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Nuevos retos y oportunidades en alergia alimentaria

Oral Deucrictibant Immediate-Release Capsule for On-Demand Treatment of Hereditary Angioedema Attacks: Phase 3 RAPIDe-3 Trial Results

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Conflicts of interest disclosure

COI: R.L.: AEDAF, BioCryst, CSL, 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, US Hereditary Angioedema Association; **P.H.L.:** ADARx Pharmaceuticals, Argo Biopharma, Astria Therapeutics, BioCryst Pharmaceuticals, CSL Behring, Intellia Therapeutics, KalVista Pharmaceuticals, Pharvaris, Takeda; **M.M.:** Argo, Astria, BioCryst, CSL Behring, Intellia, KalVista, Octapharma, Otsuka, Pharvaris, Takeda; **P.L.:** employee of Pharvaris, holds stocks in Pharvaris; **D.M.C.:** ADARx, Astria Therapeutics, BioCryst, CSL Behring, Gentili Neopharma, HAEi Central Eastern Europe and the Benelux, Intellia, Ionis, KalVista, Otsuka, Pharvaris, Takeda.

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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:

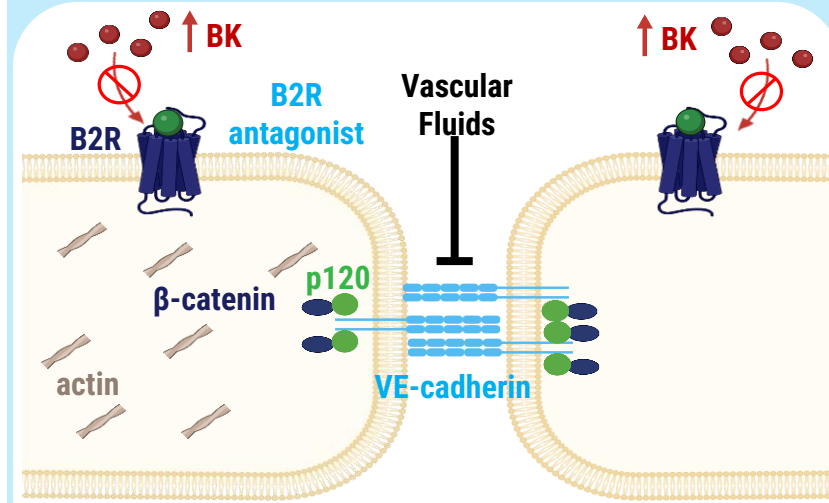


Inhibiting excessive BK-mediated signaling that drives disruption of adherens and tight junctions^{1,2}



Preventing increased vascular permeability^{1,2}

AE-BK Attack Treatment with a B2R Antagonist

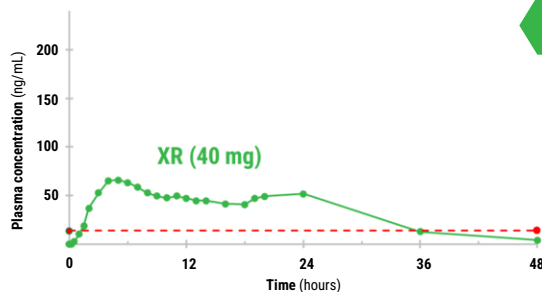


Bradykinin B2 receptor antagonism can effectively treat bradykinin-mediated angioedema attacks.³⁻⁵

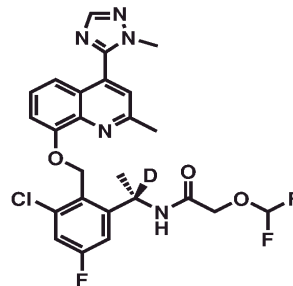
AE-BK, bradykinin-mediated angioedema; BK, bradykinin; B2R, bradykinin B2 receptor; VE, vascular endothelial. 1. Terzuoli E, et al. *PLoS ONE*. 2014;9(1):e84358. 2. Kempe S, et al. *Microcirculation*. 2019;27(2):e12592. 3. Vázquez DO, et al. *World Allergy Organ J*. 2026;19(5):101335. 4. Suffritti C, et al. *Clin Exp Allergy*. 2014;44(12):1503-1514. 5. Maurer M, et al. *Lancet Haematol*. 2026;13(4):e200-14.

