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

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## Key takeaways

Results from the pivotal RAPIDe-3 trial for the 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 immediate-release (IR) capsule. This trial met its 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

TEAE, treatment-emergent adverse event. [a]The primary and first 6 of 11 hierarchical order-ranked secondary endpoints are included in this presentation.

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

## Background

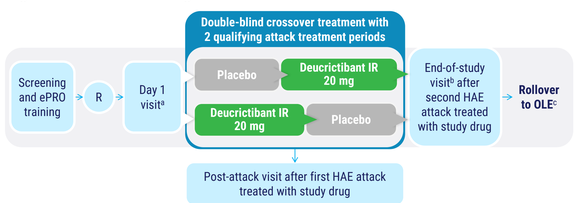
- **Hereditary angioedema (HAE):** a bradykinin-mediated condition with painful swelling attacks affecting multiple locations in the body.[1]
- **Unmet need:** an unmet need remains for additional orally administered treatments combining ease of administration, rapid and sustained effects, and a well-tolerated safety profile.[2,3]
- **Oral deucrictibant:** a selective bradykinin B2 receptor antagonist under development for both prophylactic and on-demand treatment of bradykinin-mediated angioedema attacks.[4-10]

## Objective

To assess the efficacy, safety, and tolerability of oral deucrictibant immediate-release (IR) capsule for on-demand treatment of attacks in adolescents and adults with HAE, including participants with HAE with normal C1 inhibitor (HAE-nC1INH).

## Methods

**Figure 1. RAPIDe-3 trial design**




ePRO, electronic patient-reported outcome; HAE, hereditary angioedema; IR, immediate-release; OLE, open-label extension; R, randomization. RAPIDe-3, ClinicalTrials.gov identifier: NCT06343779. https://www.clinicaltrials.gov/study/NCT06343779. Accessed May 22, 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 OLE study with deucrictibant. [c]Rollover to the OLE was optional.

- **RAPIDe-3 (NCT06343779)*:** a global, Phase 3, randomized, double-blind, placebo-controlled trial.
- **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 non-laryngeal or non-severe laryngeal attacks without breathing difficulties or stridor, and with at least one symptom item score of ≥20 on the Angioedema syMptom Rating scAle (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.

## Methods

**Table 1. Selected efficacy[a] and safety endpoints**

| Endpoint | Instrument | Definition |
|---|---|---|
| **Primary endpoint** | | |
| Time to onset of symptom relief | PGI-C | Time to a PGI-C rating of at least "a little better" for 2 consecutive timepoints within 12 hours post-treatment |
| **Secondary endpoints** | | |
| Proportion of attacks achieving onset of symptom relief | PGI-C | Proportion of study-drug treated attacks achieving a PGI-C rating of at least "a little better" at 4 hours post-treatment |
| Time to substantial symptom relief | PGI-C | Time to a PGI-C rating of at least "better" for 2 consecutive timepoints within 12 hours post-treatment |
| Time to reduction in attack severity | PGI-S | Time to a ≥1-level reduction in PGI-S score from pre-treatment for 2 consecutive timepoints within 12 hours post-treatment |
| Time to complete symptom resolution | PGI-S | Time to PGI-S rating of "none" within 48 hours post-treatment |
| Time to end of progression in attack symptoms | PGI-C | Time to the earliest post-treatment timepoint after which all subsequent PGI-C ratings are stable or improved within 12 hours |
| Use of conventional on-demand treatment as rescue medication | – | Proportion of study-drug treated attacks using conventional on-demand treatment as rescue medication to treat an attack within 24 hours post-treatment |
| **Safety endpoint** | | |
| TEAEs and serious TEAEs | – | TEAE defined as an adverse event from the first study drug administration through the end-of-study visit |

PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity; TEAE, treatment-emergent adverse event. [a]The primary and first 6 of 11 hierarchical order-ranked secondary endpoints.

## 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.
- Demographics and baseline characteristics were generally balanced across treatment groups.

**Table 2. Participant demographics and baseline disease characteristics**

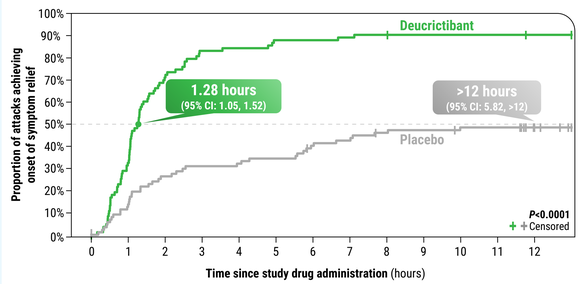
| Participant characteristics | All randomized participants (N=134) |
|---|---|
| **Age in years,** mean (SD) | 39.0 (14.7) |
| ≥12 to <18, n (%) | 10 (7.5) |
| ≥18 to <65, n (%) | 116 (86.6) |
| ≥65, n (%) | 8 (6.0) |
| **Sex: Female,** n (%) | 76 (56.7) |
| **BMI,** mean (SD) | 26.5 (5.9) |
| **Race,** n (%) | |
| White | 93 (69.4) |
| Asian | 19 (14.2) |
| Black or African American | 10 (7.5) |
| American Indian or Alaska Native | 1 (0.7) |
| Other | 7 (5.2) |
| Not reported | 4 (3.0) |
| **Region,** n (%)[a] | |
| Europe | 56 (41.8) |
| Rest of world | 40 (29.9) |
| North America | 38 (28.4) |
| **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 HAE-C1INH type 1 or 2 | 2 (1.5) |
| HAE-nC1INH[b] | 4 (3.0) |
| **Current LTP use,** n (%)[c] | 31 (23.1) |

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]Included participants with HAE-nC1INH associated with a documented genetic variant. [c]LTP medication included lanadelumab (13 [9.7%]), berotralstat (8 [6.0%]), c1 esterase inhibitor (6 [4.5%]), and other (4 [3.0%]).

