Oral Deucrictibant Immediate-Release Capsule for On-Demand Treatment of Hereditary Angioedema Attacks: Regional Subgroup Analysis From the Phase 3 RAPIDe-3 Trial

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Bradykinin Symposium 2026
Berlin, Germany; September 3–4, 2026

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Conflicts of interest disclosure

COI: M.M.: Argo, Astria, BioCryst, CSL Behring, Intellia, KalVista, Octapharma, Otsuka, Pharvaris, Takeda; **M.A.R.:** ADARx, Astria, BioCryst, BioMarin, Celldex, CSL Behring, Cycle Pharma, Grifols, Intellia, Ionis, KalVista, Novartis, Pharming, Pharvaris, Sanofi-Regeneron, Takeda; **P.H.L.:** Astria, BioCryst, CSL Behring, KalVista, Novartis, Pharvaris, Takeda; **A.A.:** Astria, BioCryst, CSL Behring, Intellia, Ionis Pharmaceuticals, Kalvista, Octapharm, Pendopharm, Pharvaris, Takeda; **M.C.:** ADARx, BioCryst, Chiesi, CSL Behring,Gentili, KalVista, Menarini, MSD, NeoPharmed, Novartis,Otsuka, Pharming, Pharvaris, Sobi, Takeda, UCB; **M.Sto.:** BioCryst, CSL Behring, KalVista, Pharming, Pharvaris, Takeda; **A.V.:** AstraZeneca, Astria, Berlin-Chemie/Menarini Group, CSL Behring, Ewopharma, Ionis, KalVista, Novartis, Organon, Pharming, Pharvaris, Shire/Takeda, SOBI, Stallergenes Greer, Teva; **A.S.G.:** AstraZeneca, Astria, BioMarin, Brazilian research Entity (CNPq), Catalyst, CSL Behring, Exeltis, KalVista, Kedrion, Multicare, Pharvaris, Pint-Pharma, Takeda, The Binding Site; **W.R.L.:** AstraZeneca, Astria, BioCryst, BioMarin, CSL Behring, Fresenius-Kabi, GlaxoSmithKline, Grifols, Intellia, Ionis, KalVista, Magellan, Optinose, Pharming, Pharvaris, Regeneron, Sanofi, Takeda, Teva; **D.F.S.:** BioCryst, CSL Behring, Intellia, Ionis, KalVista, Pharvaris, Takeda; **N.B.:** none to report; **N.L.F.:** Bago, CSL Behring, Pint Pharma, Sanofi, Takeda, Director of HAE committee for AAAeIC; **R.H.:** BioCryst, CSL Behring, Genesis Pharma, KalVista, Pharming, Pharvaris, Takeda; **H-R.K.:** Astria, BioCryst, CSL Behring, KalVista, Pharvaris, Takeda; **G.K.:** CSL Behring, Er-kim İlaç, Ionis, Pharvaris, Polifarma, Takeda, Vem İlaç; **B.K.:** Pharvaris; **H.H.L.:** BioCryst, CSL Behring, Intellia, Ionis, Pharming, Pharvaris, Takeda, Medical Advisory Board US HAEA; **J.P.:** Pharming, Takeda; **A.R.:** BioCryst, CSL Behring, Deutsche Forschungsgemeinschaft (DFG), EUROIMMUN Medizinische Labordiagnostika AG, Pierre Fabre Pharma, Neopharmed Gentili, Novartis,Otsuka, Pharming, Pharvaris, Stallergenes, Swedish Orphan Biovitrum, Otsuka, Takeda; **R.T.:** ADMA, ARS, AstraZeneca, Astria, BioCryst, CSL Behring, GlaxoSmithKline, Grifols, Intellia, Ionis, KalVista, Lilly, Novartis, Pharming, Pharvaris, Sanofi/Regeneron, Takeda; **P.T.:** Abbvie, Biocryst, CSL Behring, KalVista, Takeda; **A.Z.:** Astria, BioCryst, CSL Behring, Intellia, KalVista, Otsuka, Pharming, Pharvaris, Takeda; **J.A.:** Astria, BioCryst, CSL Behring, Intellia, Ionis, KalVista, Pharming, Pharvaris, Takeda; **E.A-P.:** Astria, BioCryst, BioMarin, CSL Behring, Intellia, KalVista, Otsuka, Pharming, Pharvaris, Takeda; **T.C.:** ADARx, ARGO, Astria, BioCryst, BioMarin, CSL Behring, GlaxoSmithKline, Grifols, Intellia, Ionis, KalVista Pharma, Pharvaris, Takeda, Director of ACARE International Hereditary Angioedema Center, member of the Medical Advisory Board for the HAE-A; **H.F.:** ADARx, Astria, BioCryst, CSL Behring, Intellia, Ionis, Kalvista, Otsuka, Pharming, Pharvaris, Takeda; **F.G.:** BioCryst, CSL Behring, Ionis, KalVista, Takeda; **P.G-B.:** CSL Behring, Pharvaris, Pint Pharma, Takeda, participates in the World Allergy Organization and Associação Brasileira de Alergia e Imunologia; **S.K.:** none to report; **T.K.:** ADARx, Astria, BioCryst, CSL Behring, KalVista, Otsuka, Pharvaris, Sanofi/Regeneron, Takeda; **I.M-S.:** Biocryst, CSL Behring, KalVista, Octapharma, Pharming, Pharvaris, Takeda; **F.P.:** BioCryst, CSL Behring, Otsuka, Pharvaris, Takeda; **K.V.S.:** Achieve Life Sciences, ADARx, AstraZeneca, Astria, Bellus, BioCryst, CSL Behring, Evidera, GlaxoSmithKline, Jasper, KalVista, Nocion, Novartis, Pharvaris, Teva; **M.Sta.:** none to report; **H.J.W.:** BioCryst, BioMarin, CSL Behring, Genentech, GlaxoSmithKline, Takeda; **R.H.Z-U.:** BioCryst, KalVista, Pharming, Takeda; **R.D.Z.:** AbbVie, Bago, CSL Behring, KalVista, Novartis, Panalab, Pharvaris, Pint-Pharma, Sanofi, Takeda; **A.G.:** Pharvaris; **F.A.:** BioCryst, CSL Behring, KalVista, Otsuka, Takeda; **R.A.:** none to report; **A.P.B.:** KalVista, Pharvaris, Takeda; **R.d.A.C.:** CSL Behring, Pharvaris, Pint Pharma, Takeda; **A.D.D.:** Astria, BioCryst, CSL Behring, Ionis, KalVista, Otsuka, Pharvaris, Takeda; **M.P.L.F.:** Pharvaris, Pint Pharma, Takeda; **A.F.:** BioCryst, CSL Behring, Kaken, KalVista, Pharvaris, Takeda, Torii Pharmaceutical Company Ltd.; committee chair for Japanese Dermatological Association Urticaria Treatment Guidelines 4th Edition, Creation; **D.G.:** Astria, BioCryst, CSL Behring, Ionis, Kalvista, Otsuka, Pharvaris, Takeda; **P.G.:** BioCryst, CSL Behring, KalVista, Pharming, Takeda; **M.H.:** Astria, BioCryst, CSL Behring, Kaken, KalVista, Otsuka, Pharvaris, Takeda, Torii Pharmaceuticals; **D.I.H.:** KalVista, Pharvaris; **E.I.:** BioCryst, CSL Behring, Kao Corporation, KalVista Japan, Pharvaris, Takeda, Torii Pharmaceuticals; **J.S.J.:** BioCryst, CSL Behring, Cycle Pharma, Intellia, Ionis, KalVista, Pharming, Pharvaris Takeda; **C.H.K.:** AstraZeneca, CSL Behring, GlaxoSmithKline, Novartis, Pebbles trial, Pharvaris, Sanofi, Takeda; **L.L.:** BioCryst, CSL Behring, Novartis, Takeda; **R.L.:** BioCryst, CSL Behring, Ionis, KalVista, Otsuka, Pharvaris, Takeda; **M.E.M.:** AstraZeneca, Astria, BioCryst, Blueprint, Celldex, Cogent, CSL Behring, GlaxoSmithKline, Intellia, Ionis, KalVista, Merck, Novartis, Pharming, Pharvaris, Regeneron, Takeda, Teva; **S.M.:** none to report; **S.O.:** none to report; **C.J.R.:** Amgen, GlaxoSmithKline, Pfizer, Pharvaris, Sanofi, Takeda; **J.L., L.Z., J.M., U.K., G.G., M.Y., P.L.:** employees of Pharvaris, holds stocks in Pharvaris; **R.C.:** employee of RC Consultancy; consultant to Pharvaris and holds stocks in Pharvaris; **A.L.:** employee of GrayMatters Consulting, consultant to Pharvaris and holds stocks/stock options in Pharvaris; advisor to Kosa Pharma; **D.M.C.:** ADARx, Astria Therapeutics, BioCryst, CSL Behring, Gentili Neopharma, Intellia, Ionis, KalVista, Otsuka, Pharvaris, Takeda, is a Regional Medical Advisory Panel Member for HAEi Central Eastern Europe and the Benelux.

