# Treatment of HAE attacks with oral deucrictibant: RAPIDe-2 extension results

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*Notes: Use QR code overleaf to view full author details.*
*These data were presented at the Bradykinin Symposium in September 2024.*
**Our distinguished colleague and friend, Prof. Maurer, sadly passed away during the finalization of this poster.*

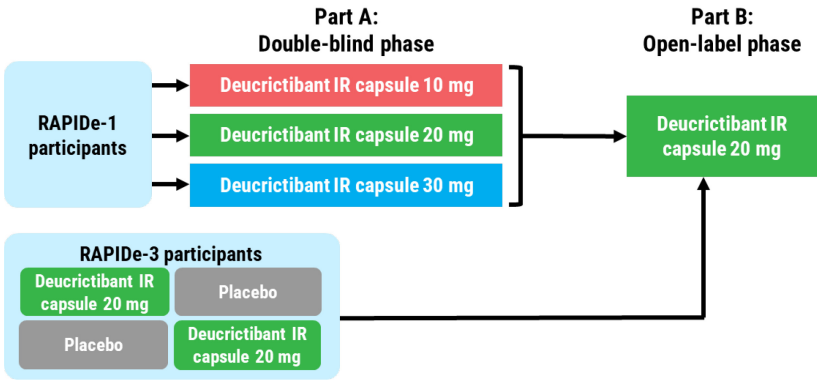
Results from the ongoing RAPIDe-2 extension are consistent with the Phase 2 RAPIDe-1 study and provide evidence on the long-term safety and efficacy of oral deucrictibant IR capsule for the repeat treatment of HAE attacks.

- The deucrictibant immediate-release (IR) capsule was well-tolerated with no safety signals observed.
- Participants reported a median time to onset of symptom relief of 1.1 hours, with onset achieved by 12 hours for 98.5% of attacks.
- Participants reported a median time to complete attack resolution of 11.5 hours, with resolution achieved by 24 hours for 85.8% attacks.

## Methods

- RAPIDe-2 (NCT05396105) is an ongoing two-part Phase 2/3 open-label extension study evaluating the long-term safety and efficacy of the orally-administered deucrictibant IR capsule for the treatment of HAE attacks.
- Part A enrolls (≥18 years) participants who completed the Phase 2 RAPIDe-1 trial (NCT04618211). Participants self-administer the same double-blinded dose of deucrictibant IR capsule as during RAPIDe-1 to treat qualifying nonlaryngeal attacks, and laryngeal attacks presenting without breathing difficulties.
- Results shown for combined dose group.
- The primary endpoint assessed safety.

**Figure 1. RAPIDe-2 study design**




IR, immediate-release.

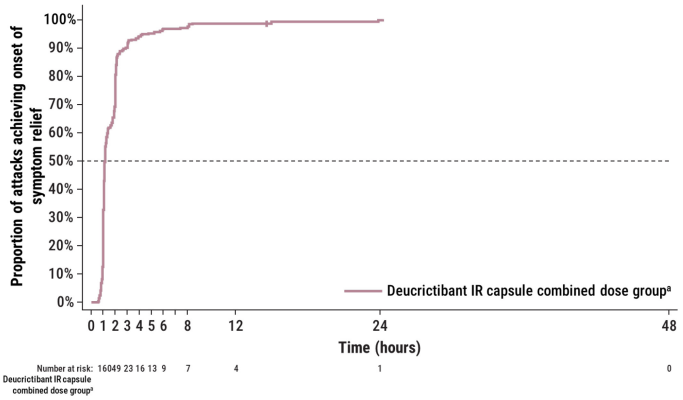
## Results

**Table 1. TEAEs within 5 days after administration of study drug**

| Adverse events | Deucrictibant IR capsule (combined dose group) |
|---|---|
| Number of attacks treated[a] | 337 |
| Number of participants[a] | 19 |
| Attacks with any TEAE, n (%) | 13 (3.9) |
| Treatment-related TEAEs, n | 0 |
| Serious TEAEs, n | 1[b] |
| Treatment-related serious TEAEs, n | 0 |
| TEAEs leading to study drug discontinuation, study withdrawal, or death, n | 0 |

IR, immediate-release; TEAE, treatment-emergent adverse event (defined as an adverse event occurring during time window from first study drug administration).
[a]Number in the safety analysis set at data cutoff (10 June 2024).
[b]Tooth caries unrelated to treatment.

**Figure 2. Kaplan-Meier plot of time to onset of symptom relief**




**Using PGI-C, the median time to onset of symptom relief was 1.1 hours (95% CI, 1.0, 1.2).**

CI, confidence interval; IR, immediate-release; PGI-C, Patient Global Impression of Change.
[a]Includes 10 mg, 20 mg, and 30 mg dose groups.