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

DEUCRICITIBANT extended-release (XR) tablet sustained absorption¹

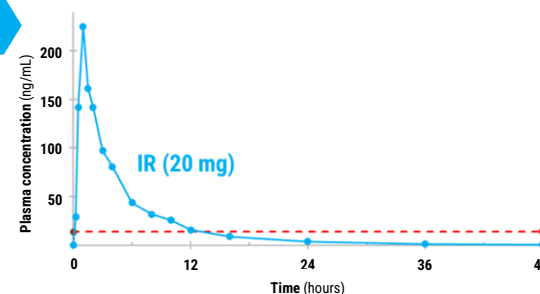


In studies, deucricitibant maintained sustained therapeutic exposure over 24 hours¹ from day 1, allowing for once-daily oral prevention of HAE attacks²



Deucricitibant

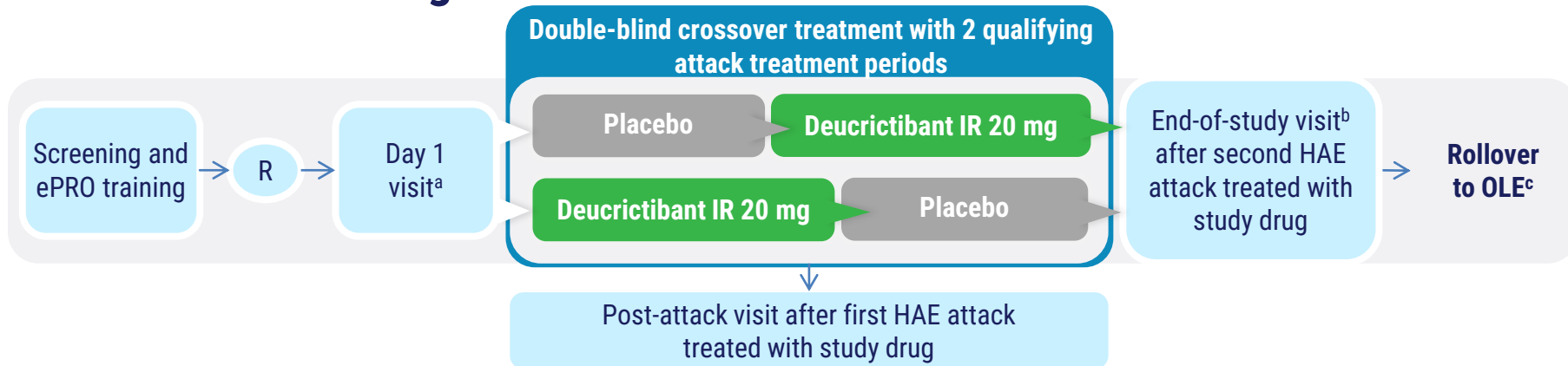
DEUCRICITIBANT immediate-release (IR) capsule rapid absorption³



In studies, deucricitibant rapidly reached therapeutic exposure within 15–30 minutes³, 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. C1INH Workshop; May 29-June 1, 2025. 2. CHAPTER-3. ClinicalTrials.gov identifier: NCT06669754. <https://clinicaltrials.gov/study/NCT06669754>. Accessed September 23, 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. American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting; March 2026; Philadelphia, PA, USA.