## Results

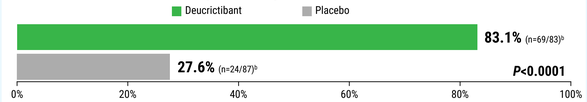
### Efficacy

**Figure 2. Primary endpoint: Significantly faster onset of symptom relief with deucrictibant compared with placebo[a,b]**



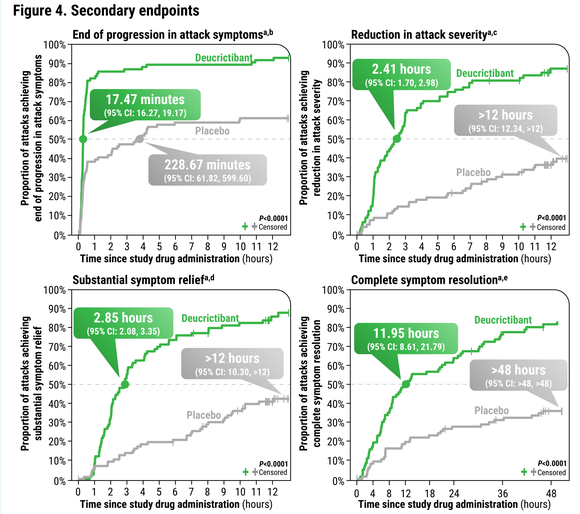

CI, confidence interval; PGI-C, Patient Global Impression of Change. [a]If the event of interest was not achieved within the pre-specified timeframe, the attack was right censored at the last observation before the upper end of the data entry window. For attacks with rescue medication use, they were 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.

**Figure 3. Significantly higher proportion of attacks achieved onset of symptom relief at 4 hours[a] with deucrictibant compared with placebo**




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 of participants with PGI-C data within 4 hours post-treatment.

**Figure 4. Secondary endpoints**




CI, confidence interval; PGI-C, Patient Global Impression of Change; 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]End of progression time is the earliest post-treatment timepoint after which all subsequent PGI-C ratings are stable or improved within 12 hours. [c]A ≥1-level reduction in PGI-S score from pre-treatment for 2 consecutive timepoints within 12 hours post-treatment. [d]PGI-C rating of at least "better" for 2 consecutive timepoints within 12 hours post-treatment. [e]PGI-S rating of "none" within 48 hours post-treatment.

## Results

**Figure 5. More than 80% of deucrictibant-treated attacks were treated with a single capsule and more than 90% did not require rescue medication**

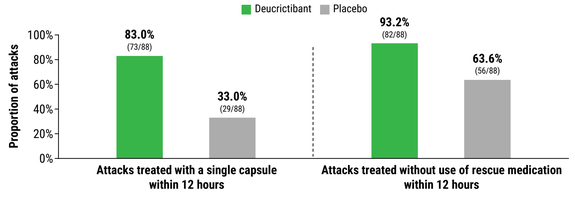
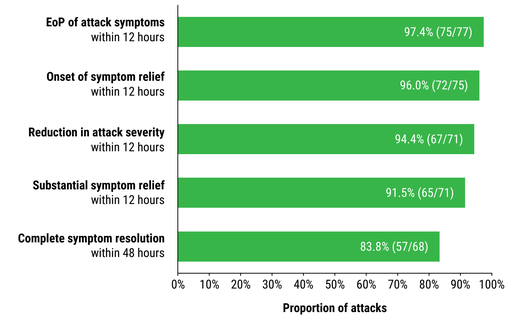



**Figure 6. Majority of deucrictibant-treated attacks achieved efficacy endpoints with a single capsule**




EoP, end of progression.

### Safety

- 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.

**Table 3. Treatment-emergent adverse events occurring within 3 days post-treatment**

| | Non-attack deucrictibant (N=10)[a] | | Treated attack deucrictibant (N=100) | | Treated attack placebo (N=101) | |
|---|---|---|---|---|---|---|
| Adverse events | n (%)[b] | no. of events | n (%)[c] | no. of events | n (%)[c] | no. of events |
| **Any TEAE** | 0 | 0 | 15 (15.0) | 17 | 2 (2.0) | 3 |
| **Treatment-related TEAEs[d]** | 0 | 0 | 5 (5.0) | 6 | 1 (1.0) | 1 |
| **Any severe TEAE[e]** | 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]Adolescent participants only. [b]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. [c]Defined as the number of participants with an adverse event that started within 3 days post-treatment of attack. [d]One related TEAE each of dyspepsia, fatigue, lethargy, brain fog, headache, and somnolence in deucrictibant-treated participants, and 1 event of pruritus in placebo-treated participants. [e]All reported TEAEs were graded 1 (mild) or 2 (moderate) and there were no reported TEAEs graded 4 (life-threatening) or 5 (fatal).

## References

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