20. DEUTSCHER ALLERGIE KONGRESS

Sebetralstat for On-Demand Treatment of Hereditary Angioedema Attacks in European Participants: Interim Analysis from KONFIDENT-S

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Background and Objective

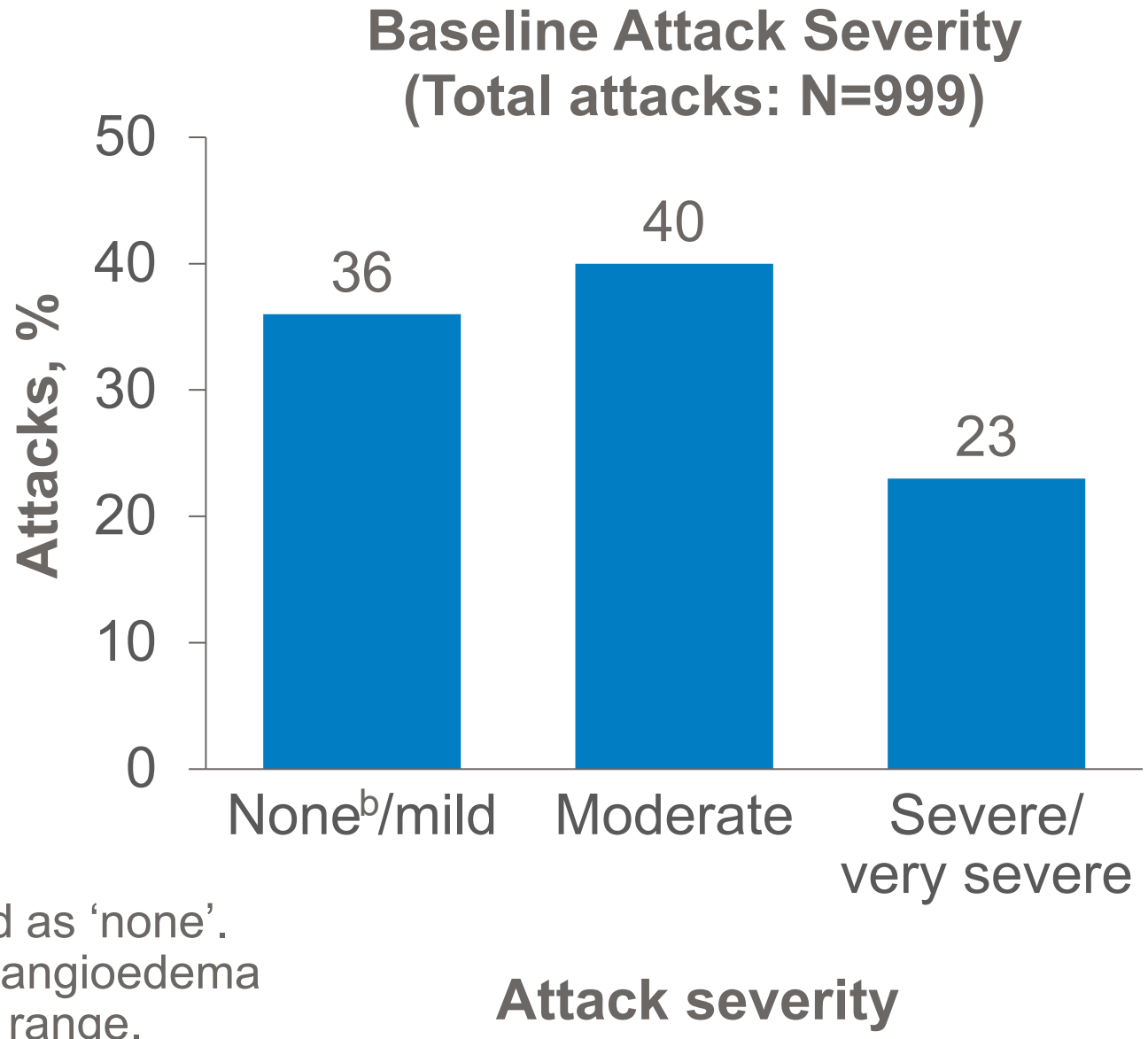
- Sebetralstat—an oral plasma kallikrein inhibitor—was recently approved in the EU for the on-demand treatment for HAE attacks in adults and adolescents aged ≥12 years[1,2]
- In the phase 3 KONFIDENT trial in patients with HAE, sebetralstat compared with placebo resulted in shorter times to beginning of symptom relief, reduction in attack severity, and complete attack resolution; sebetralstat was well tolerated[3]

Herein, we present safety and efficacy data from an interim analysis of the European subgroup of KONFIDENT-S, an ongoing, 2-year, open-label extension study of sebetralstat for the on-demand treatment of HAE

ClinicalTrial.gov: NCT05505916, EudraCT: 2021-001176-42.
EU, European Union; HAE, hereditary angioedema.
1. Sebetralstat USPI. 2025. 2. Sebetralstat SmPC (Ireland). 2025. 3. Riedl MA et al. *New Engl J Med.* 2024;391(1):32-43.