RAPIDe-3 trial design

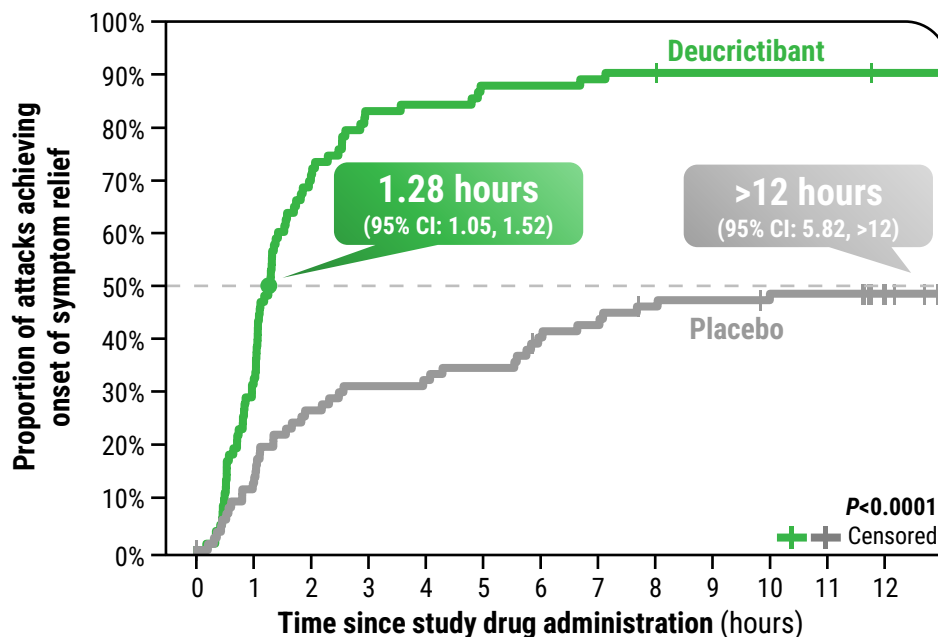


- **Participants:** adolescents (aged ≥ 12 to < 18 years) and adults (aged ≥ 18 to ≤ 75 years) with HAE-C1INH type 1 or 2, or HAE-nC1INH. Participants on long-term HAE prophylaxis were also enrolled.
- **Study drugs:** participants self-administered deucricitbant IR capsule 20 mg or placebo to treat 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.

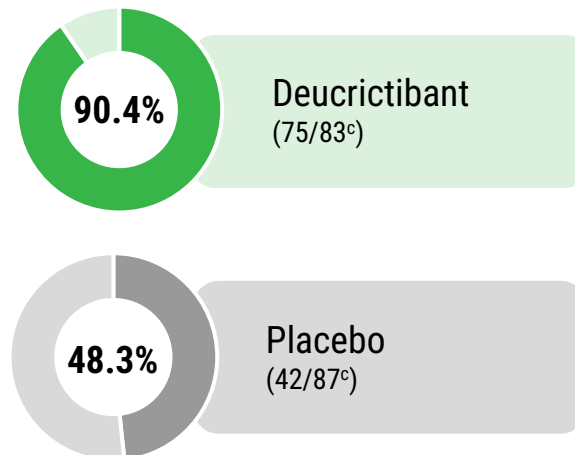
c1INH, C1 inhibitor; ePRO, electronic patient-reported outcome; HAE, hereditary angioedema; IR, immediate-release; nC1INH, normal C1 inhibitor; OLE, open-label extension; R, randomization. ^aAdolescent participants received a non-attack dose for pharmacokinetic sampling at day 1 visit prior to randomization. ^bData from end-of-study visit could be used to qualify the participant for an OLE study with deucricitbant. ^cRollover to the OLE was optional. Riedl MA, et al. *Lancet*. 2026; doi: 10.1016/S0140-6736(26)01296-1.

