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Satisfaction with Sebetralstat for On-Demand Treatment of HAE Attacks: Real-World Data from the EARLY Study

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Key Takeaways

Participants treating HAE attacks with sebetralstat in a real-world setting reported rapid time to treatment, symptom relief, and attack resolution

Median time	0.6 Hours	1.4 Hours	5.1 Hours
	Decision to treat	Beginning of symptom relief	Attack resolution

Real-world satisfaction with sebetralstat treatment was consistent with findings from KONFIDENT-S OLE[1]:

In 84% of HAE attacks, participants reported satisfaction with sebetralstat

In 96% of HAE attacks, participants reported no dissatisfaction

For 92% of attacks, participants preferred sebetralstat over their previous injectable on-demand therapy

Background

- Sebetralstat is the first approved oral on-demand treatment for patients aged 12 years or older[2] and is included as a first-line option in international hereditary angioedema treatment guidelines[3]
- Approval for sebetralstat was based on the phase 3 KONFIDENT trial[4]; its safety and effectiveness have been further demonstrated in the KONFIDENT-S OLE trial[5,6]
- Among 115 participants in KONFIDENT-S who provided satisfaction data for 1,593 attacks treated with sebetralstat, satisfaction and no dissatisfaction for sebetralstat was reported for 84.7% and 91.1% of attacks, respectively[1]

Objectives

- To evaluate real-world effectiveness of sebetralstat for on-demand treatment of HAE attacks
- To assess real-world satisfaction with sebetralstat

Methods

- EARLY is an ongoing, phase 4, prospective, real-world, observational study evaluating the effectiveness of sebetralstat in participants with HAE

Inclusion Criteria

- ≥12 years of age
- Based in the US
- Self-reported and/or physician-confirmed HAE-C1INH Type 1 or 2
- Participant was prescribed sebetralstat and had received it from the pharmacy
- Participant may or may not have yet treated an HAE attack with sebetralstat
- Other HAE medications, including long-term prophylaxis (LTP), were allowed in addition to sebetralstat

Data Collection

Baseline Data

- At enrollment, participants recorded information about their
  - Demographics
  - Medical history
  - Characteristics of last attack treated with on-demand treatment

Observational Period

- eDiary assessments of each HAE attack were recorded up to 48 hours after the first dose of on-demand treatment
- All study data were summarized descriptively
- Data were collected from January to June 2026

Month −3 — Enrollment — End of Study

Treatment Switch | Day 0 | Interim Analysis June 2026 | Month 12

Results

Participant Demographics and HAE Attack Treatment Patterns

- As of June 2026, 56 adult or adolescent participants with hereditary angioedema with C1-inhibitor protein deficiency (HAE-C1INH) Type 1 or 2 were enrolled in EARLY; 49 participants (88%) were receiving LTP at baseline
- Among 35 participants, 130 HAE attacks were recorded, 109 (84%) of which were treated using on-demand treatment
  - 102 attacks (94%) were treated with sebetralstat in 35 participants (**Table 1**)
    - One participant receiving LTP treated 28 attacks with sebetralstat
  - 7 attacks (6%) were treated with injectable on-demand therapy (n=4 participants treating their last attack)
- 21 attacks (16%) were not treated (n=5 participants)

Table 1. Demographics of Participants Who Treated an HAE Attack Using Sebetralstat

		Participants n=35
	Age, mean (range), years	36.2 (12-64)
	Adults (≥18 years), n (%)	28 (80)
	Adolescents (12-17 years), n (%)	7 (20)
HAE type	Type 1: Deficiency of C1INH, n (%)	25 (71)
	Type 2: Dysfunction of C1INH, n (%)	10 (29)
Gender	Female, n (%)	21 (60)
	Male, n (%)	13 (37)
	Non-binary, n (%)	1 (3)
Ethnicity[a]	White/Caucasian, n (%)	31 (89)
	Hispanic/Latino, n (%)	4 (11)
	Black, n (%)	5 (14)
	Asian, n (%)	1 (3)
LTP use at baseline	Receiving LTP, n (%)	31 (89)
	Not receiving LTP, n (%)	4 (11)

[a]Participants were asked to select all that applied.
C1INH, C1 esterase inhibitor; HAE, hereditary angioedema; LTP, long-term prophylaxis.