Baseline Patient and Attack Characteristics

Baseline patient characteristics	Total patients n=69[a]
Age, median (IQR), y	35.0 (22.0–48.0)
Sex, female, n (%)	39 (56.5)
Race, White, n (%)	64 (92.8)
BMI, median (IQR), kg/m²	25.5 (22.4–30.8)
HAE-C1INH type, n (%)	
Type 1	66 (95.7)
Type 2	3 (4.3)



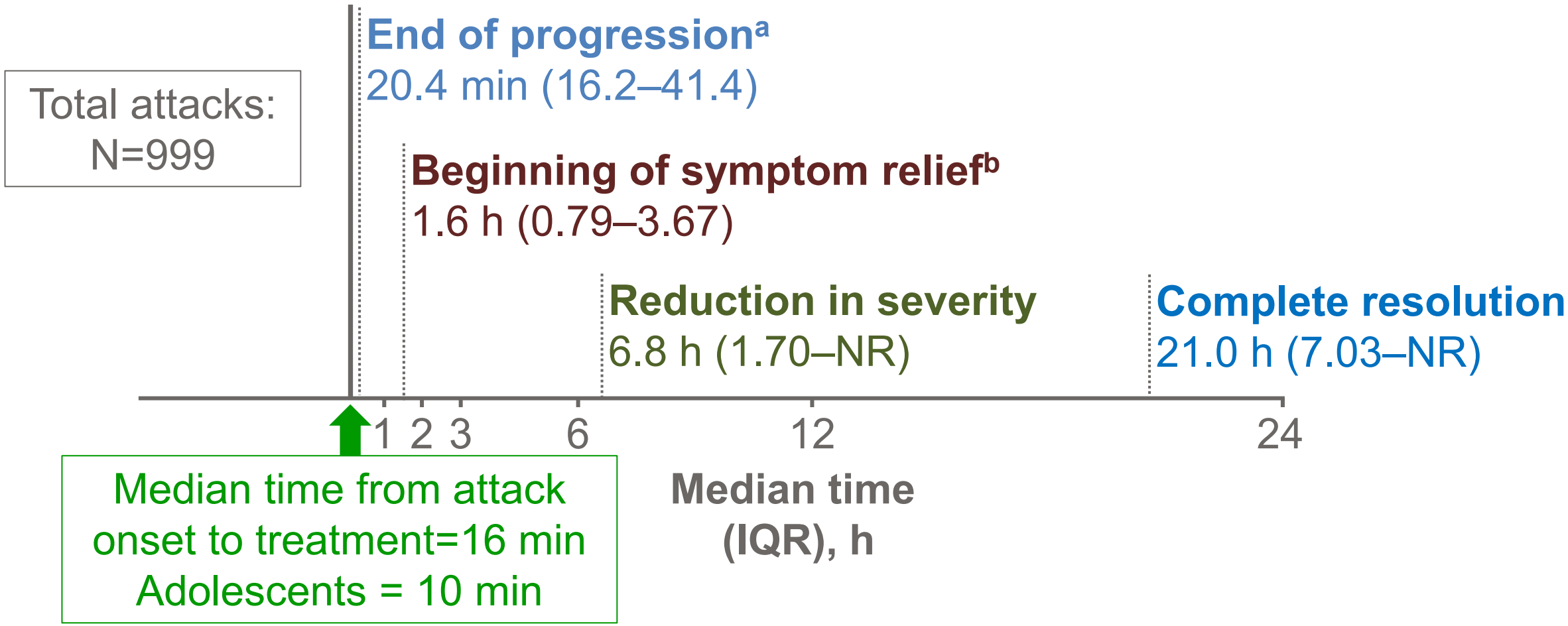
Data cutoff: September 14, 2024.
[a]Germany, n=9 (13%). [b]1.2% of attacks reported as 'none'.
BMI, body mass index; HAE-C1INH, hereditary angioedema due to C1 inhibitor deficiency; IQR, interquartile range.

Safety Outcomes After First Dose of Sebetralstat

Participants experiencing TEAE, n (%)	Total n=69
Any TEAE	40 (58.0)
Treatment related[a]	6 (8.7)
Any TEAE ≤3 days of sebetralstat administration	27 (39.1)
Any grade ≥3 TEAE	6 (8.7)
Treatment related	0
Any serious TEAE	6 (8.7)
Treatment related	0
Any TEAE leading to hospitalization	5 (7.2)
Any TEAE leading to study discontinuation	2 (2.9)
Any TEAE leading to death	0

Data cutoff: September 14, 2024.
[a]Six patients reported treatment-related TEAEs, including headache (n=3), influenza-like illness (n=3), vomiting (n=3), skin burning sensation (n=2), myalgia (n=2), and tremor (n=1).
TEAE, treatment-emergent adverse event.

Timing of Efficacy Outcomes of Sebetralstat-treated Attacks



Data cutoff: September 14, 2024. [a]End of progression (post hoc) defined as the time when the worst attack severity was recorded on the PGI-S scale for attacks treated with sebetralstat. [b]PGI-C rating of at least “A little better” for ≥2 consecutive time points (with missing data entries in between) ≤12 hours of first sebetralstat dose. IQR, interquartile range; NR, not reached; PGI-C, Patient Global Impression of Change; PGI-S, Patient Global Impression of Severity.

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