Efficacy and Safety of On-Demand Treatment of Hereditary Angioedema Attacks With Oral Deucrictibant Immediate-Release Capsule: Phase 3 RAPIDe-3 Trial Results

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

Conflicts of interest disclosure

P.H.L.: Astria, BioCryst, CSL Behring, KalVista, Novartis, Pharvaris, Takeda; **M.A.R.:** ADARx, Astria, BioCryst, BioMarin, Celldex, CSL Behring, Cycle Pharma, Grifols, Intellia, Ionis, KalVista, Novartis, Pharming, Pharvaris, Sanofi-Regeneron, Takeda; **A.A.:** Astria, BioCryst, CSL Behring, Intellia, Ionis, KalVista, Octapharma, 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.:** Astria, AstraZeneca, Berlin-Chemie/Menarini Group, CSL Behring, Ewopharma, Ionis, KalVista, Organon, Novartis, Pharming Group, Pharvaris, Sobi, Stallergenes Greer, Shire/Takeda, 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, Grifols, GSK, Intellia, Ionis, KalVista, Magellan, Optinose, Pharming, Pharvaris, Regeneron, Sanofi, Takeda, Teva; **D.F.S.:** BioCryst, CSL Behring, Intellia, Ionis, KalVista, Pharming, 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, Pharvaris, Pharming, 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, Novartis, Otsuka, Pharming, Pharvaris, Pierre Fabre Pharma, Stallergenes, Swedish Orphan Biovitrum, Takeda; **R.T.:** ADMA, Astria, BioCryst, CSL Behring, Intellia, Ionis, KalVista, Pharvaris, Takeda. Speaker presentations: ARS, AstraZeneca, BioCryst, CSL Behring, Grifols, GSK, Ionis, KalVista, Lilly, Novartis, Pharming, 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, Ionis, KalVista, Pharming, Pharvaris, Takeda; **E.A-P.:** Astria, BioCryst, BioMarin, CSL Behring, Intellia, KalVista, Otsuka, Pharming, Pharvaris, Takeda; **T.J.C.:** ADARx, ARGO, Astria, BioCryst, BioMarin, CSL Behring, GlaxoSmithKline, Grifols, Intellia, Ionis, KalVista, 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, World Allergy Organization, Associação Brasileira de Alergia e Imunologia; **S.K.:** None to report; **T.K.:** ADARz, Astria, BioCryst, CSL Behring, KalVista, Otsuka, Pharvaris, Sanofi/Regeneron, Takeda; **I.M-S.:** BioCryst, CSL Behring, KalVista, Pharming, Pharvaris, Octapharma, 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, GSK, 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.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, and is a 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.M.:** Astria, Argo, BioCryst, CSL Behring, Intellia, KalVista, Octapharma, Otsuka, Pharvaris, Takeda; **M.E.M.:** AstraZeneca, Astria, BioCryst, Blueprint, Celldex, Cogent, CSL Behring, GSK, Ionis, Intellia, KalVista, Merck, Novartis, Pharming, Pharvaris, Regeneron, Takeda, Teva; **S.M.:** None to report; **S.O.:** None to report; **C.J.R.:** Amgen, GSK, Pfizer, Pharvaris, Sanofi, Takeda; **J.L., L.Z., J.M., U.K., G.G., M.Y., P.L.:** employees of Pharvaris and holds stocks in Pharvaris; **R.C.:** employee of RC Consultancy and consultant to Pharvaris, holds stocks in Pharvaris; **A.L.:** employee of GrayMatters Consulting and consultant to Pharvaris, holds stocks/stock options in Pharvaris; advisor to Kosa Pharma; **D.M.C.:** ADARx, Astria, BioCryst, CSL Behring, Gentili Neopharma, Ionis, Intellia, KalVista, Otsuka, Pharvaris, Takeda, and is a Regional Medical Advisory Panel Member for HAEi Central Eastern Europe and the Benelux.

