End of Progression of Attack Manifestations With Oral Deucrictibant Immediate-Release Capsule for On-Demand Treatment of Hereditary Angioedema Attacks in the Phase 3 RAPIDe-3 Trial

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Key takeaways

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, deucrictibant 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 deucrictibant IR

>90%

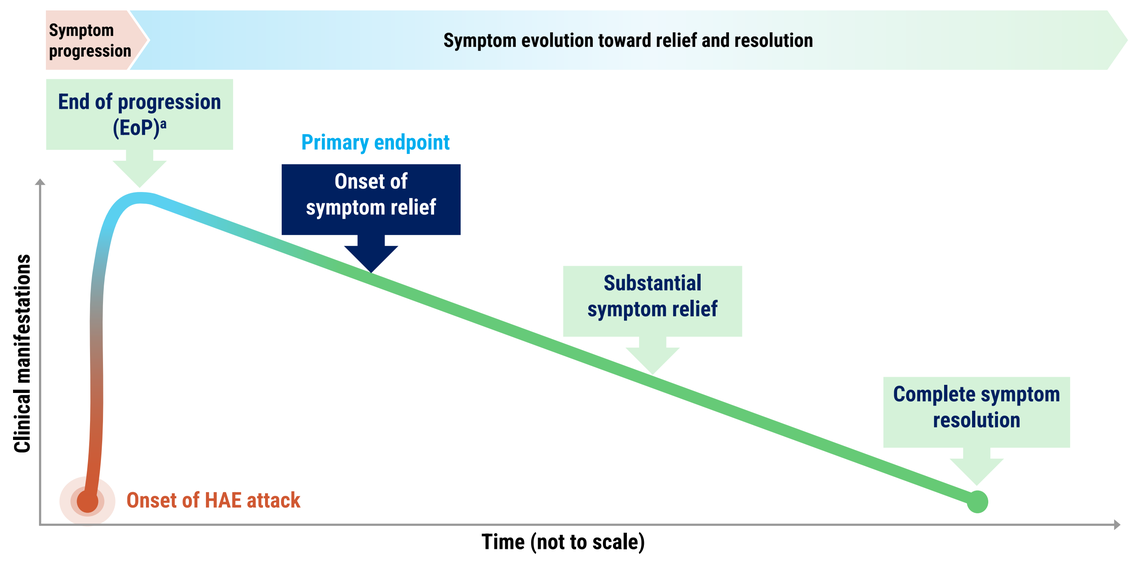
of participants taking deucrictibant achieved EoP of attack manifestations in 12 hours

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 may 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:** 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 deucrictibant:** a selective bradykinin B2 receptor antagonist under development for both prophylactic and on-demand treatment of bradykinin-mediated angioedema attacks.[5-12]

Figure 1. Evolution of an HAE attack



HAE, hereditary angioedema; PGI-C, Patient Global Impression of Change. [a]In RAPIDe-3, EoP was defined as the earliest post-treatment timepoint after which all subsequent PGI-C ratings were stable or improved within 12 hours.

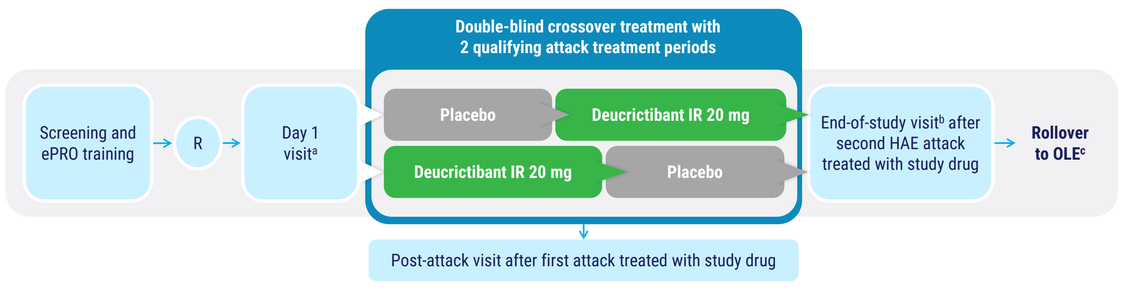
Objective

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 deucrictibant immediate-release (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 2, or HAE with normal C1 inhibitor (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 non-laryngeal or non-severe laryngeal attacks without breathing difficulties or stridor, and with at least one symptom item score ≥20 on the Angioedema syMptom Rating scAle assessment.
- **Analysis set:** primary efficacy analysis included all randomized participants who had two attacks treated with study drug in accordance with the crossover design.

Figure 2. RAPIDe-3 trial design[7]



ePRO, electronic patient-reported outcome; HAE, hereditary angioedema; IR, immediate-release; OLE, open-label extension; R, randomization. [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 OLE study with deucrictibant. [c]Rollover to the OLE was optional.

Methods

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

Parameter	Details
Time to EoP of 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.

EoP, end of progression; HAE, hereditary angioedema.