RAPIDe-3 was a Pharvaris-sponsored clinical study. ClinicalTrials.gov identifier: NCT06343779.

Acknowledgments: Medical writing services were provided by Jonny Turner, PhD, of Envision Medical Communications, and funded by Pharvaris.

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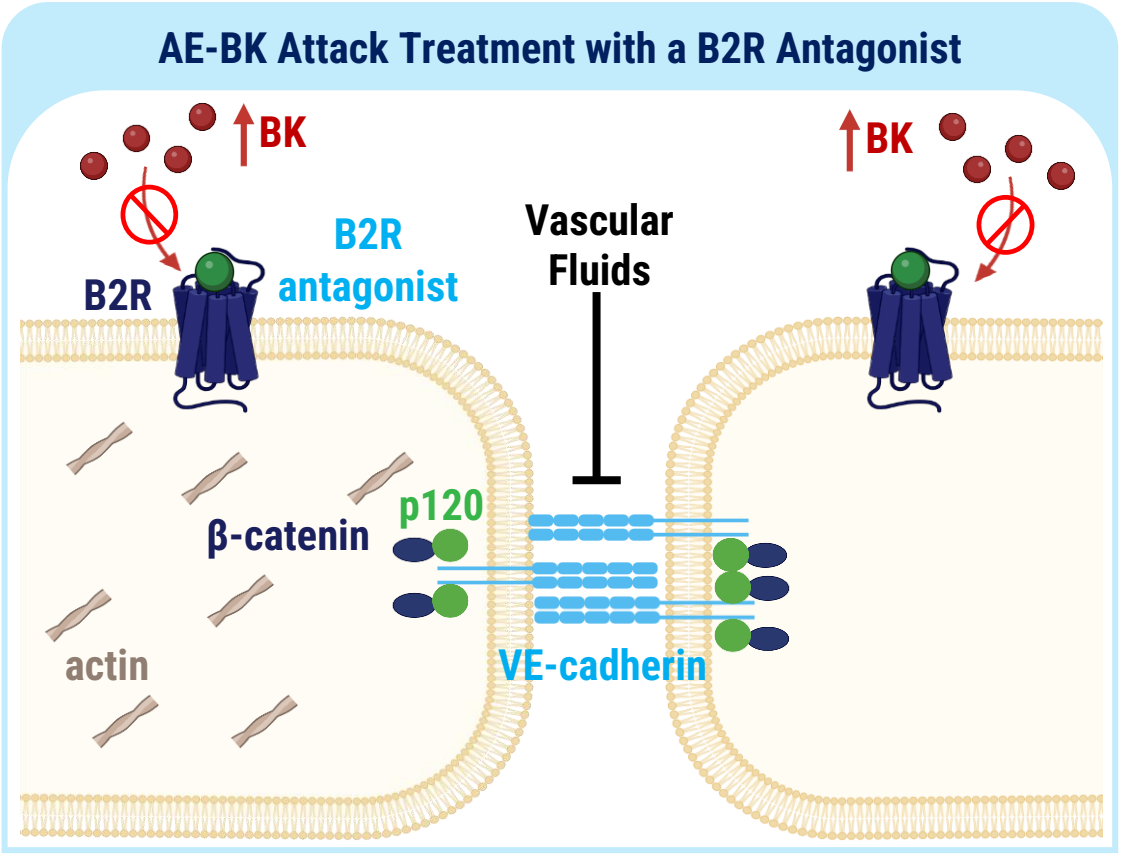
B2R antagonism inhibits downstream signaling and decreases excessive endothelial permeability during an AE-BK attack

Treatment with a B2R antagonist can end the progression of AE-BK attacks by:

- **Inhibiting excessive BK-mediated signaling that drives disruption of adherens and tight junctions[1,2]**
- **Preventing increased vascular permeability[1,2]**



Bradykinin B2 receptor antagonism can effectively treat bradykinin-mediated angioedema attacks.[3-6]

AE-BK, bradykinin-mediated angioedema; BK, bradykinin; B2R, bradykinin B2 receptor; VE, vascular endothelial. **1.** Terzuoli E, et al. *PLoS ONE* 2014;9(1):e84358. **2.** Kempe S, et al. *Microcirculation*. 2019;27(2):e12592. **3.** Maurer M, et al. *Allergy*. 2022;77:1961-90. **4.** Cicardi M, et al. *N Eng J Med*. 2010;363:532-41. **5.** Suffritti C, et al. *Clin Exp Allergy*. 2014;44(12):1503-1514. **6.** Maurer M, et al. *Lancet Haematol*. 2026;13(4):e200-14.

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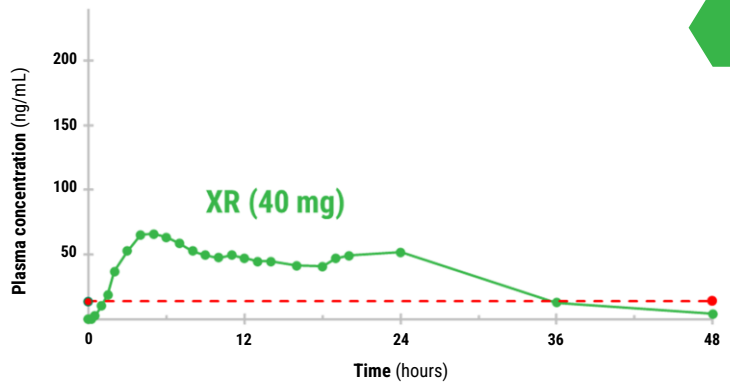
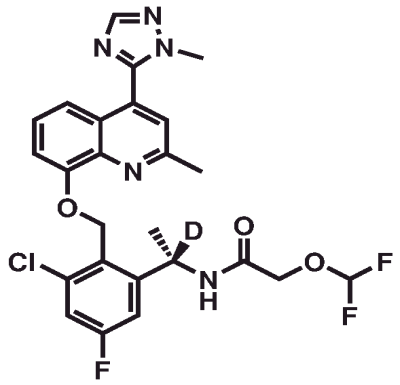
Deucrictibant is an orally administered, B2R antagonist in development for the prophylactic and on-demand treatment of AE-BK attacks

DEUCRICTIBANT extended-release (XR) tablet

sustained absorption[1]



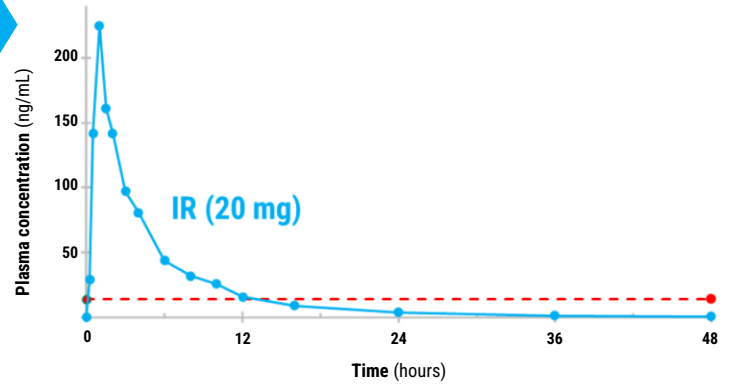
In studies, deucrictibant maintained sustained therapeutic exposure over 24 hours[1] from day 1, allowing for once-daily oral prevention of HAE attacks[2]



Deucrictibant

DEUCRICTIBANT immediate-release (IR) capsule

rapid absorption[3]



In studies, deucrictibant rapidly reached therapeutic exposure within 15–30 minutes[3], supporting on-demand oral treatment of HAE attacks[4, 5]

AE-BK, bradykinin-mediated angioedema; B2R, bradykinin B2 receptor; HAE, hereditary angioedema; IR, immediate-release; XR, extended-release. **1.** Zhang et al. Presented at C1INH Workshop; May 29-June 1, 2025. **2.** CHAPTER-3. ClinicalTrials.gov identifier: NCT06669754. https://clinicaltrials.gov/study/NCT06669754. Accessed August 13, 2026. **3.** Maurer M, et al. *Lancet Haematol.* 2026; 13(4):e200-14. **4.** Riedl MA, et al. *Lancet*. 2026; In press. **5.** Riedl MA, et al. Presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting; March 2026; Philadelphia, PA, USA.

