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Reasons for Switching to Oral Sebetralstat for HAE Attacks: Real-World Data from the EARLY Study

William R. Lumry,[1] Aleena Banerji,[2] Jonathan A. Bernstein,[3] Marc A. Riedl,[4] Paolo Bajcic,[5*] Julia Morawski,[5*] Julie Ulloa,[6] Joshua Jacobs[7]

[1]AARA Research Center, Dallas, TX, USA; [2]Massachusetts General Hospital, Harvard University, Boston, MA, USA; [3]University of Cincinnati College of Medicine, Cincinnati, OH, USA; [4]University of California, San Diego, La Jolla, CA, USA; [5]KalVista Pharmaceuticals, a company of the Chiesi Group (*former employee), Framingham, MA, USA; [6]Outcomes Insights, Inc., Calabasas, CA, USA; [7]Allergy and Asthma Clinical Research, Walnut Creek, CA, USA

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Key Takeaways

Preparing and administering injectable on-demand treatment had a significant or severe impact on daily activities in

50% of real-world participants

Participant-reported reasons for switching to sebetralstat:

Convenience	No syringe	Can take in public	No injection pain
98%	82%	76%	67%

Background

- Until recently, all approved on-demand treatments for hereditary angioedema (HAE) were injectable[1]
- While effective, these treatments can be difficult to have on hand and painful to administer, leading patients to delay or forgo treatment[2]
- Delayed treatment is associated with more severe and prolonged attacks and increased risk of mortality[3]
- Sebetralstat is the first approved oral on-demand treatment for patients aged 12 years or older[4] and is included as a first-line option in international HAE treatment guidelines[5]

Objectives

- To evaluate participants' prior treatment history with injectable on-demand therapies and reasons for switching to sebetralstat
- To assess real-world treatment preference for orally administered sebetralstat for on-demand treatment of HAE attacks

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 LTP Use

- 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 (**Table 1**)

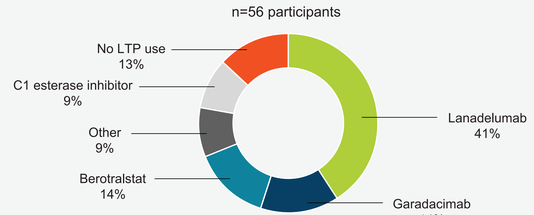
Table 1. Participant Demographics

		Participants n=56
	Age, mean (range), years	35.6 (12-64)
	Adults (≥18 years), n (%)	48 (86)
	Adolescents (12-17 years), n (%)	8 (14)
HAE type	Type 1: Deficiency of C1INH, n (%)	41 (73)
	Type 2: Dysfunction of C1INH, n (%)	15 (27)
Gender	Female, n (%)	35 (63)
	Male, n (%)	20 (36)
	Non-binary, n (%)	1 (2)
Ethnicity[a]	White/Caucasian, n (%)	49 (88)
	Hispanic/Latino, n (%)	6 (11)
	Black, n (%)	5 (9)
	Asian, n (%)	4 (7)

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

- 49 (88%) participants were receiving LTP, most commonly lanadelumab, which was taken by 23 (41%) participants (**Figure 1**)

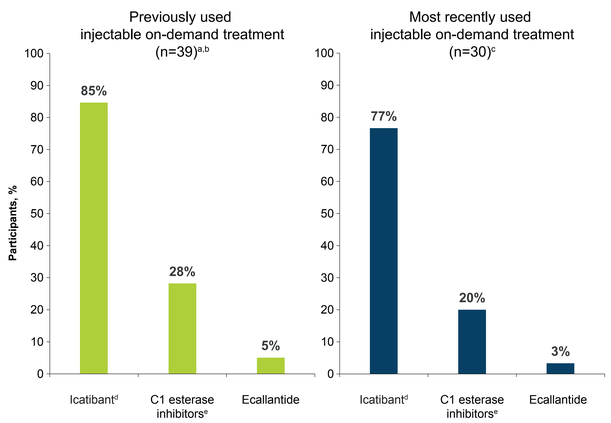
Figure 1. Long-Term Prophylaxis Use



Participant Injectable On-demand Treatment History at Baseline

- Of 56 participants, 49 (88%) previously used an injectable on-demand treatment before switching to sebetralstat, and 7 (13%) were treatment-naive
- 39 participants who switched to sebetralstat provided data on their previous HAE therapies
  - The most common injectable on-demand treatment was icatibant, used by 33 (85%) participants (**Figure 2**)
  - Among the 30 participants who had used injectable on-demand treatment during the 3 months before switching to sebetralstat, 23 (77%) used icatibant for their most recent attack (**Figure 2**)

Figure 2. Prior Injectable On-demand Treatment Used

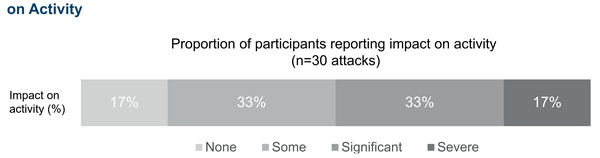


[a]39 of 49 participants who switched provided information on their previous therapies. [b]Some participants had access to more than 1 injectable on-demand treatment. [c]Among the 30 participants who had used an injectable on-demand treatment for an HAE attack in the 3 months before starting sebetralstat. [d]Includes both Firazyr and generic icatibant. [e]Includes Berinert, Cinryze, and Ruconest.
HAE, hereditary angioedema.

Preparation and Administration of Injectable On-demand HAE Treatment

- Among participants who provided information on their most recently treated attack (n=30):
  - Half (50%) of participants reported that preparation and administration of injectable on-demand therapy had a significant or severe impact on their daily activity during their most recently treated attack (**Figure 3**)

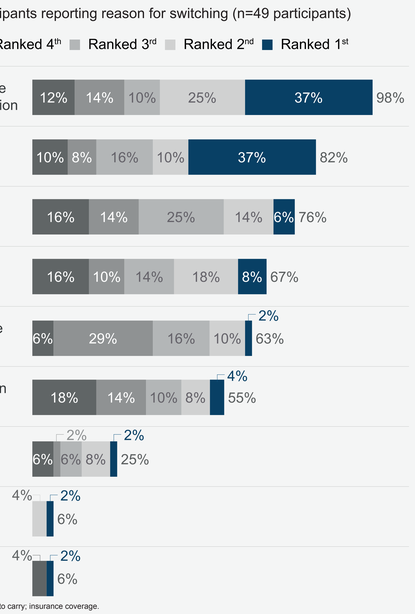
Figure 3. Impact of Preparing and Administering Injectable On-demand Therapy on Activity



Reasons for Switching from Injectable On-demand Treatment to Sebetralstat

- At baseline, 46 participants (82%) had treated a median (IQR) of 2 (1, 4) HAE attacks with sebetralstat
- The most frequently cited primary reasons for switching to sebetralstat were convenience of taking an oral tablet (37%) and not having to use needles or syringes (37%) (**Figure 4**)

Figure 4. Reasons for Switching to Sebetralstat



[a]Other specified as: I can travel easily with it; easy to carry; insurance coverage.

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