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

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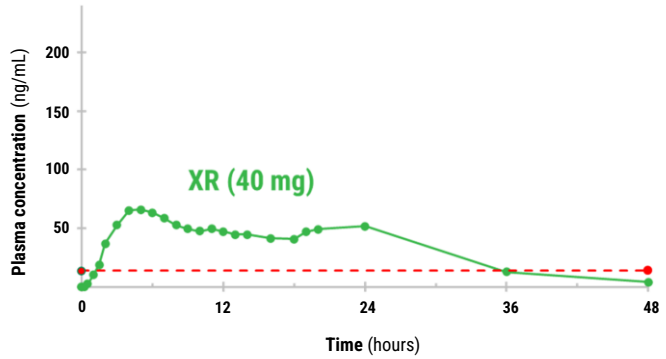
Deucrictibant is an investigational, oral, bradykinin B2 receptor antagonist for the prophylactic and on-demand treatment of bradykinin-mediated attacks

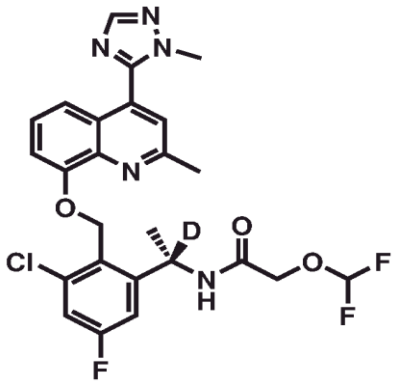
- Excess bradykinin is the main mediator of the clinical manifestations of bradykinin-mediated angioedema attacks, including HAE.[1]

DEUCRICTIBANT extended-release (XR) tablet

sustained absorption[2]



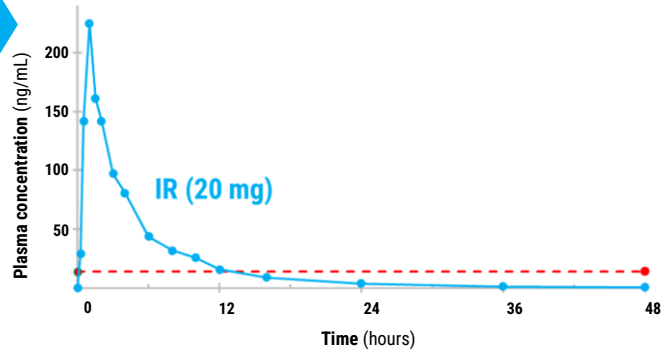
In studies, deucrictibant maintained sustained therapeutic exposure over 24 hours[2] from day 1, allowing for once-daily oral prevention of HAE attacks[3]



deucrictibant

DEUCRICTIBANT immediate-release (IR) capsule

rapid absorption[4]



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

HAE, hereditary angioedema; IR, immediate-release; XR, extended-release. **1.** Busse PJ, et al. *N Engl J Med*. 2020;382:1136-48. **2.** Zhang et al. Presented at C1INH Workshop; May 29-June 1, 2025. **3.** CHAPTER-3. ClinicalTrials.gov identifier: NCT06669754. https://clinicaltrials.gov/study/NCT06669754. Accessed April 2, 2026. **4.** Maurer M, et al. *Lancet Haematol*. 2026;13(4):e200-14. **5.** RAPIDe-3. ClinicalTrials.gov identifier: NCT06343779. https://www.clinicaltrials.gov/study/NCT06343779. Accessed April 2, 2026. .