1.28 hours median time to onset of symptom relief with deucricitbant

PGI-C rating of at least "a little better" for two consecutive timepoints within 12 hours post-treatment



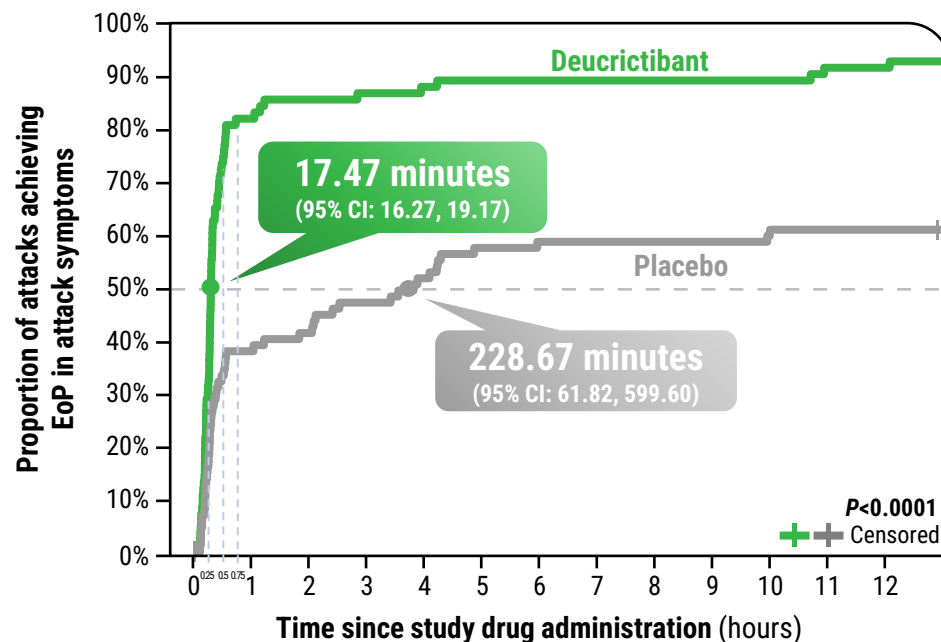
Proportion of attacks shown to achieve onset of symptom relief by 12 hours^{a,b}



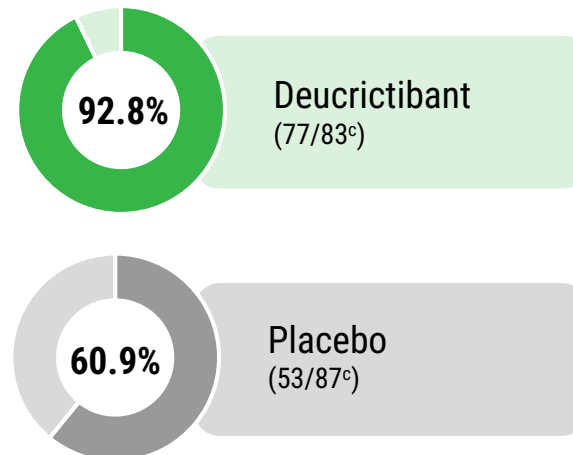
CI, confidence interval; PGI-C, Patient Global Impression of Change. ^aIf the event of interest was not achieved within the pre-specified timeframe, the attack was right censored at the last observation before the upper end of the data entry window. For attacks with rescue medication use, they were treated as right-censored at the upper end of the data entry window. ^bPGI-C rating of at least "a little better" for two consecutive timepoints within 12 hours post-treatment. ^cNumber of attacks with post-treatment data within specified timeframe.

