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# Satisfaction With Sebetralstat as On-demand Treatment of Hereditary Angioedema Attacks in KONFIDENT-S


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## Key Takeaways

**87.8%**

Participants were satisfied when using sebetralstat as an on-demand treatment for a total of 1593 hereditary angioedema (HAE) attacks

**81%-88%**

Regardless of attack severity, attack location, time to treatment, or participant age, satisfaction was high across attacks treated with sebetralstat

## Background

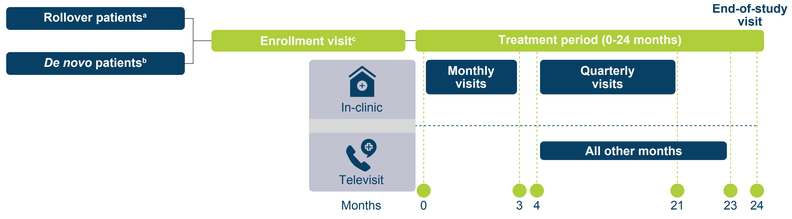
- Despite global HAE guideline recommendations to consider treating all attacks,[1-4] patients often delay or avoid using injectable on-demand treatment due to logistical challenges and injection-related anxiety,[5] highlighting a need for less invasive treatment options
- Sebetralstat, an oral on-demand plasma kallikrein inhibitor, was recently approved for the treatment of HAE attacks in patients aged ≥12 years[6]

## Objective

- To assess treatment satisfaction among participants who treated HAE attacks with sebetralstat in an interim analysis of the KONFIDENT-S study

## Methods

### Figure 1. KONFIDENT-S OLE Trial Design




NCT05505916, EudraCT: 2021-001176-42.
[a]Completed the phase 3 KONFIDENT trial.
[b]All other patients, including those who participated in the phase 2 trial.
[c]For *de novo* patients, the enrollment visit is a screening visit.
OLE, open-label extension.

- KONFIDENT-S is an ongoing, 2-year, multicenter, open-label extension trial (NCT05505916; EudraCT: 2021-001176-42; **Figure 1**)
  - Eligible patients were aged ≥12 years with HAE due to C1-inhibitor deficiency (HAE-C1INH) and had ≥2 documented attacks within 3 months before enrollment, or had completed the phase 3 KONFIDENT trial (NCT05259917)
  - Multiple real-world elements were incorporated into the trial design: there was no attack qualification by investigators; all attack locations and severities were eligible; and portable multidose packs were provided

### Figure 2. Treatment Satisfaction Rating (7-point Likert Scale)

| –3 | –2 | –1 | 0 | +1 | +2 | +3 |
|---|---|---|---|---|---|---|
| Extremely dissatisfied | Very dissatisfied | Dissatisfied | Neutral | Satisfied | Very satisfied | Extremely satisfied |

- Treatment satisfaction was assessed 24 hours after the first dose of sebetralstat for each attack using a 7-point Likert scale (**Figure 2**)
  - No dissatisfaction was defined as a score of either neutral (0) or satisfied (+1, +2, or +3)
  - Participants with a mean treatment satisfaction of >0 were considered satisfied with sebetralstat

## Results

### Participants and Attacks

- As of September 30, 2025, 115 participants in KONFIDENT-S provided satisfaction data for 1593 attacks treated with sebetralstat (**Table 1; Table 2**)

**Table 1. Participant Demographics[a]**

| | N=115 |
|---|---|
| **Age, median (IQR), years** | 36.0 (22.0-49.0) |
| **Sex, female, n (%)** | 78 (67.8) |
| **Race, White, n (%)** | 86 (74.8) |
| **BMI, median (IQR), kg/m²** | 25.1 (22.3-30.0) |
| **HAE-C1INH-Type1, n (%)** | 106 (92.2) |

[a]For participants with treatment satisfaction data available.
Data cutoff: September 30, 2025.
BMI, body mass index; HAE-C1INH-Type1, HAE due to C1INH deficiency type 1; IQR, interquartile range.

**Table 2. Attack Characteristics in Sebetralstat-treated Attacks**

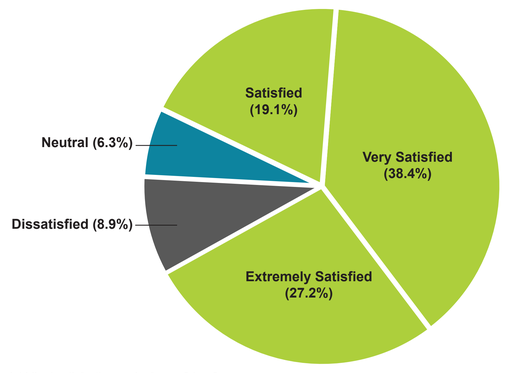
| | N=1593 |
|---|---|
| **Baseline severity (PGI-S), n (%)[a]** | |
| **Mild[b]** | 661 (41.5) |
| **Moderate** | 682 (42.8) |
| **Severe/Very severe** | 249 (15.6) |
| **Primary pooled attack location, n (%)[a]** | |
| **Mucosal[c]** | 671 (42.1) |
| **Laryngeal** | 28 (1.8) |
| **Subcutaneous only[c]** | 921 (57.9) |
| **Time to treatment, median (IQR), minutes** | 20.0 (1.0-77.0) |
| **Treated within <1 hour, n (%)** | 1057 (66.3) |
| **Attacks treated with a second dose, n (%)[d]** | 351 (22.0) |
| **Attacks treated with conventional treatment, n (%)[d]** | 80 (5.0) |