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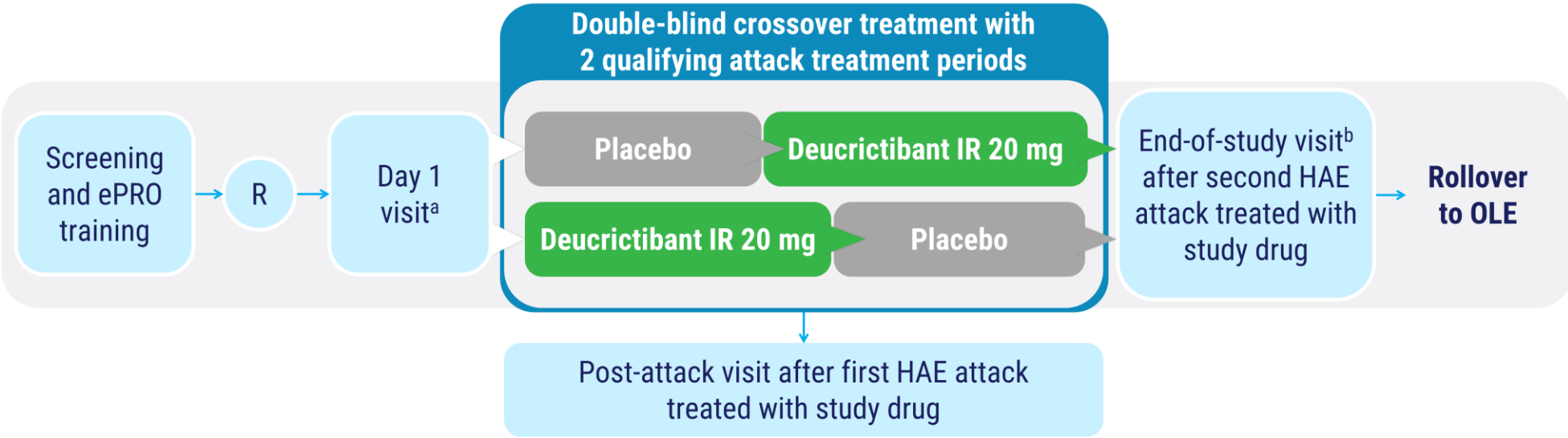
RAPIDe-3: a global, Phase 3, randomized, double-blind, placebo-controlled trial



Objective: to assess the efficacy, safety, and tolerability of oral deucrictibant IR capsule for on-demand treatment of attacks in adolescents and adults with HAE, including participants with HAE-nC1INH.
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.
Qualifying attacks: defined as either non-laryngeal or non-severe laryngeal attacks without breathing difficulties or stridor, and with at least one symptom item score of ≥20 on the AMRA assessment.
Analysis sets: primary efficacy analysis included all randomized participants who treated the two attacks with study drug (one per period) in the 2×2 crossover design. Safety analysis included all participants who received ≥1 dose of study drug.

AMRA, Angioedema syMptom Rating scAle; C1INH, C1 inhibitor; ePRO, electronic patient-reported outcome; HAE, hereditary angioedema; HAE-nC1INH, HAE with normal C1 inhibitor; IR, immediate-release; OLE, open-label extension; R, randomization. RAPIDe-3, ClinicalTrials.gov identifier: NCT06343779. https://www.clinicaltrials.gov/study/NCT06343779. Accessed April 2, 2026. [a]Adolescent participants received a non-attack dose for pharmacokinetic sampling at day 1 visit prior to randomization. [b]Data from end-of-study visit could be used to qualify the participant for an open-label extension study with deucrictibant.