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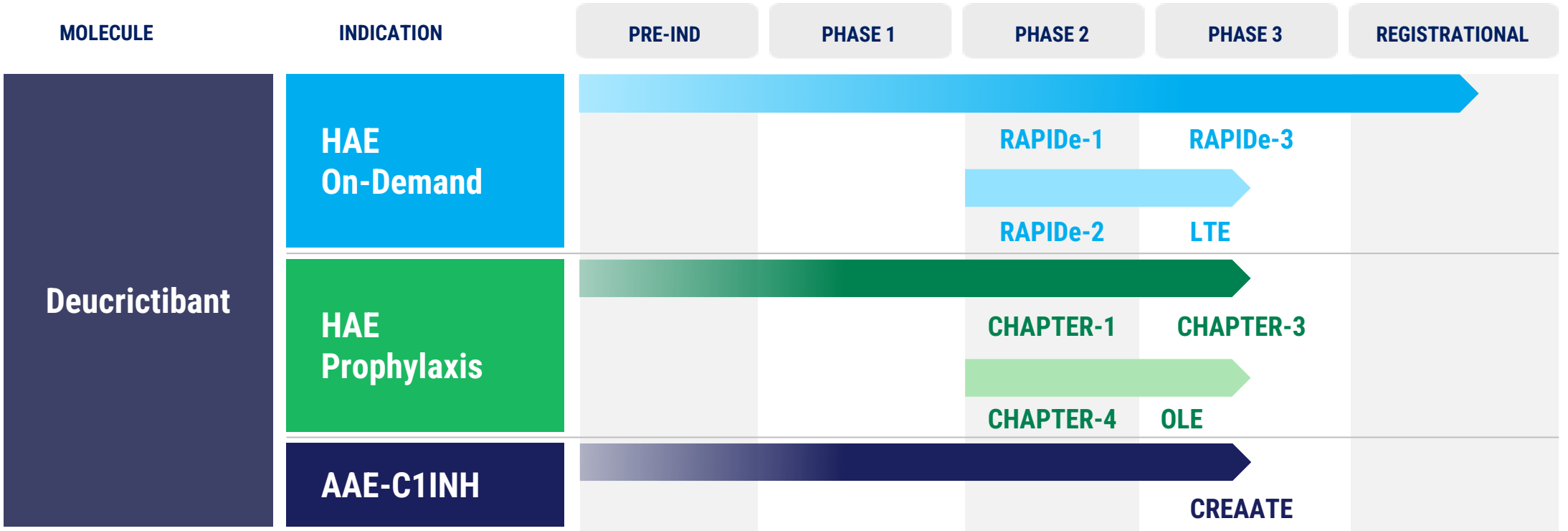
Deucrictibant development program in AE-BK



Presentations at BK Symposium 2026

1. Riedl MA, et al. RAPIDe-3 regional subgroup analysis
2. Farkas H, et al. RAPIDe-3 End of progression
3. Cohn D, et al. RAPIDe-3 End of progression validation
4. Aygören-Pürsün E, et al. CHAPTER-1 OLE final results
5. Stobiecki M, et al. CHAPTER-1 OLE patient-reported outcomes
6. Loenders B, et al. Cardiovascular safety of deucrictibant
7. Bravo J, et al. Safety margins of deucrictibant IR capsule with deucrictibant XR tablet
8. Doering NP, et al. Modelling deucrictibant complexes in-silico
9. DeGeer J, et al. LC-MS particle-based plasma proteomics in BK-mediated angioedema
10. Bravo J, et al. NHP BK-challenge model

AAE-C1INH, acquired angioedema due to C1INH deficiency; AE-BK, bradykinin-mediated angioedema; BK, bradykinin; C1INH, C1 inhibitor; IR, immediate-release; LC-MS, liquid chromatography mass spectrometry; LTE, long-term extension; NHP, non-human primate; OLE, open-label extension; XR, extended-release.

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RAPIDe-3 findings to date

The study enrolled **134 participants** with HAE globally, with 201 HAE attacks treated with double-blinded study drug; 88 participants had paired attacks for the primary analysis

The study met the **primary and all secondary endpoints**, demonstrating pronounced efficacy in achieving swift EoP, rapid symptom relief, and early resolution of HAE attacks

Deucrictibant IR showed **consistent efficacy in treating HAE attacks**, regardless of HAE subtypes, age group, LTP use, and attack severity and locations

Deucrictibant IR was **well tolerated, with no safety signals identified** from TEAEs, laboratory parameters, ECG, and vital signs

ECG, electrocardiogram; EoP, end of progression; HAE, hereditary angioedema; IR, immediate-release; LTP, long-term prophylaxis; TEAE, treatment-emergent adverse event. Riedl MA, et al. *Lancet*. 2026; In press.

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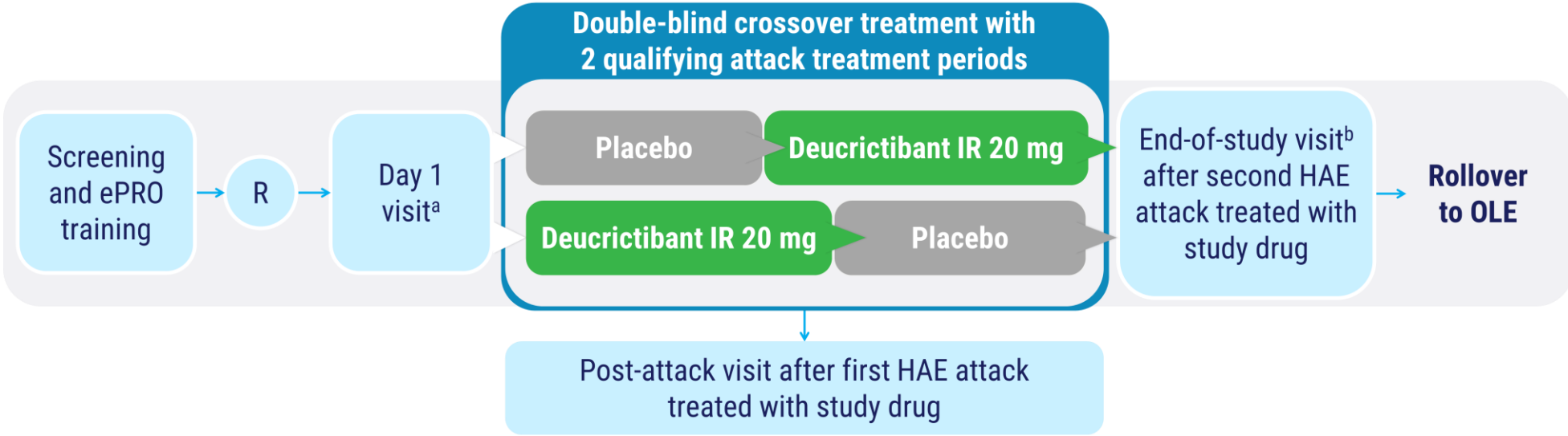
RAPIDe-3 trial design



- **Participants:** adolescents (aged ≥12 to <18 years) and adults (aged ≥18 to ≤75 years) with HAE-C1INH type 1 or 2, or HAE-nC1INH. Participants on long-term HAE prophylaxis were also enrolled.
- **Study drugs:** participants self-administered deucrictibant IR capsule 20 mg or placebo to treat two qualifying attacks in a crossover design. Qualifying attacks were defined as either a non-laryngeal attack with at least one symptom item score of ≥20 on the Angioedema syMptom Rating scAle (AMRA) assessment, or a non-severe laryngeal attack without breathing difficulties or stridor.
- **Analysis sets:** subgroup analysis included all participants with treated attacks. Safety analysis included all participants who received ≥1 dose of study drug.

