

End of Progression of Hereditary Angioedema Attack Manifestations With Oral Deucrictribant Immediate-Release Capsule: Results From the RAPIDe-3 Phase 3 Trial

Raffi Tachdjian¹, Marc A. Riedl², Philip H. Li³, Adil Adatia⁴, Mauro Cancian⁵, Marcin Stobiecki⁶, Anna Valerieva⁷, Anete S. Grumach⁸, William R. Lumry⁹, Daniel F. Soteres¹⁰, Nicholas Brodski¹¹, Natalia L. Fili¹², Roman Hak¹³, Hye-Ryun Kang^{14,15,16,17}, Gul Karakaya¹⁸, Birger Kränke¹⁹, H. Henry Li²⁰, Jonny Peter^{21,22}, Andreas Recke²³, Paola Triggianese²⁴, Andrea Zanichelli^{25,26}, John Anderson²⁷, Emel Aygören-Pürsün²⁸, Timothy J. Craig^{29,30}, Henriette Farkas³¹, Francesco Giardino³², Pedro Giavina-Bianchi³³, Sujeong Kim³⁴, Tamar Kinacian³⁵, Immaculada Martinez-Saguer³⁶, Francesca Perego³⁷, Karl V. Sitz³⁸, Maria Staevska⁷, H. James Wedner³⁹, Rafael H. Zaragoza-Urdaz⁴⁰, Ricardo D. Zwiener⁴¹, Asli Gelincik⁴², Francesco Arcoleo⁴³, Rand Arnaout⁴⁴, Alan P. Baptist⁴⁵, Régis Albuquerque Campos⁴⁶, Anthony D. Dorr⁴⁷, Mariana Paes Leme Ferriani⁴⁸, Atsushi Fukunaga⁴⁹, Delphine Gobert⁵⁰, Padmalal Gurugama⁵¹, Michihiro Hide⁵², David I. Hong⁵³, Eisuke Inage⁵⁴, Joshua S. Jacobs⁵⁵, Constance H. Katelaris⁵⁶, Lucy Leeman⁵⁷, Ramón Lleónart⁵⁸, Markus Mager^{59,60}, Michael E. Manning⁶¹, Satoshi Mano⁶², Seido Ooka⁶³, Cristina J. Ramos⁶⁴, Jinzhong Liu⁶⁵, Li Zhu⁶⁵, Joan Mendivil⁶⁶, Umar Katbeh⁶⁶, Giorgio Giannattasio⁶⁶, Rafael Crabbé⁶⁷, Ming Yu⁶⁵, Anne Lesage⁶⁸, Peng Lu⁶⁵, Danny M. Cohn⁶⁹