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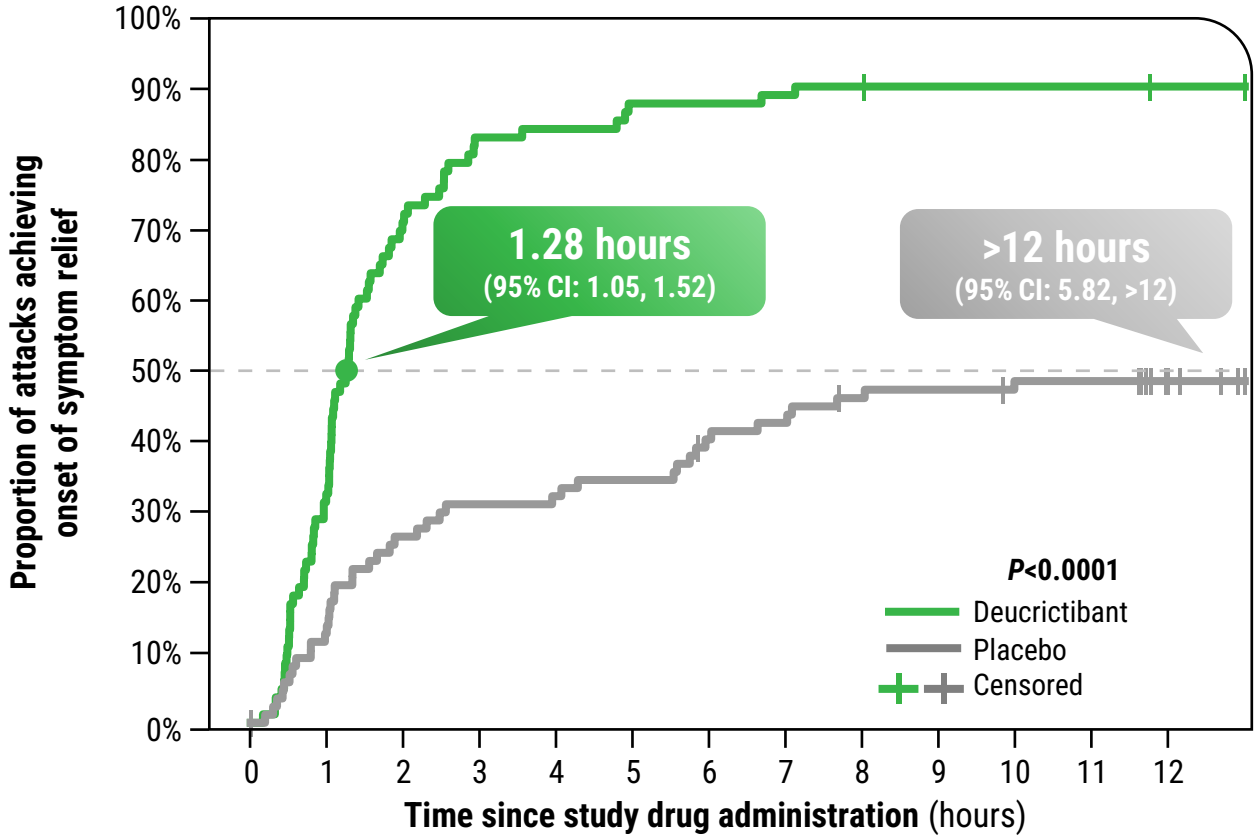
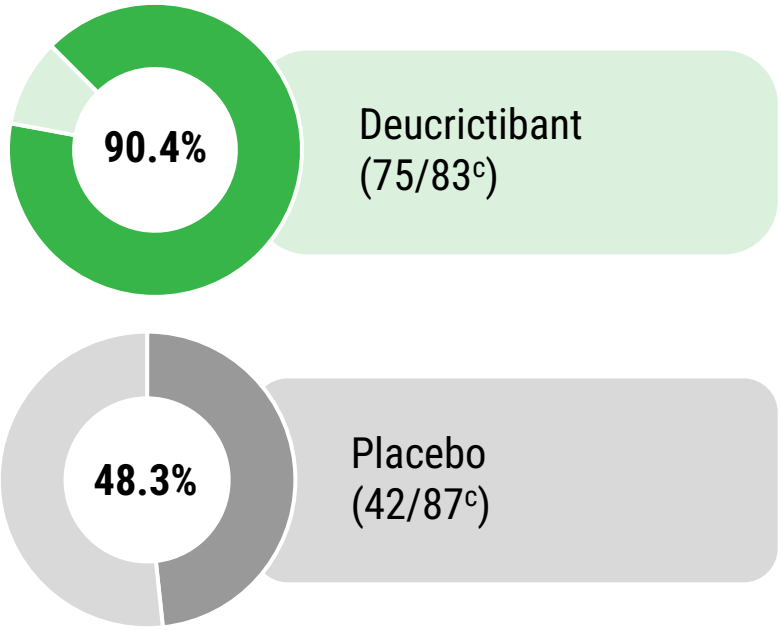
1.28 hours median time to onset of symptom relief with deucrictibant

PGI-C rating of at least “a little better” for 2 consecutive timepoints within 12 hours post treatment



Proportion of attacks achieving onset of symptom relief by 12 hours[a,b]



CI, confidence interval; 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 attacks with post-treatment data within specified timeframe.