ePRO, electronic patient-reported outcome; HAE, hereditary angioedema; IR, immediate-release; OLE, open-label extension; R, randomisation. [a]Adolescent participants received a non-attack dose for pharmacokinetic sampling at Day 1 visit prior to randomisation. [b]Data from end-of-study visit could be used to qualify the participant for an open-label extension study with deucrictibant. Riedl MA, et al. *Lancet*. 2026; In press

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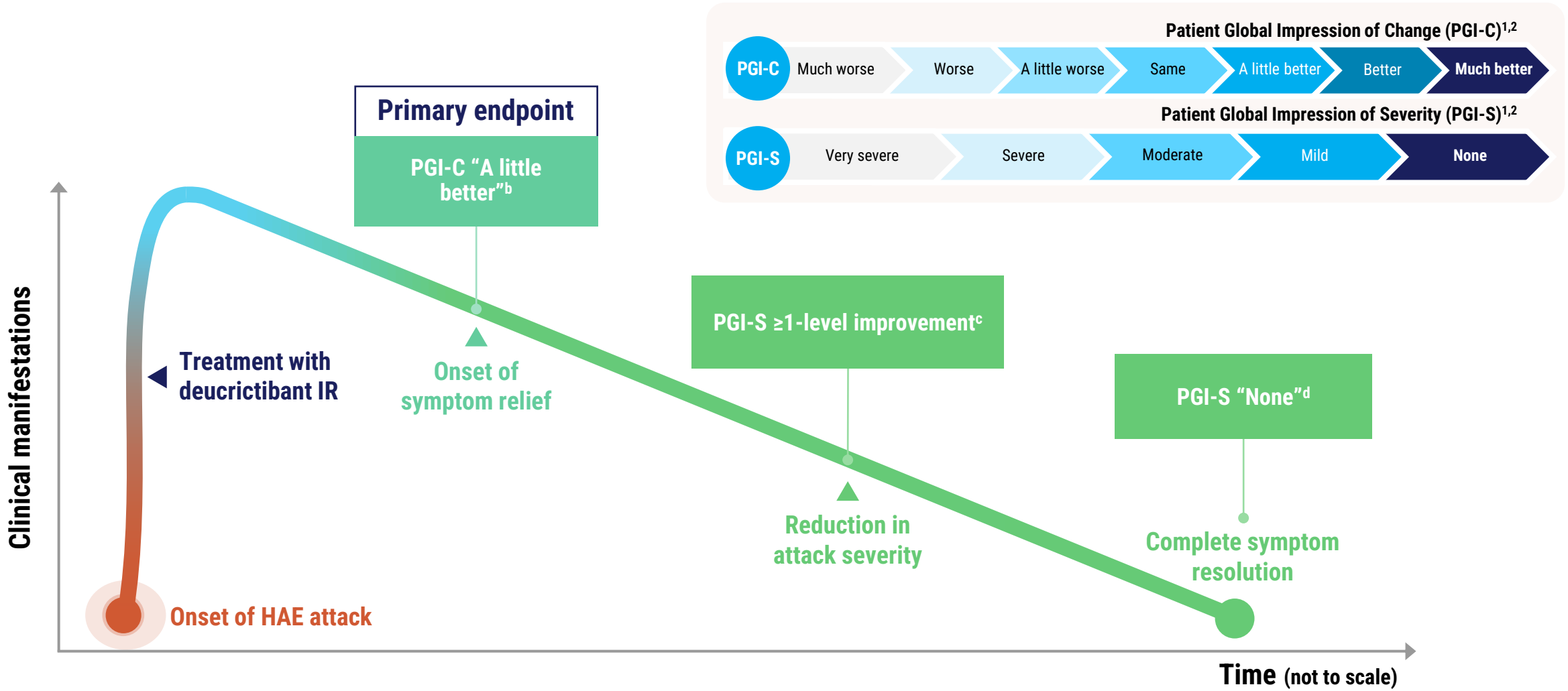
Selected efficacy endpoints[a]



EoP, end of progression; HAE, hereditary angioedema; IR, immediate-release; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity. [a]The primary and 3 of 11 hierarchical order-ranked secondary endpoints. [b]PGI-C "a little better": Primary endpoint is time to onset of symptom relief, defined as PGI-C rating of at least "a little better" for 2 consecutive timepoints within 12 hours post-treatment; [c]PGI-S ≥1-level improvement: Time to substantial symptom relief by PGI-S, defined as achieving ≥1-level improvement in PGI-S from pre-treatment for 2 consecutive timepoints within 12 hours post-treatment; [d]PGI-S "none": Time to complete symptom resolution, defined as achieving PGI-S rating of "none" within 48 hours post-treatment. **1.** Cohn DM, et al. *Clin Transl Allergy*. 2023;13(9):e12288. **2.** Mendivil J, et al. *Clin Rev Allergy Immunol*. 2026;69(1):14.

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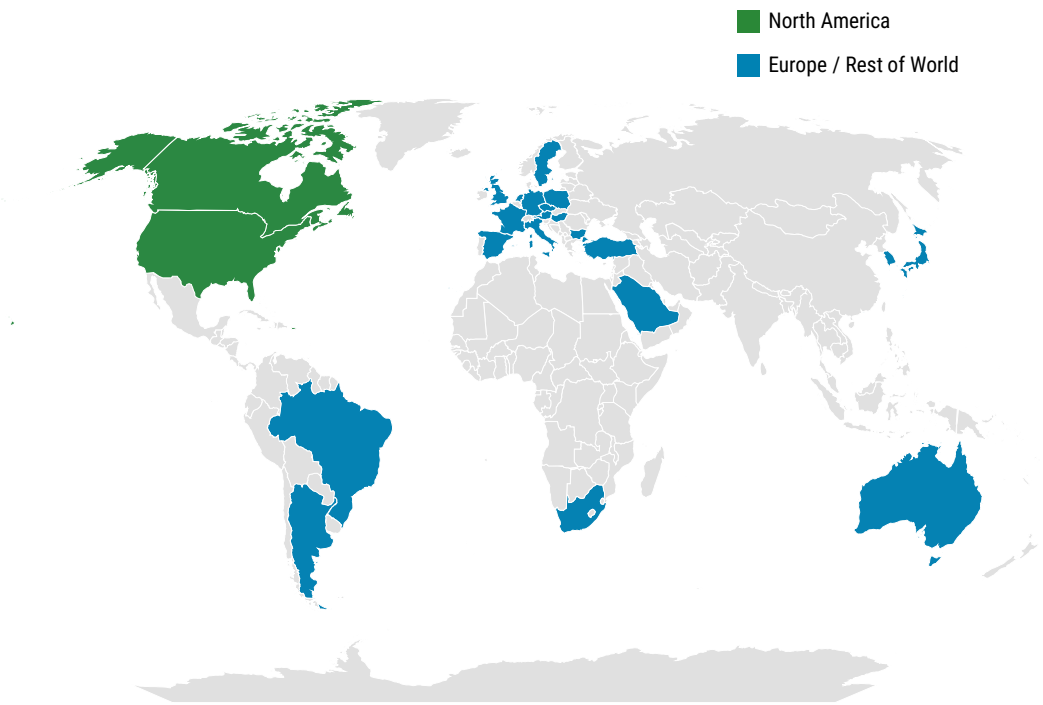
Participant demographics and baseline disease characteristics



Participant characteristics	North America (N=38)[a]	Europe/Rest of World (N=96)[a]
Age in years, mean (SD)	39.0 (14.9)	39.0 (14.7)
≥12 to <18, n (%)	3 (7.9)	7 (7.3)
≥18 to <65, n (%)	34 (89.5)	82 (85.4)
≥65, n (%)	1 (2.6)	7 (7.3)
Sex: Female, n (%)	20 (52.6)	56 (58.3)
BMI, mean (SD)	29.2 (7.8)	25.5 (4.7)
Race, n (%)		
White	25 (65.8)	68 (70.8)
Asian	1 (2.6)	18 (18.8)
Black or African American	7 (18.4)	3 (3.1)
American Indian or Alaska Native	1 (2.6)	0
Other	3 (7.9)	4 (4.2)
Not reported	1 (2.6)	3 (3.1)
Years since HAE diagnosis, mean (SD)	20.6 (14.7)	16.5 (12.2)
Number of attacks within 3 months before screening, mean (SD)	3.4 (2.5)	4.8 (3.5)[b]
HAE type, n (%)		
HAE-C1INH type 1	35 (92.1)	83 (86.5)
HAE-C1INH type 2	0	10 (10.4)
Unspecified HAE-C1INH type 1 or 2	2 (5.3)	0
HAE-nC1INH[c]	1 (2.6)	3 (3.1)
Current LTP use, n (%)	13 (34.2)[d]	18 (18.8)[e]

BMI, body mass index; C1INH, C1 inhibitor; HAE, hereditary angioedema; LTP, long-term prophylaxis; nC1INH, normal C1 inhibitor; SD, standard deviation. [a]Geographic region of North America included Canada, Puerto Rico, United States of America; Europe included Austria, Bulgaria, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of World included Argentina, Australia, Brazil, Hong Kong, Japan, Saudi Arabia, South Africa, South Korea, Turkey. [b]n=94. [c]Included participants with HAE-nC1NH associated with a documented genetic variant. [d]LTP medication included lanadelumab (6 [15.8%]), complement c1 inhibitor (4 [10.5%]), berotralstat (2 [5.3%]),and other (1 [2.6%]). [e]LTP medication included lanadelumab (7 [7.3%]), complement C1 inhibitor (2 [2.1%]), berotralstat (6 [6.3%]), and other (3 [3.1%]).