¹University of California at Los Angeles, Los Angeles, CA, USA; ²University of California San Diego, La Jolla, CA, USA; ³Queen Mary Hospital, University of Hong Kong, Hong Kong; ⁴University of Alberta, Edmonton, AB, Canada; ⁵Azienda Ospedale Università di Padova, Padua, Italy; ⁶Jagiellonian University Medical College, Kraków, Poland; ⁷Medical University of Sofia, Sofia, Bulgaria; ⁸Centro Universitario FMAB, São Paulo, Brazil; ⁹AARA Research Center, Dallas, TX, USA; ¹⁰Colorado Allergy and Asthma Society, University CO Health Sciences Center, Asthma & Allergy Associates and Research Center, P.C., Colorado Springs, CO, USA; ¹¹Children's Hospital, Skåne University Hospital, Lund, Sweden; ¹²Hospital Público Materno Infantil, Salta, Argentina; ¹³St. Anne's University Hospital in Brno and Faculty of Medicine, Masaryk University, Brno, Czech Republic; ¹⁴Seoul National University College of Medicine, Seoul, South Korea; ¹⁵Seoul National University College of Medicine, Seoul, South Korea; ¹⁶Institute of Allergy and Clinical Immunology, Seoul National University Medical Research Center, Seoul, South Korea; ¹⁷Korean Drug Allergy Research Consortium, Seoul, South Korea; ¹⁸Hacettepe University School of Medicine, Ankara, Turkey; ¹⁹Medizinische Universität Graz, Graz, Austria; ²⁰Institute for Asthma and Allergy, Chevy Chase, MD, USA; ²¹Groote Schuur Hospital, Division of Allergy and Clinical Immunology, Cape Town, South Africa; ²²University of Cape Town Lung Institute, Cape Town, South Africa; ²³University of Lübeck, Lübeck, Germany; ²⁴University of Rome Tor Vergata, Rome, Italy; ²⁵Università degli Studi di Milano; ²⁶R.C.C.S. Policlinico San Donato, Centro Angioedema, ID Medicina, Milan, Italy; ²⁷AlleVie Health, Birmingham, AL, USA; ²⁸Oeche University Frankfurt, Department of Pediatrics, Frankfurt am Main, Germany; ²⁹Allergy and Immunology, Departments of Medicine, Pediatrics, and Biomedical Sciences, Director ACARE International Hereditary Angioedema Resource Center, Penn State University, Hershey, PA, USA; ³⁰Vinmec-VinUni Institute of Immunology, Vinmec Hospital, Times City and Vin University, Hanoi, Vietnam; ³¹Hungarian Angioedema Center of Reference and Excellence, Semmelweis University, Budapest, Hungary; ³²A.O.U. Policlinico "G. Rodolico-San Marco", Catania, Italy; ³³Clinical Immunology and Allergy Division, Faculdade de Medicina, Universidade de São Paulo, São Paulo, Brazil; ³⁴Kyungpook National University Hospital, Daegu, South Korea; ³⁵Medical University of Vienna, Vienna, Austria; ³⁶HZRM Hämophilie Zentrum Rhein Main GmbH Gartenstraße 134, Frankfurt, Germany; ³⁷Istituto Clinico Scientifico Maugeri IRCCS, Milan, Italy; ³⁸Acuro Research, Inc., Little Rock, AR, USA; ³⁹Washington University School of Medicine, St. Louis, MO, USA; ⁴⁰Allergimuno Rttu LLC, San Juan, Puerto Rico; ⁴¹Hospital Universitario Austral, Buenos Aires, Argentina; ⁴²Istanbul Faculty of Medicine, Istanbul University, Istanbul, Turkey; ⁴³AOR Villa Sofia Cervo, Palermo, Italy; ⁴⁴King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia; ⁴⁵Henry Ford Health System, Detroit, MI, USA; ⁴⁶Ensino e Terapia de Inovação Clínica AMO, Salvador, Bahia, Brazil; ⁴⁷Barts Health NHS Trust, London, UK; ⁴⁸Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, SP, Brazil; ⁴⁹Osaka Medical and Pharmaceutical University, Takatsuki, Osaka, Japan; ⁵⁰Sorbonne Université, Médecine Interne, AP-HP, Centre de référence des angioedèmes à kinines, Hôpital Saint-Antoine, Paris, France; ⁵¹Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK; ⁵²Hiroshima University and Hiroshima City Hospital Organization, Hiroshima, Japan; ⁵³Bingham and Women's Hospital, Boston, MA, USA; ⁵⁴Junendo University Faculty of Medicine, Tokyo, Japan; ⁵⁵Allergy and Asthma Clinical Research, Walnut Creek, CA, USA; ⁵⁶Campbelltown Hospital and Western Sydney University, Sydney, NSW, Australia; ⁵⁷University Hospitals Plymouth NHS Trust, Plymouth, UK; ⁵⁸Bethune University Hospital, L'Hospitalet de Llobregat, Barcelona, Spain; ⁵⁹Institute of Allergy, Charité-Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; ⁶⁰Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Immunology and Allergy, Berlin, Germany; ⁶¹Allergy, Asthma and Immunology Associates, Ltd., Scottsdale, AZ, USA; ⁶²Junendo University Hospital, Tokyo, Japan; ⁶³St. Marianna University School of Medicine Hospital, Kanagawa, Japan; ⁶⁴FDI Clinical Research, San Juan, Puerto Rico; ⁶⁵Pharvaris Inc., Lexington, MA, USA; ⁶⁶Pharvaris GmbH, Zug, Switzerland; ⁶⁷RC Consultancy, Bassins, Switzerland; ⁶⁸GrayMatters Consulting, Schilde, Belgium; ⁶⁹Amsterdam UMC, University of Amsterdam, Amsterdam Cardiovascular Sciences, Amsterdam, The Netherlands

Summary

The Phase 3 RAPIDe-3 trial for treatment of attacks in multiple types of hereditary angioedema (HAE) demonstrated that attacks treated with the bradykinin B2 receptor antagonist, deucrictribant immediate-release (IR) capsule, achieved end of progression (EoP) of attack manifestations faster than those treated with placebo.