HAE Attack Characteristics

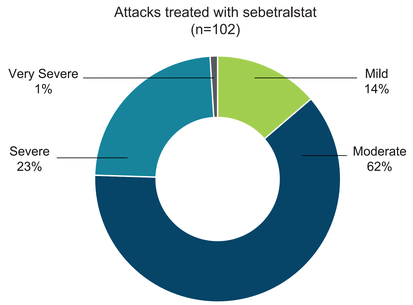
- The most common initial sites for attacks treated with sebetralstat were the abdomen/ stomach, periphery, and face/head (**Table 2**)
- At peak severity, most attacks treated with sebetralstat were of moderate severity (62%) (**Figure 1**)

Table 2. Initial Site of HAE Attacks Treated with Sebetralstat

Initial Site of Attack	Attacks n=102
Abdominal/Stomach, n (%)	49 (48)
Peripheral/Trunk, n (%)	21 (21)
Face/Head/Back of Head, n (%)	18 (18)
Genitals, n (%)	6 (6)
Tongue, n (%)	3 (3)
Throat, n (%)	1 (1)
Other,[a] n (%)	4 (4)

[a]Other specified as: Abdominal/back of neck; back; esophagus; eye and neck; left knee.
Values may not add up to 100% due to rounding.

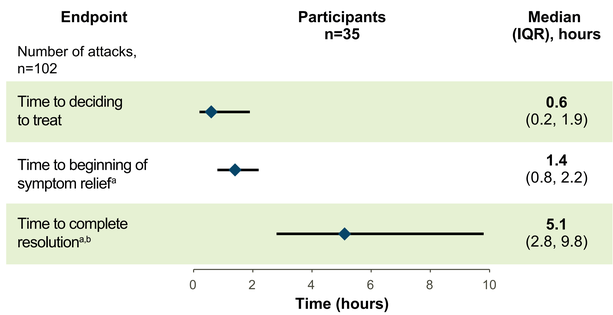
Figure 1. Peak Attack Severity



Sebetralstat Time to Treatment and Effectiveness

- Participants had sebetralstat available to them at the start of 92% of attacks (eg, were carrying it with them, or were otherwise able to access it right away)
- The median (IQR) time from attack onset to deciding to treat with sebetralstat was 0.6 hours (0.2, 1.9) (**Figure 2**)
- Beginning of symptom relief occurred a median (IQR) of 1.4 hours (0.8, 2.2) after sebetralstat administration (**Figure 2**)
- Complete resolution of the attack occurred a median (IQR) of 5.1 hours (2.8, 9.8) after sebetralstat administration (**Figure 2**)

Figure 2. Sebetralstat Real-World Time to Treatment and Effectiveness

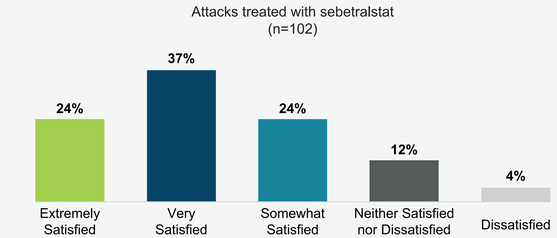


[a]Participants were asked to retrospectively evaluate their symptom relief and resolution. Neither PGI-C nor PGI-S were used.
[b]Among sebetralstat-treated attacks where symptoms had resolved at time of diary completion (24 hours) (n=60).
IQR, interquartile range; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity.

Participant Treatment Satisfaction and Preference

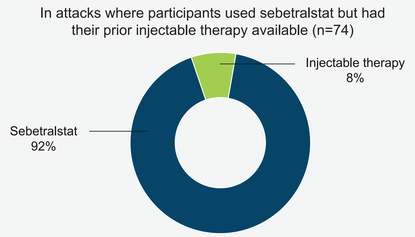
- Satisfaction was reported in 84% of attacks treated with sebetralstat (**Figure 3**)
- No dissatisfaction was reported in 96% of attacks treated with sebetralstat (**Figure 3**)
- For 92% of attacks, participants with experience using both sebetralstat and an injectable on-demand therapy preferred sebetralstat (**Figure 4**)

Figure 3. Satisfaction with Sebetralstat



Values may not add up to 100% due to rounding.

Figure 4. On-Demand Treatment Preference



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