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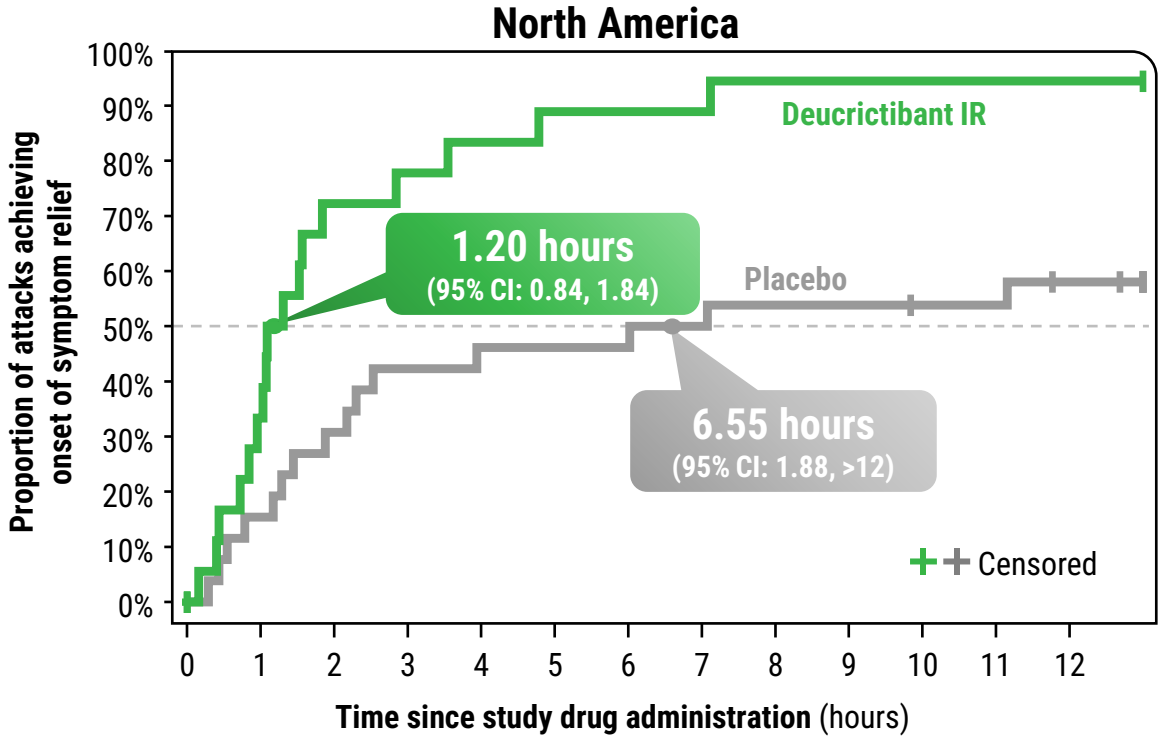
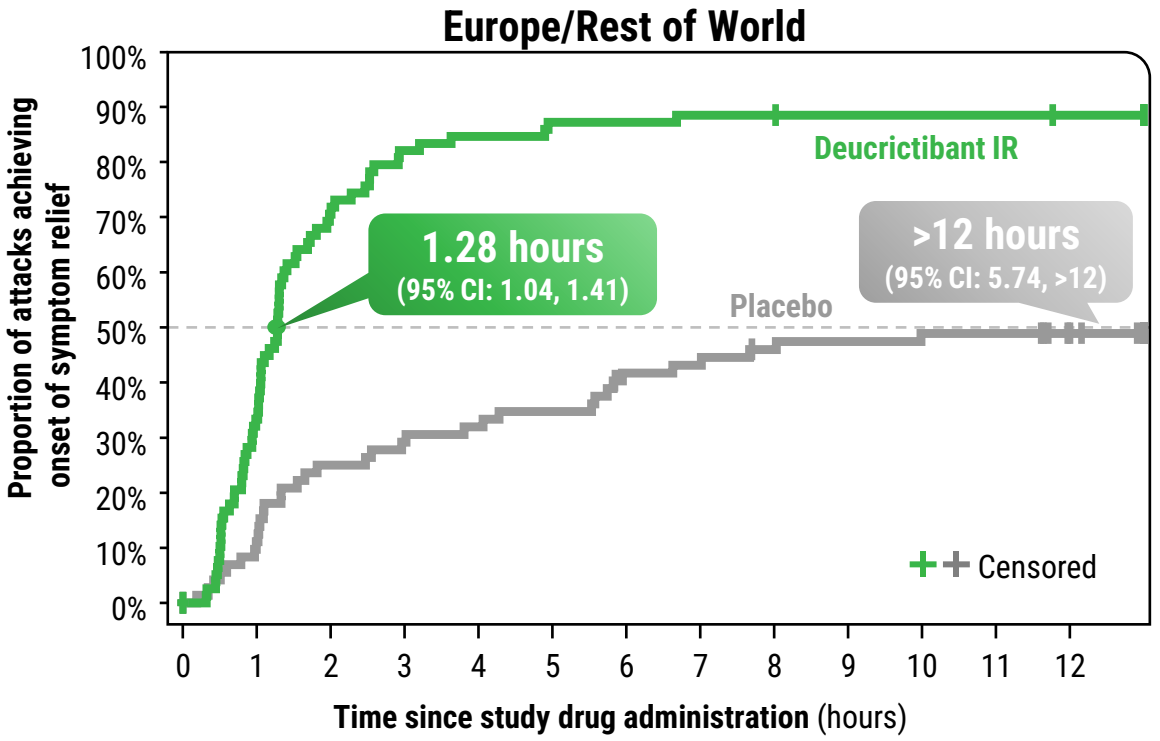
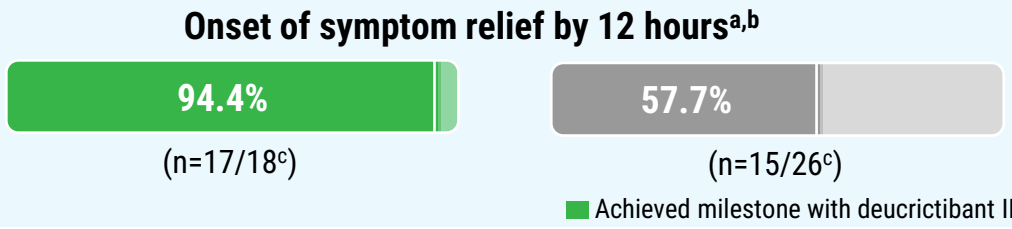
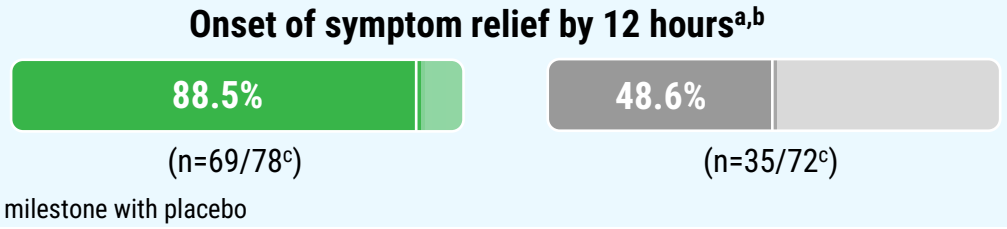
Deucrictibant-treated attacks shown to achieve onset of symptom relief faster than placebo-treated attacks in both subgroups[a,b]









Achieved milestone with deucrictibant IR Achieved milestone with placebo

CI, confidence interval; IR, immediate-release; PGI-C, Patient Global Impression of Change. [a]If the event of interest was not achieved within the pre-specified timeframe, the attack was right censored at the last observation before the upper end of the data entry window. For attacks with rescue medication use, they were treated as right censored at the upper end of the data entry window. [b]PGI-C rating of at least "a little better" for 2 consecutive timepoints within 12 hours post-treatment. [c]Number of participants with post-treatment data within specified timeframe.