EoP of HAE attack manifestations

was measured in the RAPIDe-3 trial for the first time as a pre-specified endpoint in an HAE on-demand trial



17.47 minutes

Median time to EoP of attack manifestations in participants taking deucrictribant IR

>90%

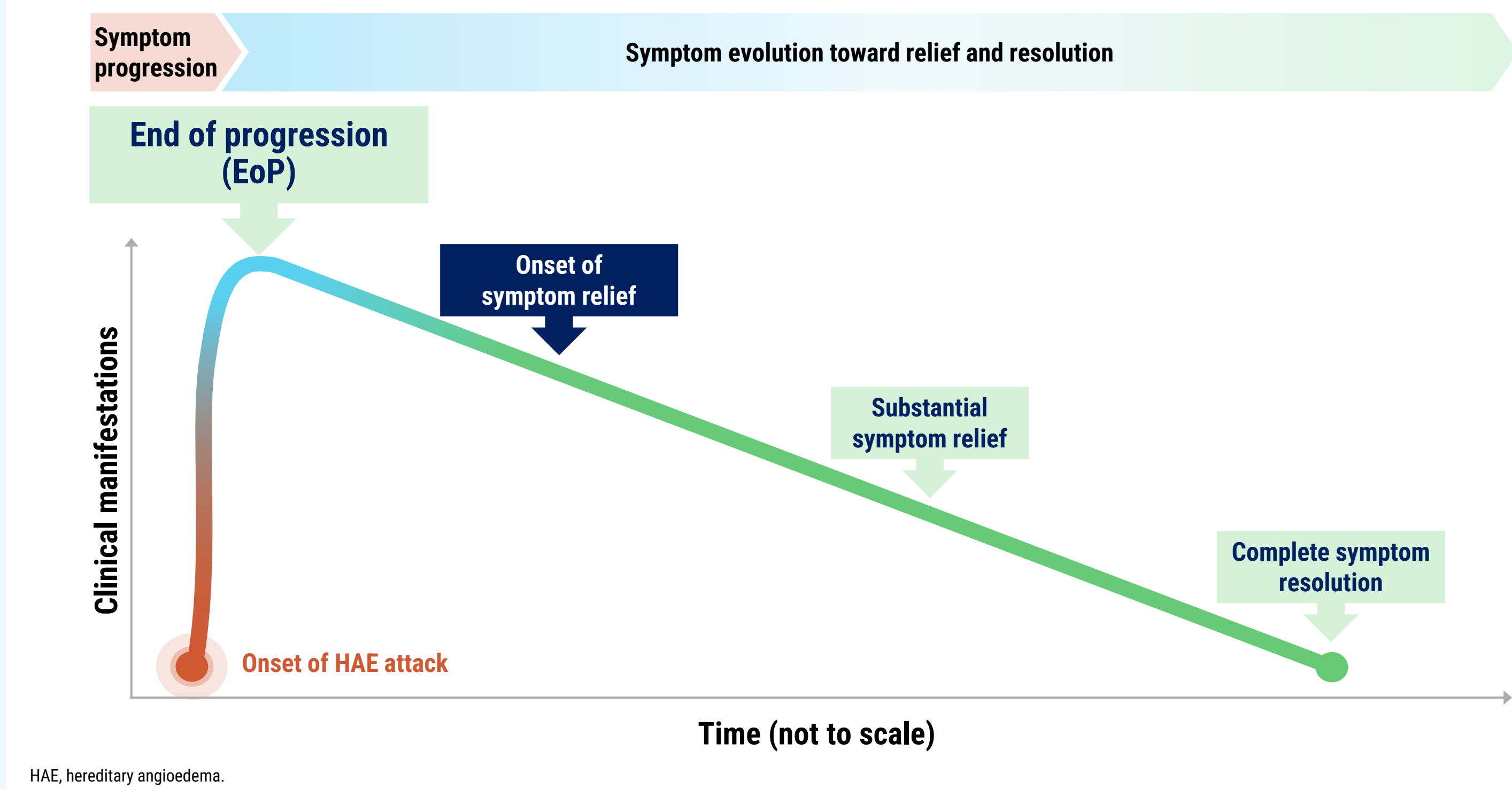
of participants taking deucrictribant IR achieved EoP of attack manifestations in 12 hours