[a]Baseline severity and primary attack location data missing for 1 attack.
[b]Includes 20 (1.3%) attacks with baseline PGI-S rating of 'None'.
[c]Mucosal: attacks with primary location of "Abdomen" and/or "Larynx/throat"; subcutaneous: other attacks not involving mucosal locations.
[d]Within 12 hours.
Data cutoff: September 30, 2025.
IQR, interquartile range; PGI-S, Patient Global Impression of Severity.

### Treatment Satisfaction

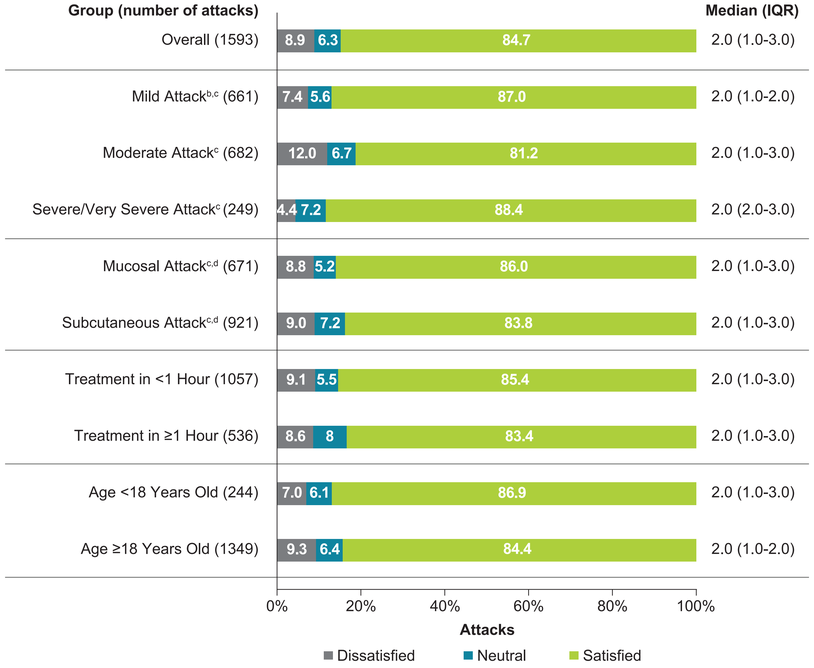
- 87.8% of participants were satisfied with sebetralstat (mean satisfaction score >0)
- No dissatisfaction was reported for 91.1% of attacks (**Figure 3**)

**Figure 3. Sebetralstat Treatment Satisfaction Scores[a]**




[a]Based on the 7-point Likert satisfaction scale, from −3 to +3.
Data cutoff: September 30, 2025.

**Figure 4. Sebetralstat Satisfaction Among Attack Subgroups[a]**




[a]Based on the 7-point Likert satisfaction scale, from −3 to +3.
[b]Includes 20 attacks with baseline PGI-S rating of 'None'.
[c]Baseline severity (by PGI-S) and primary attack location data missing for 1 attack.
[d]Mucosal: attacks with primary location of "Abdomen" and/or "Larynx/throat"; subcutaneous: other attacks not involving mucosal locations.
Data cutoff: September 30, 2025.
IQR, interquartile range; PGI-S, Patient Global Impression of Severity.

- The median satisfaction score for all attacks was 2.0 (very satisfied), and 81%-88% of attacks were rated as satisfied across subgroups (**Figure 4**)
- A trend was observed between shorter time to treatment and better treatment satisfaction (Pearson correlation, $|r|$=0.084; *P*-value=0.0008)
- No correlation was observed between baseline attack severity and treatment satisfaction

## References


1. Busse PJ et al. *J Allergy Clin Immunol Pract*. 2021;9(1):132-150.e3.
2. Maurer M et al. *Allergy*. 2022;77(7):1961–90.
3. Farkas H et al. *Allergy*. 2026;0:1–31.
4. Betschel SD et al. *Allergy Asthma Clin Immunol*. 2026;22(1):24.
5. Betschel SD et al. *Allergy Asthma Clin Immunol*. 2025;21(1):25.
6. Ekterly (sebetralstat). Prescribing information. KalVista Pharmaceuticals, Inc.; 2025.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