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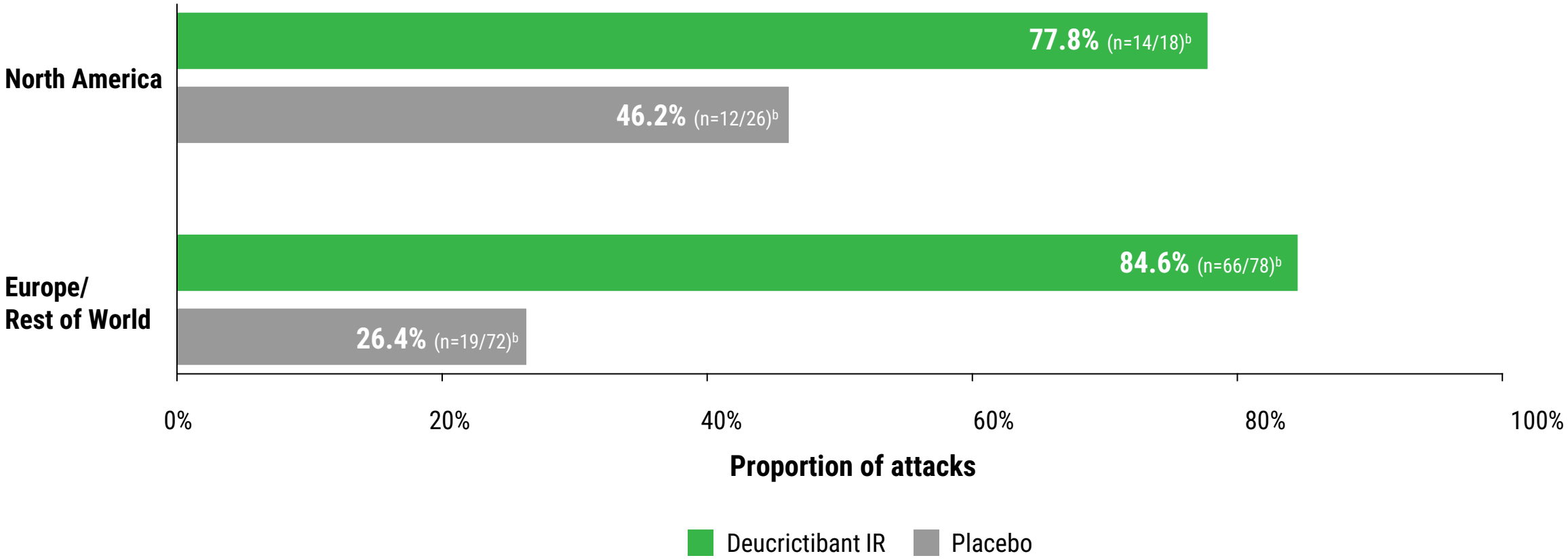
Higher proportion of attacks shown to achieve onset of symptom relief at 4 hours[a] with deucrictibant compared with placebo in both subgroups



IR, immediate-release; PGI-C, Patient Global Impression of Change. [a]Onset of symptom relief was considered achieved at 4 hours if for an attack, the last or the second-to-last available value of PGI-C prior to 4 hours post-treatment achieved "a little better" or higher response ("better" or "much better") and was sustained for 2 consecutive timepoints. Attacks with no PGI-C recorded within 4 hours post-treatment were excluded from the analysis, unless there was an intercurrent event for that attack, in which case the attack was considered as not achieving PGI-C "a little better" at 4 hours. [b]Number on participants with PGI-C data within 4 hours post-treatment.

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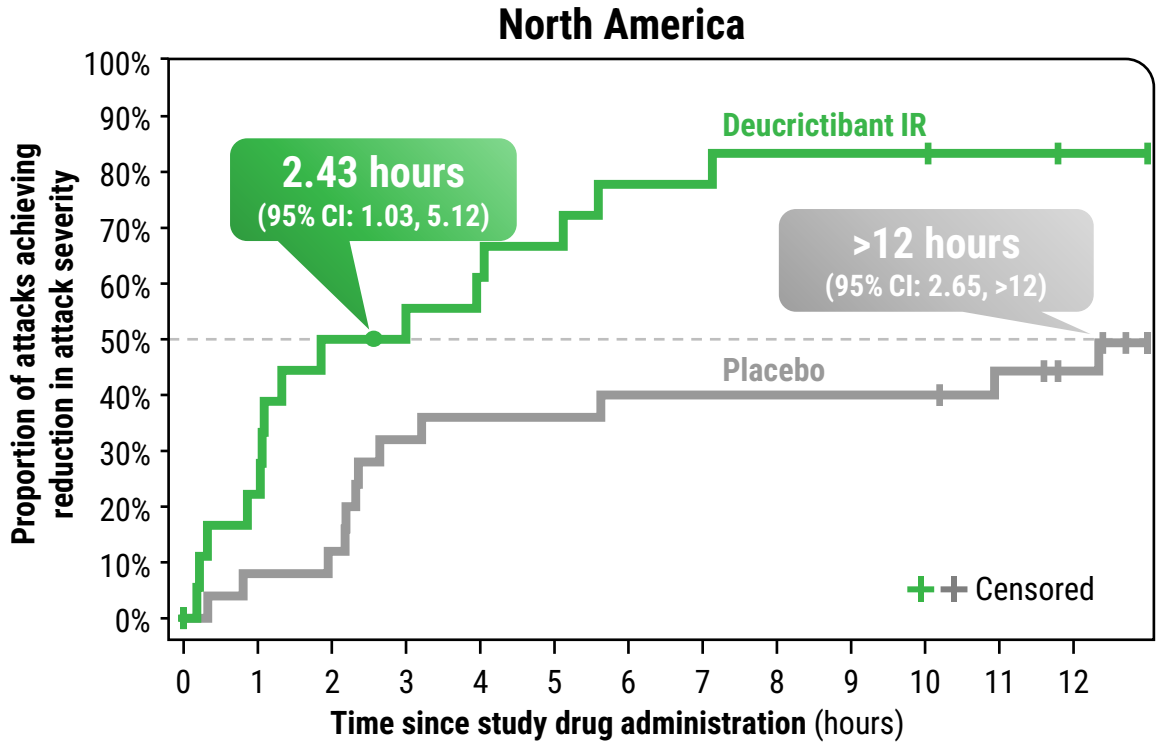
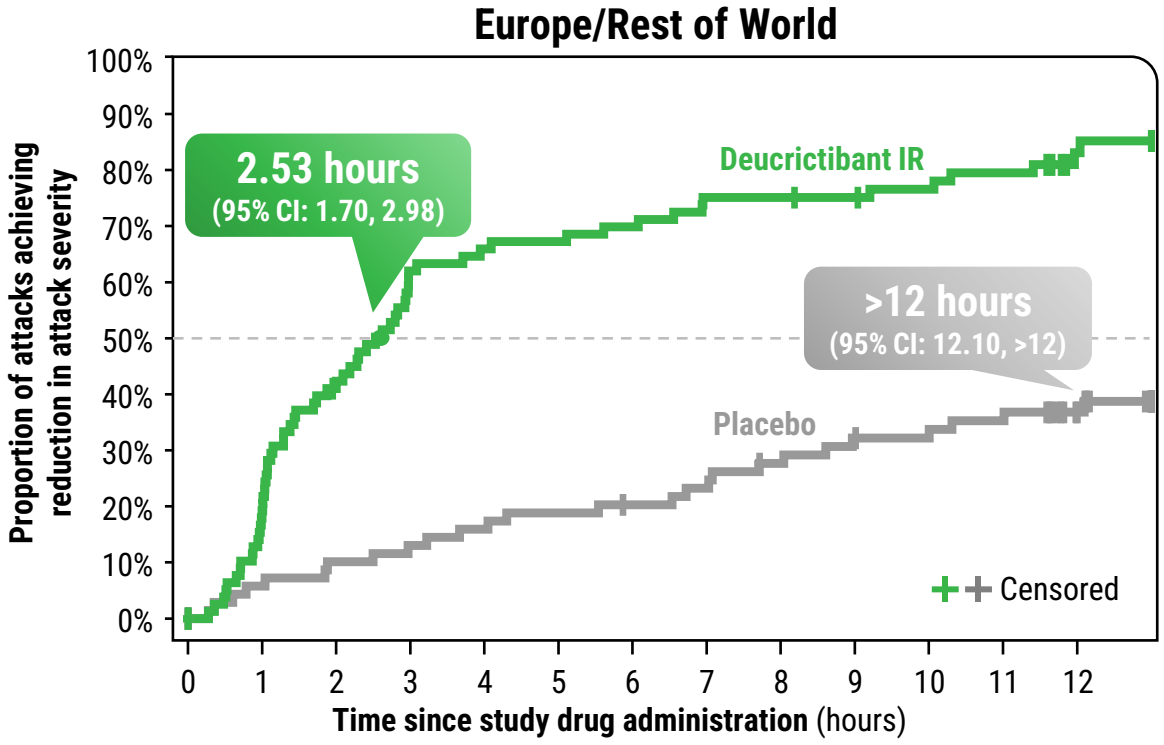
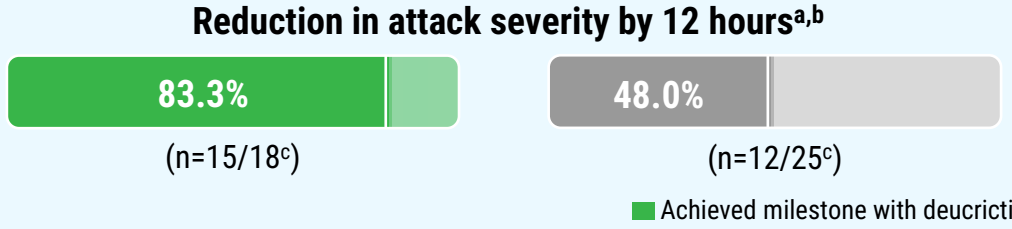
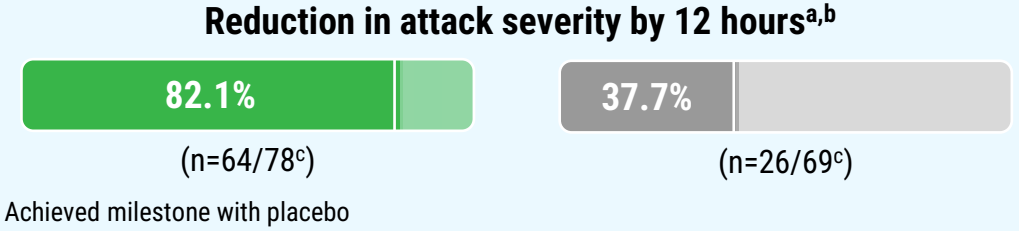
Deucrictibant-treated attacks shown to achieve reduction in attack severity faster than placebo-treated attacks in both subgroups[a,b]