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

Background

- Hereditary angioedema (HAE):** a condition characterized by excess bradykinin, which activates bradykinin B2 receptors causing increased fluid migration from the blood vessels to the surrounding tissues. HAE causes recurrent and unpredictable episodes of painful angioedema attacks affecting multiple locations in the body with varying degrees of severity.¹
- Unmet need:** an unmet need remains for additional orally administered treatments combining ease of administration, rapid and sustained effects, and a well-tolerated safety profile.^{2,4}
- End of progression (EoP):** defined as the earliest post-treatment timepoint after which attack manifestations stop worsening further, which marks the earliest evidence of treatment effects.²
 - It can serve as a clinically meaningful indicator of attacks starting to evolve to relief and resolution.²
 - Achieving EoP can also offer psychological reassurance by reducing the uncertainty associated with HAE attack escalation.
- Time to EoP as an outcome to measure treatment efficacy:** was recommended for inclusion by the Acute Treatment Outcomes in Hereditary Angioedema (AURORA) consensus project.
 - The AURORA project brought together patients, clinicians, researchers, industry representatives, and regulatory stakeholders to develop a set of core outcomes recommended for inclusion in clinical trials of on-demand treatments for HAE attacks.²
 - 95% of participants agreed that time to EoP should be included as one of the five core outcomes as it represented the earliest sign of treatment effects.²
- Oral deucrictribant:** a selective bradykinin B2 receptor antagonist under development for both prophylactic and on-demand treatment of bradykinin-mediated angioedema attacks.⁵⁻¹²

Figure 1. Schematic Representation of the Evolution of an HAE attack



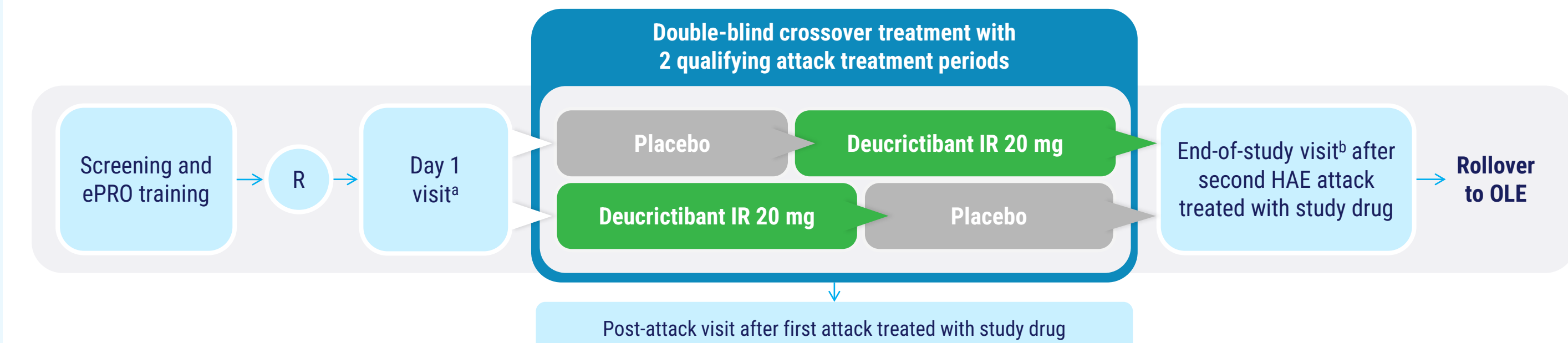
Objective

To evaluate the time to EoP of attack manifestations as a pre-specified outcome aimed to document initial or earliest clinical evidence of acute attack manifestations stopping to worsen and starting to evolve towards relief and resolution following on-demand treatment with deucrictribant IR versus placebo in adolescents and adults with HAE.