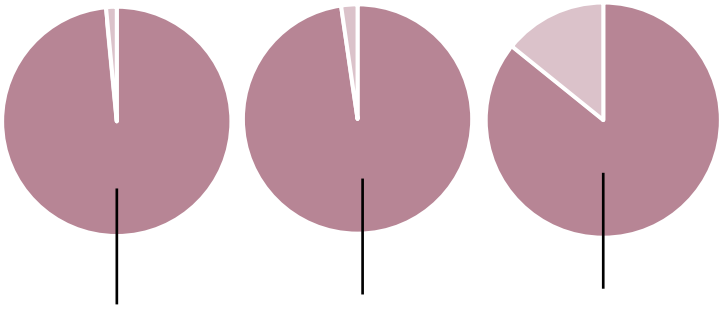
This presentation includes data for an investigational product not yet approved by regulatory authorities.

## Results (continued)

### Table 2. Median time to achieve key efficacy endpoints

| | Deucrictibant IR capsule (combined dose group) |
|---|---|
| **Number of attacks treated**[a] | 265 |
| **Number of participants with treated attacks**[a] | 17 |
| **Median time to onset of symptom relief using PGI-C,** hours (95% CI) | 1.1 (1.0, 1.2) |
| **Median time to reduction in attack severity using PGI-S**[b]**,** hours (95% CI) | 2.6 (2.0, 2.9) |
| **Median time to complete attack resolution using PGI-S**[b]**,** hours (95% CI) | 11.5 (11.0, 13.0) |

### Figure 3. Proportion of attacks achieving key efficacy endpoints



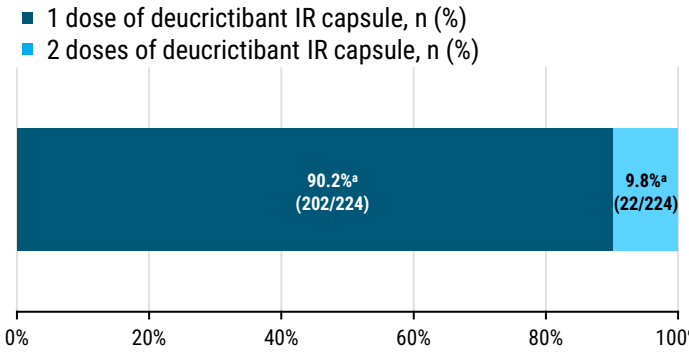
**98.5%** (261/265) of attacks achieved onset of symptom relief using PGI-C by 12 hours

**97.7%** (255/261[b]) of attacks achieved reduction in attack severity using PGI-S by 12 hours

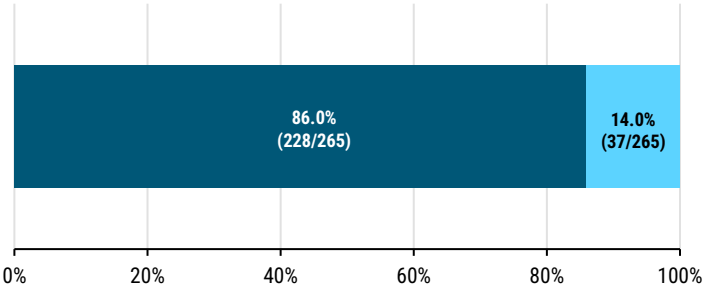
**85.8%** (224/261[b]) of attacks achieved complete attack resolution using PGI-S by 24 hours

IR, immediate-release; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity.
[a]Number in the modified intention-to-treat efficacy analysis set at data cutoff (01 March 2024). [b]261 attacks have non-missing pre-treatment PGI-S.

### Figure 4. Attacks treated with 1 or 2 doses of deucrictibant prior to achieving complete attack resolution




### Figure 5. Total attacks treated with 1 or 2 doses of deucrictibant




IR, immediate-release; PGI-S, Patient Global Impression of Severity. [a]Percentage of 224 attacks achieving complete attack resolution by 24 hours using PGI-S.

## Conclusions

- **In the current analysis of the ongoing RAPIDe-2 Phase 2/3 extension study, deucrictibant IR capsule was well-tolerated for all studied doses and no safety signals observed.**
- **Efficacy analysis showed:**
  - **1.1 hours median time to onset of symptom relief using PGI-C – 98.5% of attacks by 12 hours.**
  - **2.6 hours median time to reduction in attack severity using PGI-S – 97.7% of attacks by 12 hours.**
  - **11.5 hours median time to complete attack resolution using PGI-S – 85.8% of attacks by 24 hours.**
  - **86.0% of attacks were treated with a single dose of deucrictibant IR capsule.**
- **Results from the ongoing RAPIDe-2 extension are consistent with the Phase 2 RAPIDe-1 study and provide evidence on the long-term safety and efficacy of the deucrictibant IR capsule for repeat treatment of HAE attacks.**