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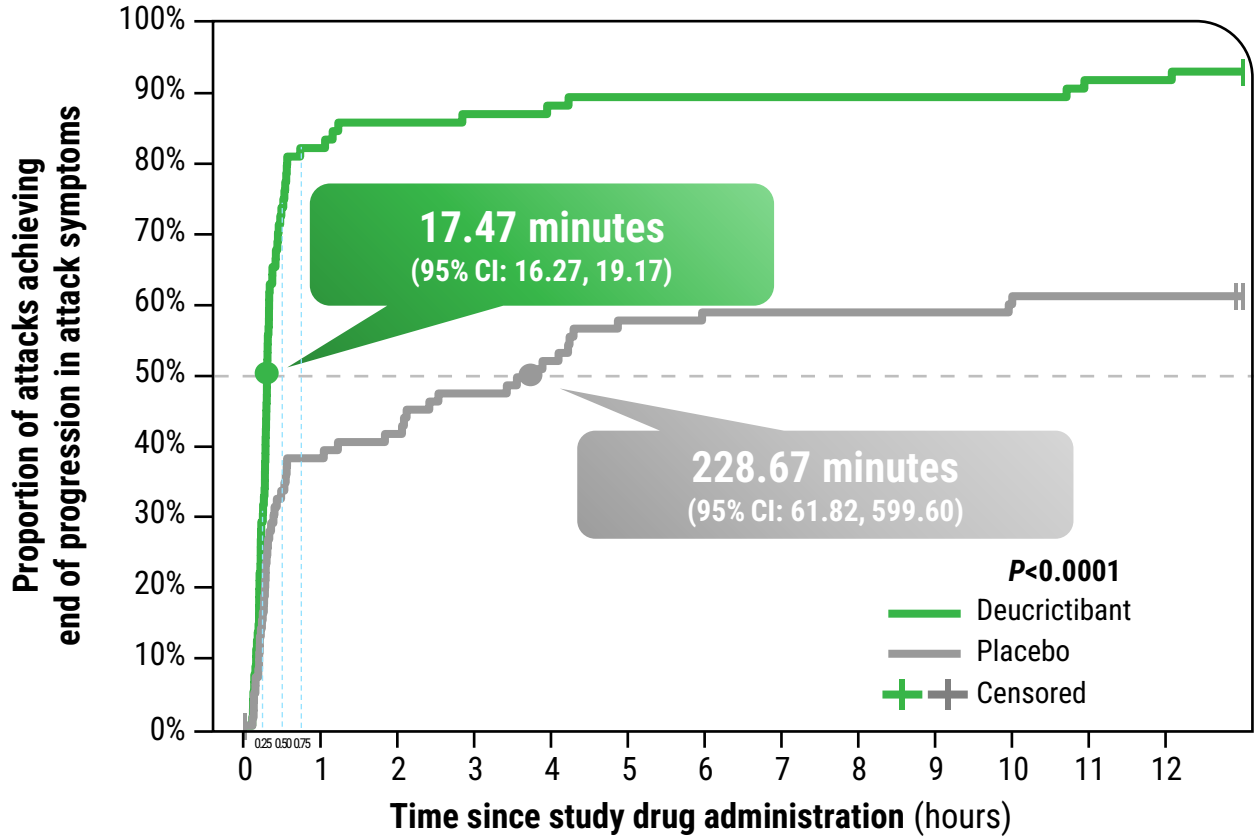
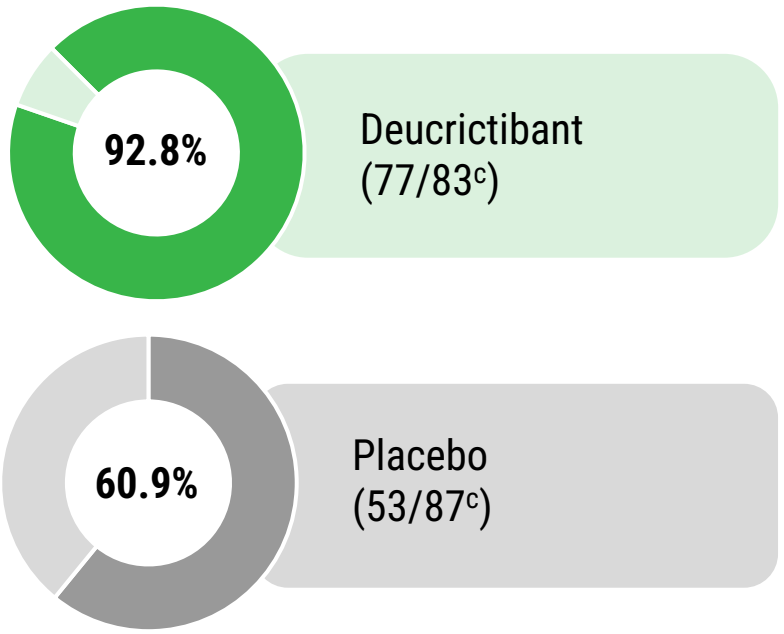
17.47 minutes median time to end of progression in attack symptoms with deucrictibant