Methods

- RAPIDe-3 (NCT06343779)*:** a global, Phase 3, randomized, double-blind, placebo-controlled, crossover trial.
- Participants:** adolescents (aged ≥12 to <18 years) and adults (aged ≥18 to ≤75 years) with HAE-C1INH type 1 or type 2, or HAE with normal C1 inhibitor (HAE-nC1INH). Participants on long-term HAE prophylaxis were also enrolled.
- Study drugs:** participants self-administered deucrictribant 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 set:** primary efficacy analysis included all randomized participants who had two attacks treated with study drug.

Figure 2. RAPIDe-3 trial design⁷



ePRO, electronic patient-reported outcome; HAE, hereditary angioedema; IR, immediate-release; OLE, open-label extension; R, randomization. *Adolescent participants received a non-attack dose for pharmacokinetic sampling at Day 1 visit prior to randomization. *Data from end-of-study visit could be used to qualify the participant for an open-label extension study with deucrictribant.

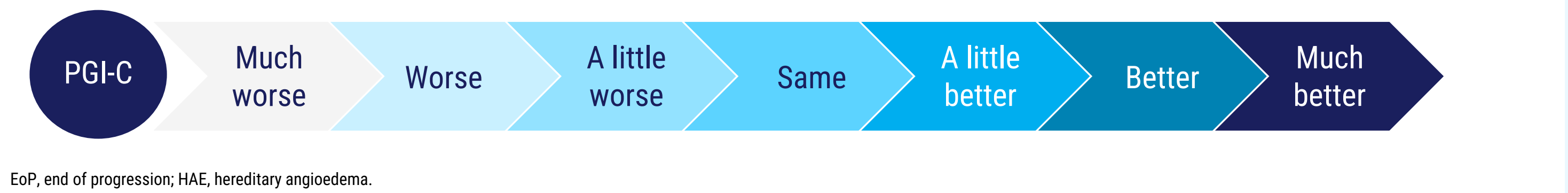
Table 1. Assessment of time to EoP of HAE attack manifestations

Parameter	Details
Time to EoP of HAE attack manifestations	The time to the earliest post-treatment timepoint after which all subsequent Patient Global Impression of Change (PGI-C) scale ratings were stable or improved within 12 hours
Instrument	PGI-C
Type of analysis	Pre-specified secondary endpoint (5th in the hierarchical testing order) ⁷
Window for endpoint assessment	Baseline to 12 (+1) hours

EoP, end of progression; HAE, hereditary angioedema.

Figure 3. Scale used to assess time to EoP of HAE attack manifestations

Patient Global Impression of Change (PGI-C)¹³: a tool that uses a seven-point Likert response scale to assess the change in HAE attack manifestations since starting study treatment compared with pre-treatment.