Results

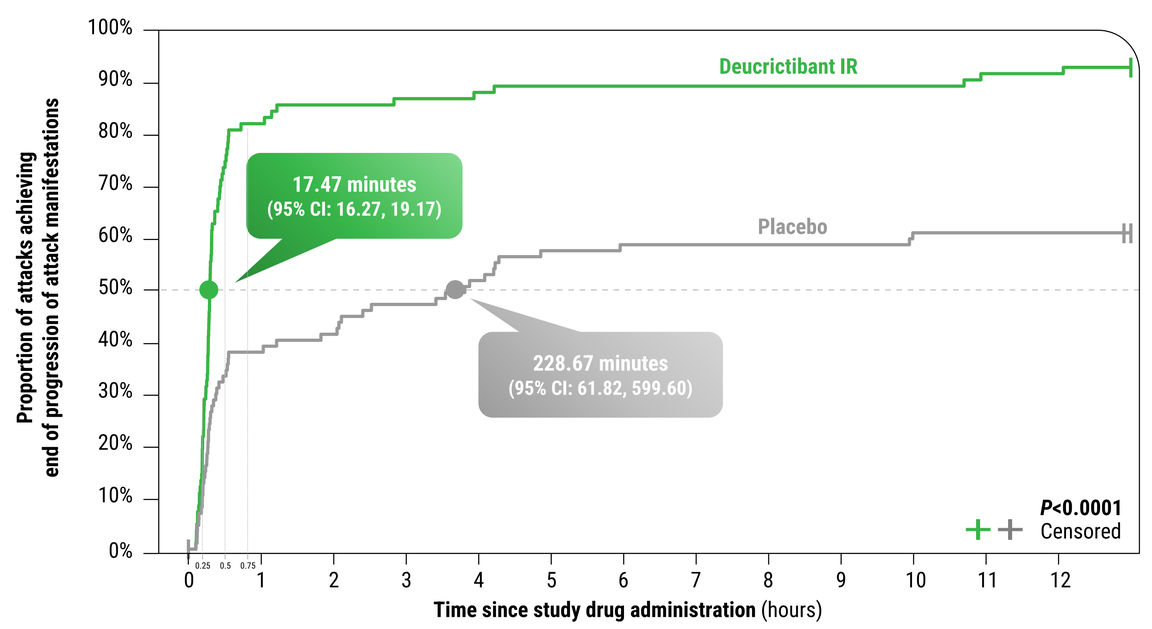
Table 2. Participant baseline demographics and disease characteristics

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, hereditary angioedema; 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. [a]HAE type not specified by participant at baseline. [b]Included participants with HAE-nC1INH associated with a documented genetic variant. [c]Long-term prophylaxis medication included lanadelumab (13 [9.7%]), berotralstat (8 [6.0%]), complement C1 esterase inhibitor (6 [4.5%]), and other (4 [3.0%]).

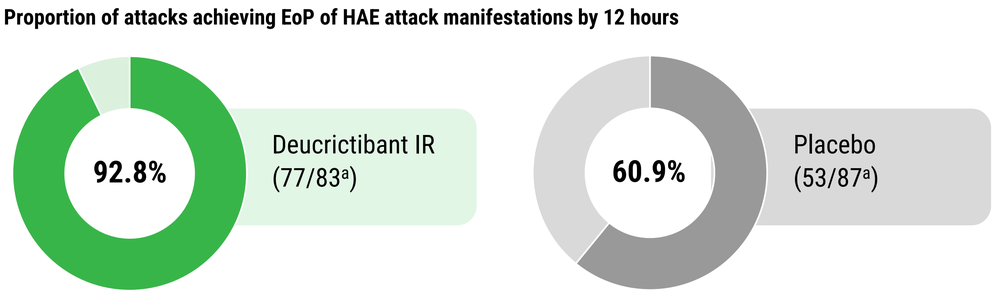
- A total of 134 eligible participants (10 [7.5%] adolescents, 4 [3.0%] with HAE-nC1INH) were enrolled and randomized at 59 sites across 24 countries on 6 continents.
- The primary efficacy analysis set included 88 participants with paired attacks; 113 participants had ≥1 attack treated with study drug.

Figure 4. EoP of HAE attack manifestations was achieved significantly faster with deucrictibant 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. [a]If the event of interest was not achieved within the pre-specified timeframe or rescue medication was used, the attack was right censored at the last observation before the upper end of the data entry window. [b]Time to EoP of attack manifestations was the earliest post-treatment timepoint after which all subsequent PGI-C ratings were stable or improved.

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



EoP, end of progression; IR, immediate-release. [a]Number of attacks with post-treatment data within the pre-specified timeframe.

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**W.R.L.:** AstraZeneca, Astria, BioCryst, BioMarin, CSL Behring, Fresenius-Kabi, GSK, 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; **P.G-B.:** Associação Brasileira de Alergia e Imunologia, CSL Behring, Pharvaris, Pint Pharma, Takeda, World Allergy Organization; **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, 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.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., 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; 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Acknowledgments: Medical writing services were provided by Natasha Drissi, PhD, of Envision Medical Communications, and funded by Pharvaris.

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