17.47 minutes median time to EoP in attack symptoms with deucricitbant

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



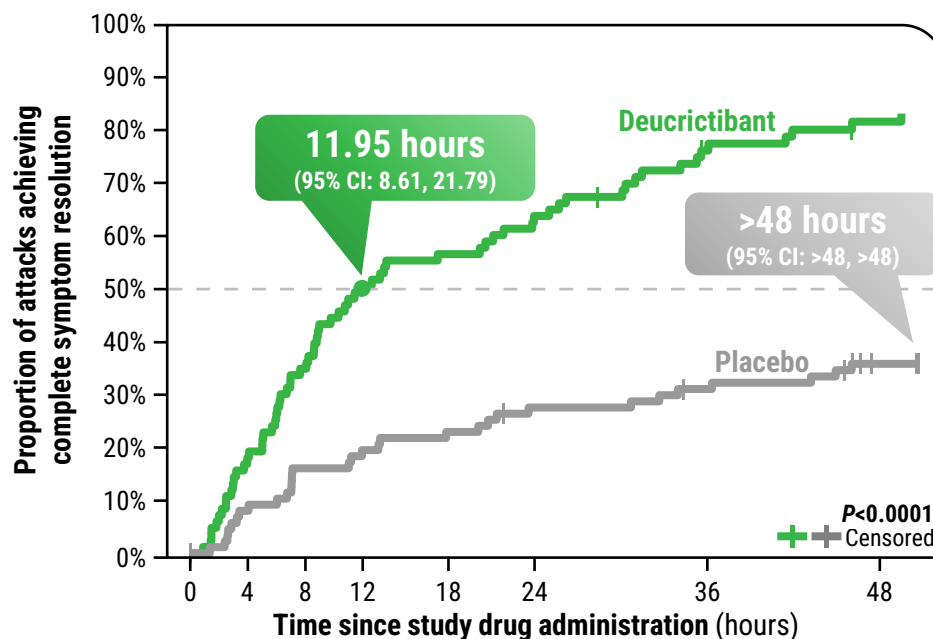
Proportion of attacks shown to achieve EoP in attack symptoms by 12 hours^{a,b}



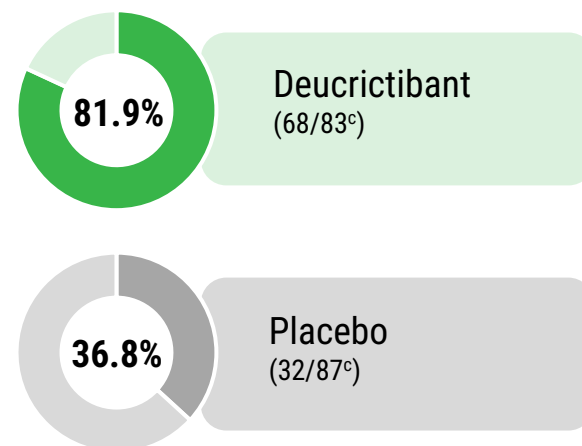
CI, confidence interval; EoP, end of progression; PGI-C, Patient Global Impression of Change. ^aIf the event of interest was not achieved within the pre-specified timeframe, the attack was right censored at the last observation before the upper end of the data entry window. For attacks with rescue medication use, they were treated as right-censored at the upper end of the data entry window. ^bEarliest post-treatment timepoint after which all subsequent PGI-C ratings were stable or improved. ^cNumber of attacks with post-treatment data within the specified timeframe.