Results

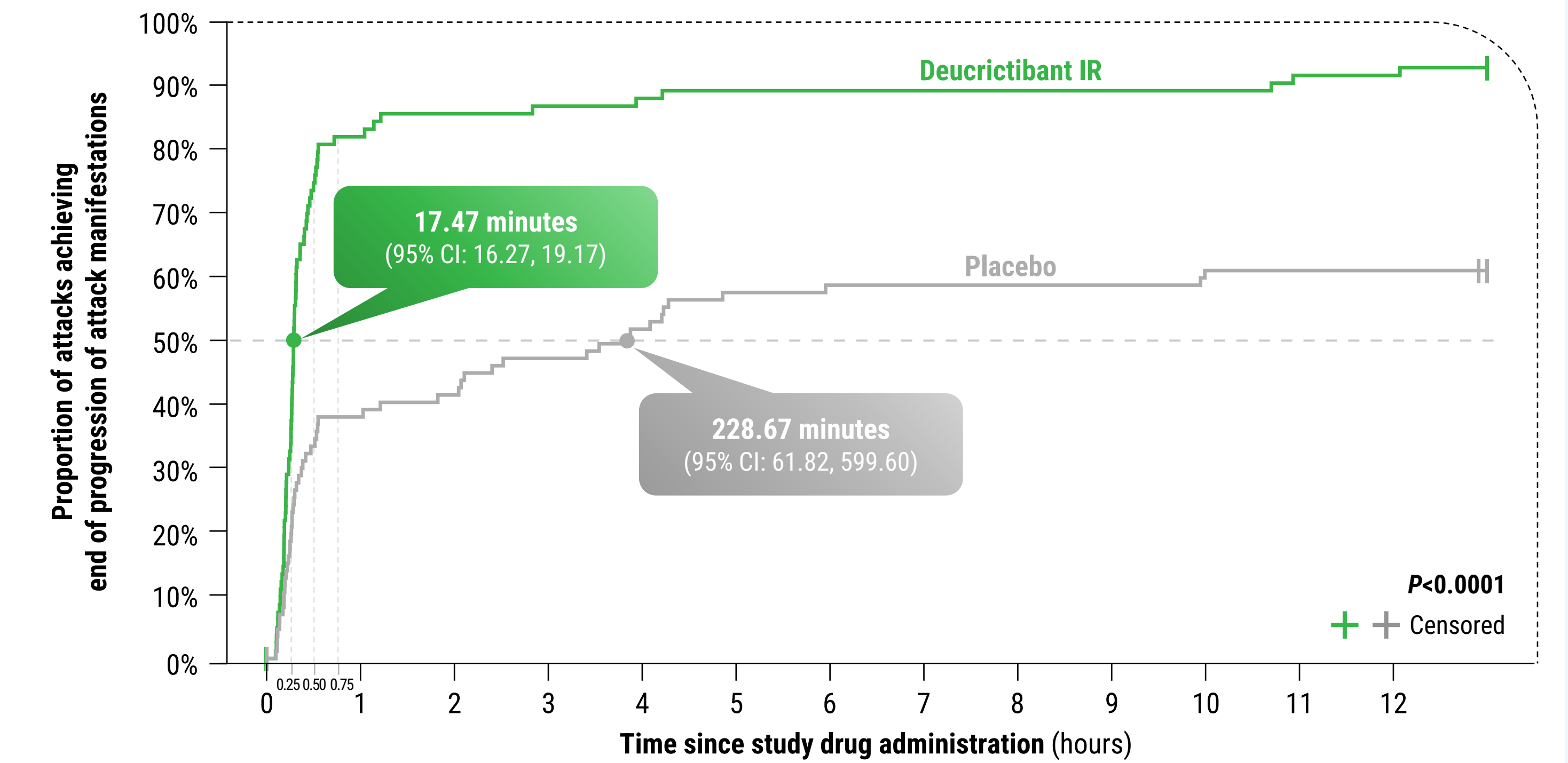
- A total of 134 eligible participants (10 [7.5%] adolescents, 4 [3.0%] with HAE-nC1INH) were enrolled and randomized at 59 sites across 24 countries on 6 continents.
- The primary efficacy analysis set included 88 participants with paired attacks; 113 participants had ≥1 attack treated with study drug.

Table 2. Participant baseline demographics and disease characteristics

Participant characteristics	All randomized participants (N=134)
Age in years, mean (SD)	39.0 (14.7)
Sex: Female, n (%)	76 (56.7)
Years since HAE diagnosis, mean (SD)	17.7 (13.0)
Number of attacks within 3 months before screening, mean (SD)	4.4 (3.3)
HAE type, n (%)	
HAE-C1INH-type 1	118 (88.1)
HAE-C1INH-type 2	10 (7.5)
Unspecified type 1 or 2 ^a	2 (1.5)
HAE-nC1INH ^b	4 (3.0)
Current long-term prophylaxis use, n (%)^c	31 (23.1)