Earliest post-treatment timepoint after which all subsequent PGI-C ratings were stable or improved



Proportion of attacks achieving end of progression in attack symptoms by 12 hours[a,b]



CI, confidence interval; 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]Earliest post-treatment timepoint after which all subsequent PGI-C ratings were stable or improved. [c]Number of attacks with post-treatment data within the specified timeframe.

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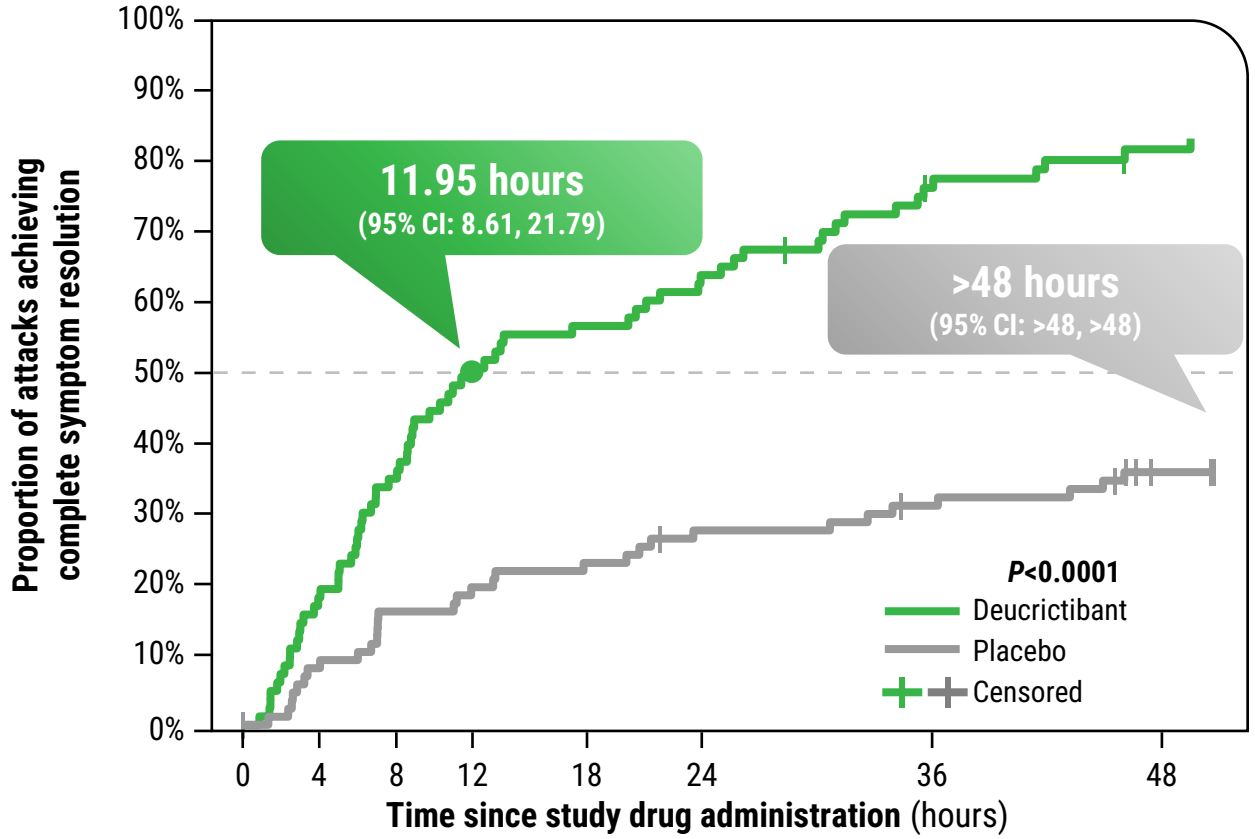
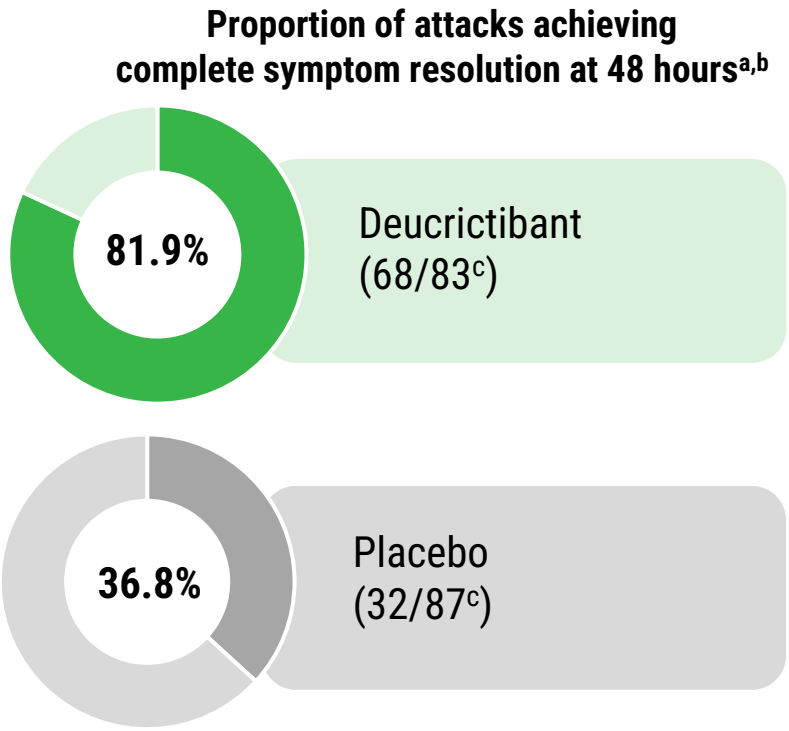
11.95 hours median time to complete symptom resolution with deucrictibant

PGI-S rating of “none” within 48 hours post-treatment





CI, confidence interval; 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 attacks with post-treatment data within specified timeframe.

