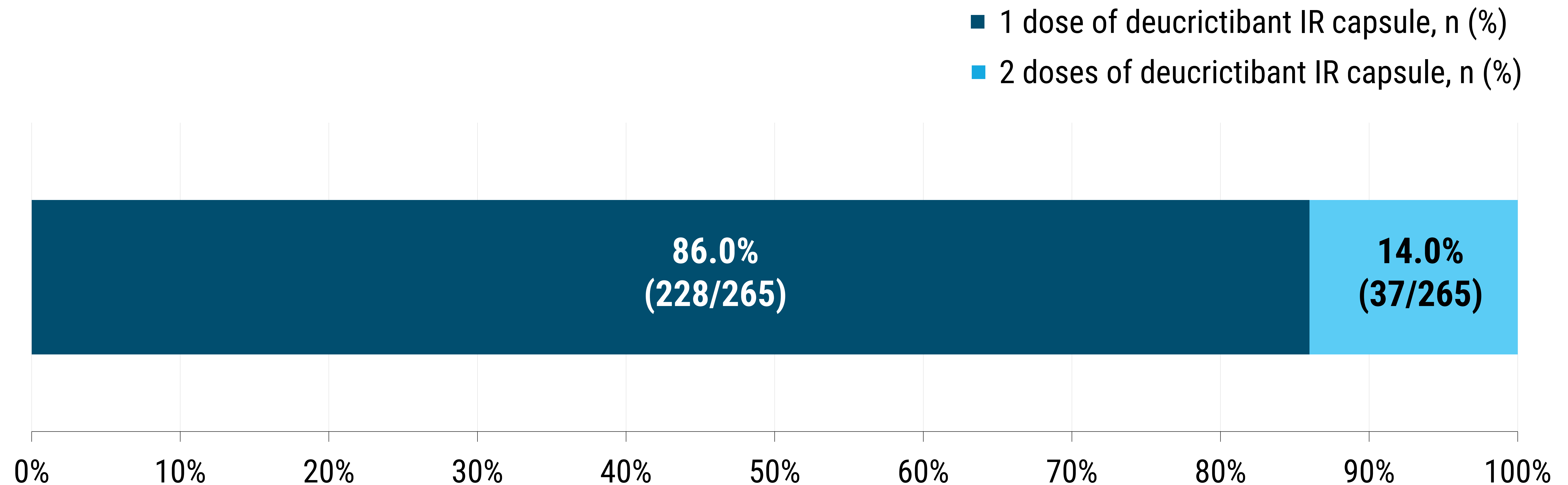
Attacks treated with 1 or 2 doses of deucricitabant prior to achieving complete attack resolution



IR, immediate-release; PGI-S, Patient Global Impression of Severity. ^aPGI-S rating of “none” at 24 hours post-treatment. ^b261 attacks have non-missing pre-treatment PGI-S. ^cPercentage of 224 attacks achieving complete attack resolution using PGI-S within 24 hours.

86.0% of attacks were treated with a single dose of deucricitibant

Attacks treated with 1 or 2 doses of deucricitibant



Conclusions

- In the current analysis of the ongoing RAPIDe-2 Phase 2/3 extension study, deucricitibant IR capsule was well-tolerated for all studied doses with no new safety signals observed.
- Efficacy analysis showed:
 - 1.1 hours median time to onset of symptom relief by PGI-C – 98.5% of attacks by 12 hours.
 - 2.6 hours median time to reduction in attack severity by PGI-S – 97.7% of attacks by 12 hours.
 - 11.5 hours median time to complete attack resolution by PGI-S – 85.8% of attacks within 24 hours.
 - 86.0% of attacks were treated with a single dose of deucricitibant IR capsule.
- Results from the ongoing RAPIDe-2 extension are consistent with the Phase 2 RAPIDe-1 study and provide evidence on the long-term safety and efficacy of deucricitibant IR capsule for repeat treatment of HAE attacks.

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