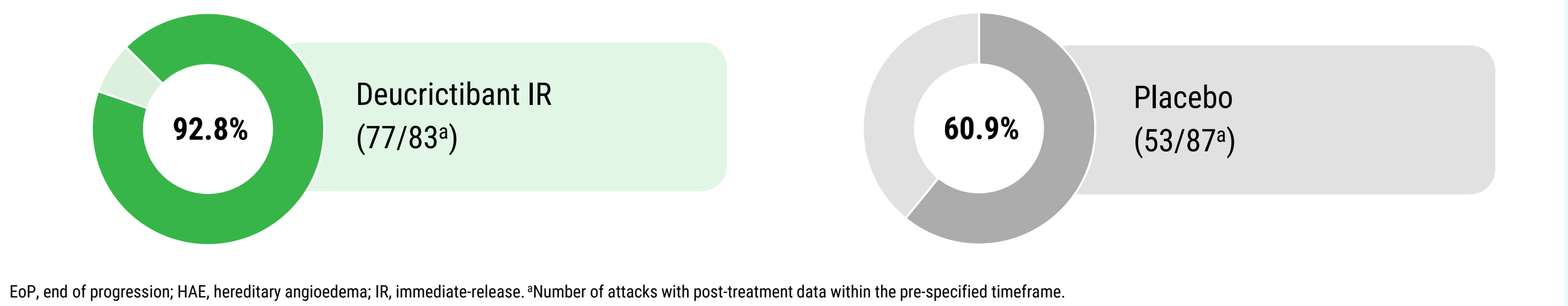
HAE-C1INH-type 1, hereditary angioedema type 1; HAE-C1INH-type 2, hereditary angioedema type 2; HAE-nC1INH, hereditary angioedema with normal C1 inhibitor; SD, standard deviation. ^aHAE type not specified by participant at baseline. ^bIncluded participants with HAE-nC1INH associated with a documented genetic variant. ^cLong-term prophylaxis medication included: lanadelumab (13 [9.7%]), berotral (8 [6.0%]), complement C1 esterase inhibitor (6 [4.5%]), and other (4 [3.0%]). Adapted from "Oral deucrictribant for on-demand treatment of hereditary angioedema attacks: a phase 3, multicentre, randomised, double-blind, placebo-controlled crossover trial" by Marc A Riedl, Philip H Li, Adil Adatia, et al., 2026, *The Lancet*, published online October 8, 2026, doi: 10.1016/S0140-6736(26)01296-1, licensed under CC BY 4.0.

Figure 4. EoP of HAE attack manifestations was achieved significantly faster with deucrictribant IR than with placebo^{a,b}



CI, confidence interval; EoP, end of progression; HAE, hereditary angioedema; IR, immediate-release; PGI-C, Patient Global Impression of Change. ^aIf 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. ^bTime to EoP of attack manifestations was the earliest post-treatment timepoint after which all subsequent PGI-C ratings were stable or improved. Reproduced from "Oral deucrictribant for on-demand treatment of hereditary angioedema attacks: a phase 3, multicentre, randomised, double-blind, placebo-controlled crossover trial" by Marc A Riedl, Philip H Li, Adil Adatia, et al., 2026, *The Lancet*, published online October 8, 2026, doi: 10.1016/S0140-6736(26)01296-1, licensed under CC BY 4.0.

Figure 5. Proportion of attacks achieving EoP of HAE attack manifestations by 12 hours



EoP, end of progression; HAE, hereditary angioedema; IR, immediate-release. ^aNumber of attacks with post-treatment data within the pre-specified timeframe.

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Speaker presentations: ARS, AstraZeneca, BioCryst, CSL Behring, Grifols, GSK, Ionis, KalVista, Lilly, Novartis, Pharming, Sanofi/Regeneron, Takeda; **M.A.R.:** Astria, BioCryst, BioMarin, Cellnex, CSL Behring, Cycle Pharma, Grifols, Intellia, Ionis, KalVista, Novartis, Pharming, Pharvaris, Sanofi-Regeneron, Takeda; **P.H.L.:** Astria, BioCryst, CSL Behring, KalVista, Pharvaris, Takeda; **A.A.:** Astria, BioCryst, CSL Behring, Intellia, Ionis, KalVista, Octapharma, Pharvaris, Takeda; **M.C.:** BioCryst, CSL Behring, KalVista, Menarini, MSD, Novartis, Otsuka, Pharming, Pharvaris, Sobi, Takeda, UCB; **M.Sto.:** BioCryst, CSL Behring, KalVista, Pharming, Pharvaris, Takeda; **A.V.:** AstraZeneca, Berlin-Chemie/Menarini Group, CSL Behring, KalVista, Novartis, Pharming, Pharvaris, Sobi, Takeda; **A.S.G.:** AstraZeneca, Astria, Biomarin, Brazilian research Entity (CNPq), Catalyst, CSL Behring, Exelltis, 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; 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