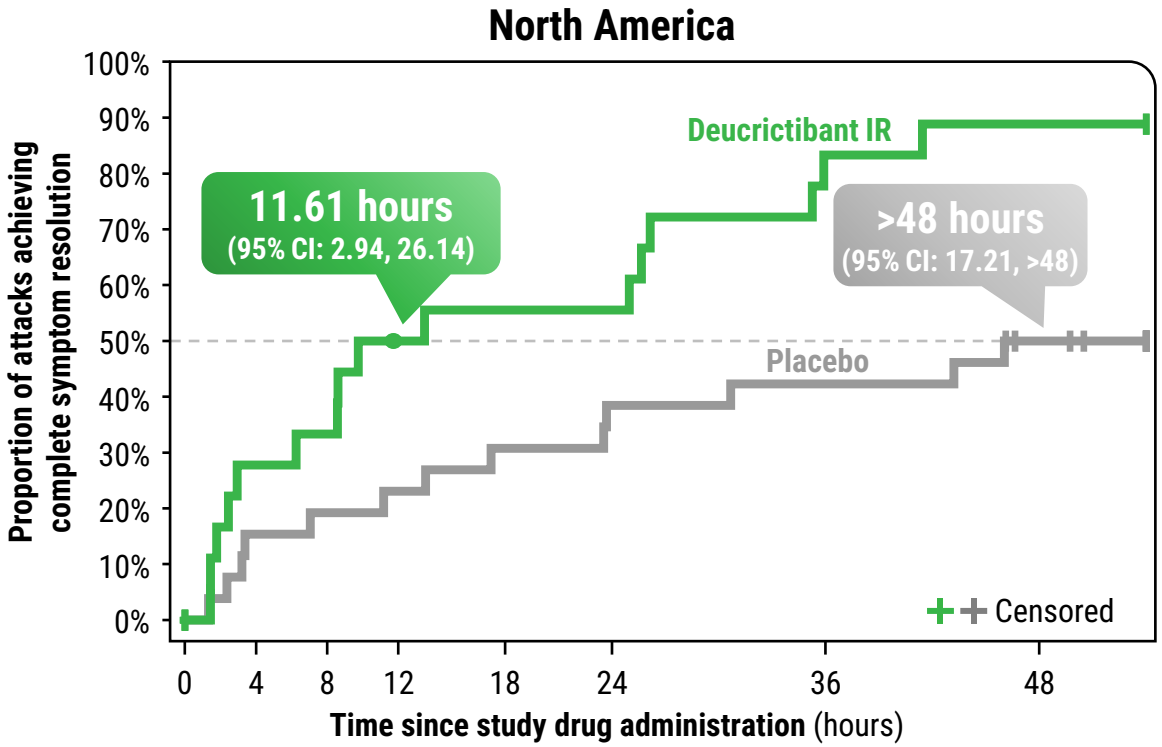


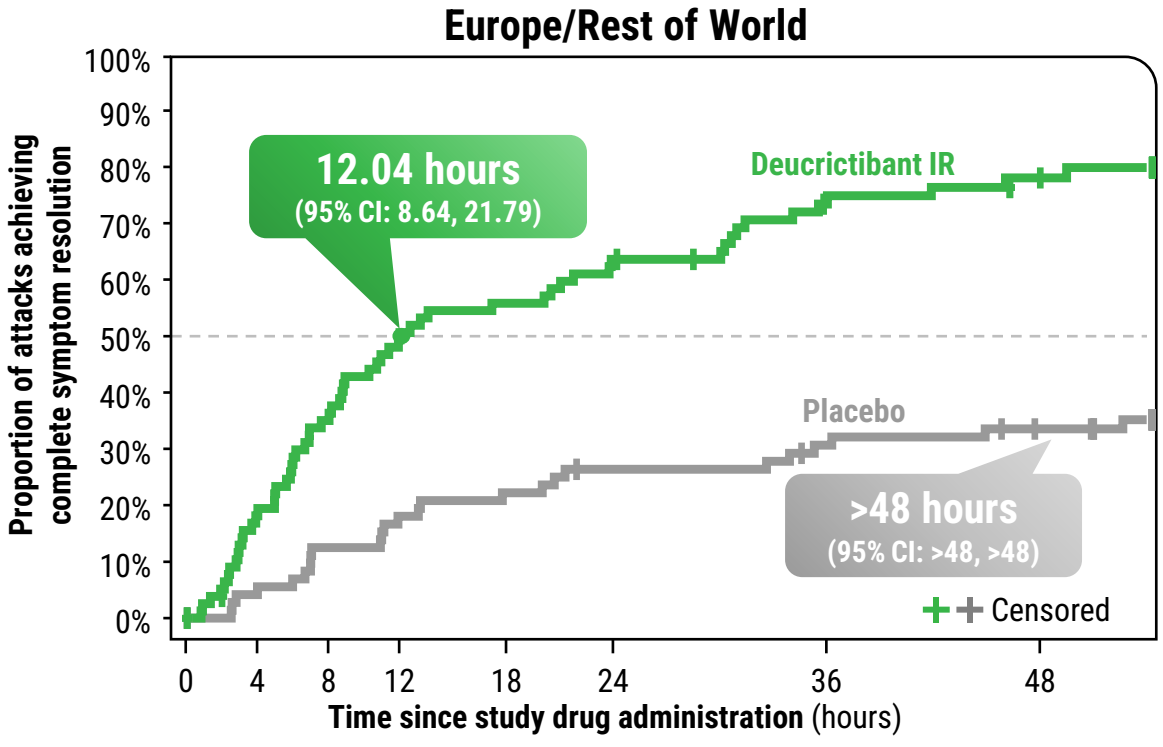


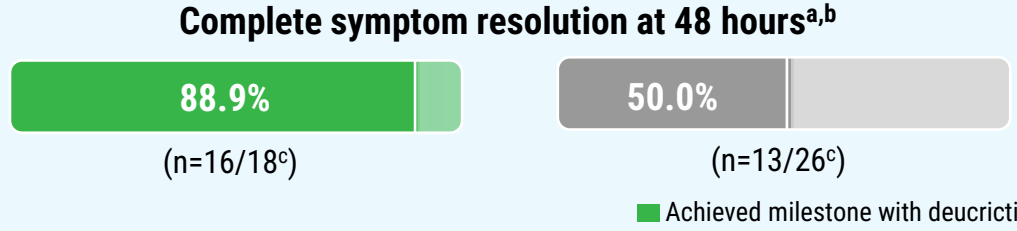
CI, confidence interval; IR, immediate-release; PGI-S, Patient Global Impression of Severity. [a]If the event of interest was not achieved within the pre-specified timeframe, the attack was right censored at the last observation before the upper end of the data entry window. For attacks with rescue medication use, they were treated as right censored at the upper end of the data entry window. [b]A ≥1-level reduction in PGI-S score from pre-treatment for 2 consecutive timepoints within 12 hours post-treatment. [c]Number of participants with post-treatment data within specified timeframe.

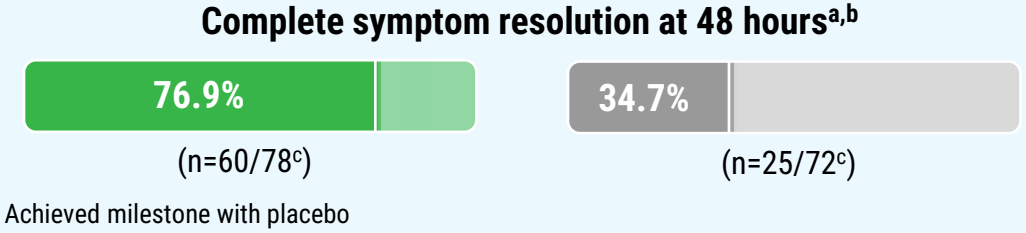
This presentation includes data for an investigational product not yet approved by regulatory authorities.

Deucrictibant-treated attacks shown to achieve complete symptom resolution faster than placebo-treated attacks in both subgroups[a,b]









CI, confidence interval; IR, immediate-release; PGI-S, Patient Global Impression of Severity. [a]If the event of interest was not achieved within the pre-specified timeframe, the attack was right censored at the last observation before the upper end of the data entry window. For attacks with rescue medication use, they were treated as right censored at the upper end of the data entry window. [b]PGI-S rating of "none" within 48 hours post-treatment. [c]Number of participants with post-treatment data within specified timeframe.

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Regional subgroup results were consistent with the overall RAPIDe-3 population

Outcome	North America[a]		Europe/Rest of World[a]		Overall[b]	
	Deucrictibant IR (n=18)	Placebo (n=26)	Deucrictibant IR (n=78)	Placebo (n=72)	Deucrictibant IR (n=83)	Placebo (n=87)
Time to onset of symptom relief, h	**1.20**	**6.55**	**1.28**	**>12**	**1.28**	**>12**
Proportion of attacks achieving onset of symptom relief by 12 hours, %	94.4	57.7	88.5	48.6	90.4	48.3
Proportion of attacks achieving onset of symptom relief at 4 hours, %	**77.8**	**46.2**	**84.6**	**26.4**	**83.1**	**27.6**
Time to reduction in attack severity, h	**2.43**	**>12**	**2.53**	**>12**	**2.41**	**>12**
Proportion of attacks achieving reduction in attack severity by 12 hours, %	83.3	48.0[c]	82.1	37.7[d]	85.5	38.1[e]
Time to complete symptom resolution, h	**11.61**	**>48**	**12.04**	**>48**	**11.95**	**>48**
Proportion of attacks achieving complete symptom resolution at 48 hours, %	88.9	50.0	76.9	34.7	81.9	36.8

IR, immediate-release. [a]All participants with treated attacks: deucrictibant IR, n = 101; placebo, n = 100. [b]Primary efficacy analysis set: deucrictibant IR, n = 88; placebo, n = 88.[c]n total = 25; [d]n total = 69; [e]n total = 84.

Deucrictibant was generally well tolerated, with no serious adverse events, no severe TEAEs, and no discontinuations due to TEAEs[a,b]

- The only event reported more than once within 3 days post-treatment was fatigue: a single event was reported by 2 participants, one of which was deemed unrelated to treatment by the investigator.
- No adverse events occurring within 3 days post-treatment were assessed as severe or serious, led to treatment discontinuation, or were associated with changes in clinical laboratory, vital signs, or electrocardiogram parameters.