11.95 hours median time to complete symptom resolution with deucricitbant

PGI-S rating of "none" within 48 hours post-treatment

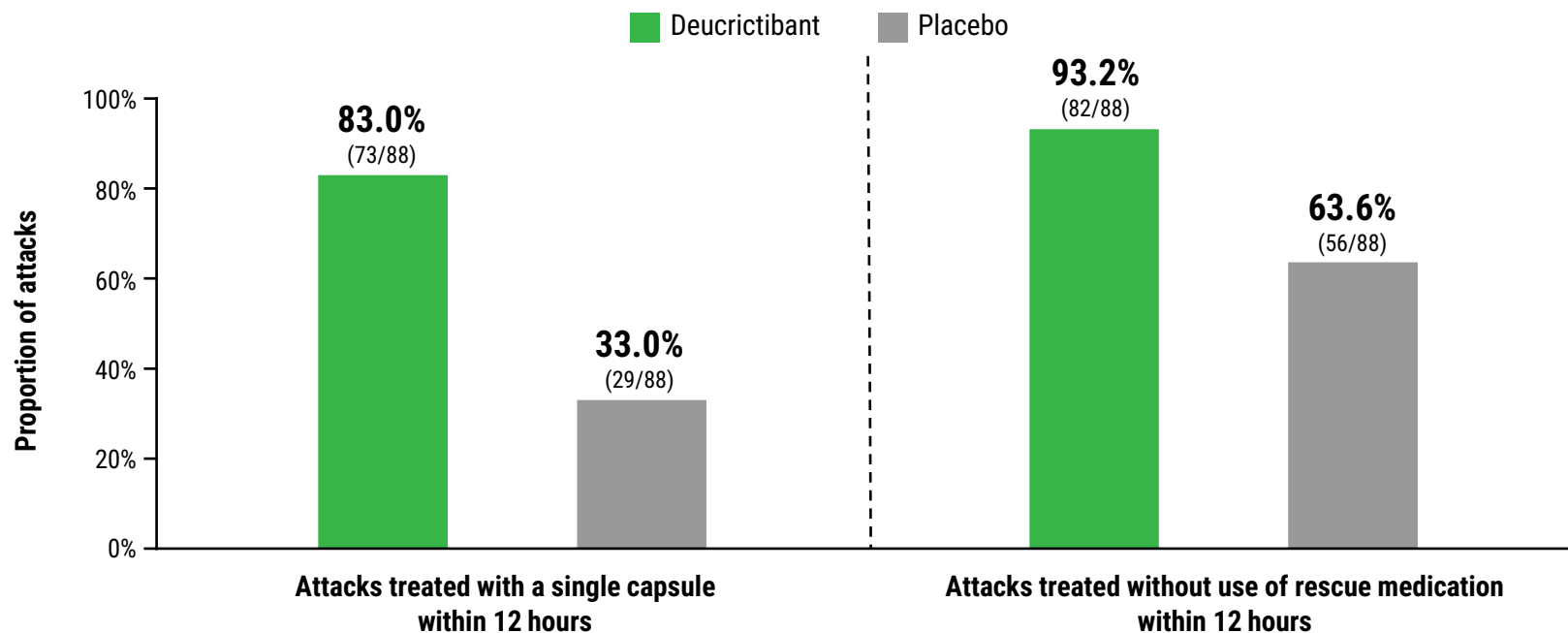


Proportion of attacks shown to achieve complete symptom resolution at 48 hours^{a,b}



CI, confidence interval; PGI-S, Patient Global Impression of Severity. ^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. ^bPGI-S rating of "none" within 48 hours post-treatment. ^cNumber of attacks with post-treatment data within specified timeframe.

More than 80% of deucrictibant-treated attacks were treated with a single capsule and more than 90% did not require rescue medication



Deucrichtibant 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 two 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 deucrichtibant (N=10) ^c		Treated attack deucrichtibant (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 at least one 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. ^aData based on safety analysis set. ^bTEAE defined as an adverse event from the first study drug administration through the end of study visit. ^cAdolescent participants only. ^dDefined 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. ^eDefined as the number of attacks with an adverse event that started within 3 days post-treatment of attack. ^fOne event each of dyspepsia, fatigue, lethargy, brain fog, headache, and somnolence in deucrichtibant-treated participants, and 1 event of pruritus in placebo-treated participants. ^gAll 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 the treatment of attacks in multiple types of HAE provide further evidence on the efficacy, safety, and tolerability of the orally administered B2R antagonist deucricitibant 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**



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

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

B2R, bradykinin B2 receptor; HAE, hereditary angioedema; IR, immediate-release; TEAE, treatment-emergent adverse event. ^aThe primary and 3 of 11 hierarchical order-ranked secondary endpoints are included in this presentation.

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GRACIAS

Después de más de 30 años dedicados al angioedema,
esta es mi última presentación en un congreso

Gracias por el camino compartido