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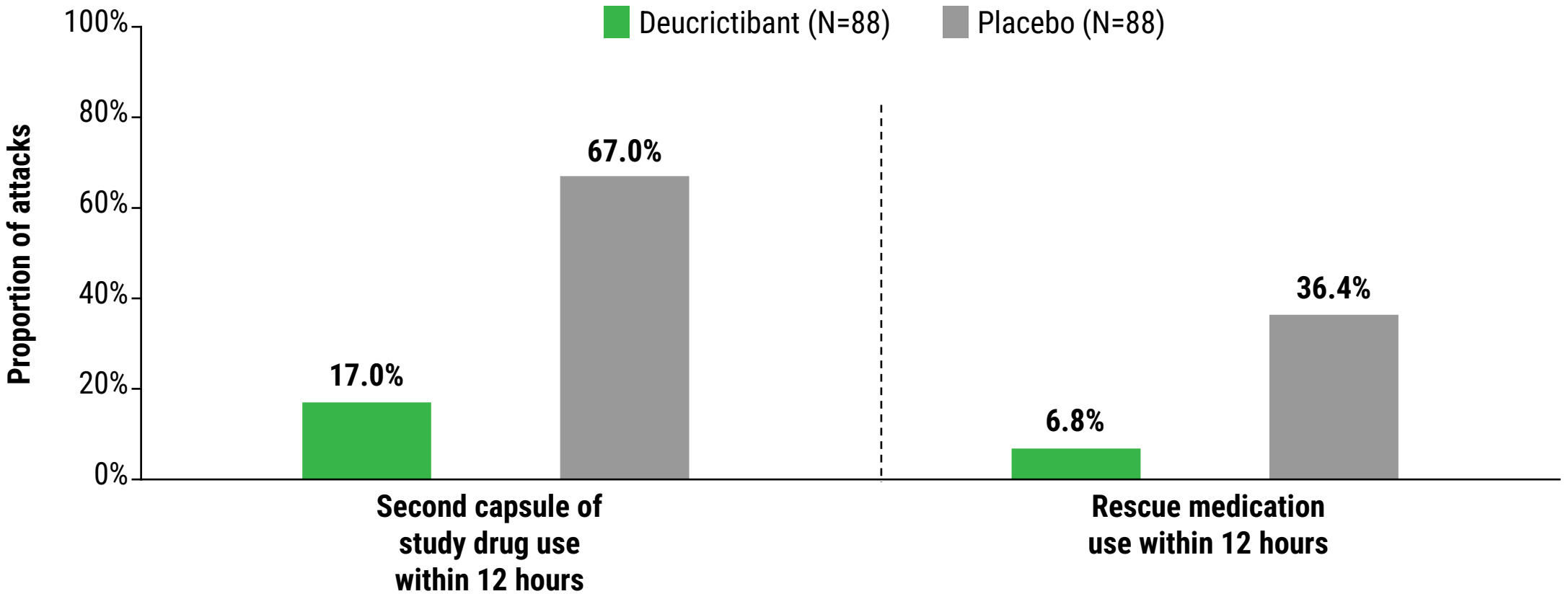
Lower proportion of attacks treated with a second capsule or rescue medication with deucrictibant compared with placebo



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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 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 (N=10)[c]		Treated attack deucrictibant (N=100)		Treated attack placebo (N=101)	
	n (%)[d]	no. of events	n (%)[e]	no. of events	n (%)[e]	no. of events
Any TEAE	0	0	15 (15.0)	17	2 (2.0)	3
Treatment-related TEAEs[f]	0	0	5 (5.0)	6	1 (1.0)	1
Any severe TEAE[g]	0	0	0	0	0	0
Serious TEAEs	0	0	0	0	0	0
TEAEs leading to study drug discontinuation, study withdrawal, or death	0	0	0	0	0	0

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 attacks with an adverse event that started within 3 days post-treatment of attack. [f]One event each of dyspepsia, fatigue, lethargy, brain fog, headache, and somnolence in deucrictibant-treated participants, and 1 event of pruritus in placebo-treated participants. [g]All reported TEAEs were graded 1 (mild) or 2 (moderate) and there were no reported TEAEs grade 4 (life-threatening), or 5 (fatal).

Conclusions

- Results from the pivotal RAPIDe-3 trial for treatment of attacks in multiple types of hereditary angioedema provide further evidence on the rapid and sustained efficacy, safety, and tolerability of the orally administered bradykinin B2 receptor antagonist deucrictibant IR capsule.
- This trial met the primary and all 11 secondary efficacy endpoints.[a]

1.28 hours

Median time to onset of symptom relief (primary endpoint)

17.47 minutes

Median time to end of progression of attack symptoms

11.95 hours

Median time to complete symptom resolution

Deucrictibant 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 site staff who have been participating in the RAPIDe-3 trial.

HAE, hereditary angioedema; IR, immediate-release; TEAE, treatment-emergent adverse event. [a]The primary and 3 of 11 hierarchical order-ranked secondary endpoints are included in this presentation.