Adverse events occurring within 3 days post-treatment	Non-attack: deucrictibant IR[c]				Treated attacks: deucrictibant IR				Treated attacks: placebo			
	NA (N=3)		EU/RoW (N=7)		NA (N=21)		EU/RoW (N=79)		NA (N=26)		EU/ROW (N=75)	
	n (%)[d]	no. of events	n (%)[d]	no. of events	n (%)[e]	no. of events	n (%)[e]	no. of events	n (%)[e]	no. of events	n (%)[e]	no. of events
Any TEAE	0	0	0	0	6 (28.6)	7	9 (11.4)	10	1 (3.8)	1	1 (1.3)	2
Treatment-related TEAEs[f]	0	0	0	0	1 (4.8)	1	4 (5.1)	5	0	0	1 (1.3)	1
Any severe TEAE[g]	0	0	0	0	0	0	0	0	0	0	0	0
Serious TEAEs	0	0	0	0	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	0	0	0	0

EU/RoW, Europe/Rest of World; IR, immediate-release; NA, North America; TEAE, treatment-emergent adverse event. N refers to the total number of participants who received ≥1 dose of study drug. Percentage is calculated based on the N in the header; percentage = 100 x n/N where N is the number of participants. [a]Data based on safety analysis set. [b]TEAE defined as an AE from the first study drug administration through the end of study visit. [c]Adolescent participants only. [d]Defined as the number of participants with an adverse event that began within 3 days post-treatment of non-attack period and before the next administration of study drug. [e]Defined as the number of participants with an adverse event that started within 3 days post-treatment of attack. [f]One related TEAE of headache in deucrictibant-treated participants in the North America subgroup, and one related TEAE each of dyspepsia, fatigue, lethargy, brain fog, and somnolence in deucrictibant-treated participants, and 1 event of pruritus in placebo-treated participants in the Europe/Rest of World subgroup. [g]All reported TEAEs were graded 1 (mild) or 2 (moderate) and there were no reported TEAEs graded 4 (life-threatening) or 5 (fatal).

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Conclusions

- Results from the pivotal RAPIDe-3 trial for the treatment of attacks in HAE, including HAE-nC1INH, provide further evidence on the rapid and sustained efficacy, safety, and tolerability of the orally administered B2R antagonist deucrictibant IR capsule.
- In this subgroup analysis, orally administered deucrictibant IR capsule provided faster onset of symptom relief, reduction in attack severity, and complete resolution in both the NA and EU/RoW subgroups compared with placebo.
  - Data were consistent across geographical locations and with the overall study population.

NA	EU/RoW
1.20 hours	1.28 hours

Median time to onset of symptom relief (primary endpoint)

NA	EU/RoW
2.43 hours	2.53 hours

Median time to reduction in attack severity

NA	EU/RoW
11.61 hours	12.04 hours

Median time to complete symptom resolution

Deucrictibant IR was generally well tolerated with no severe or serious treatment-related TEAEs

The Authors and the Sponsor would like to thank all the people with HAE as well as all study Sites' staff who participated in the RAPIDe-3 trial.

B2R, bradykinin B2 receptor; EU/RoW, Europe/Rest of World; HAE, hereditary angioedema; HAE-nC1INH, Hereditary Angioedema with Normal C1 Inhibitor; IR, immediate-release; NA, North America; TEAE, treatment-emergent adverse event.