Attack-Free Status in the HELP OLE: long-term lanadelumab prophylactic treatment for 12 months or longer

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This abstract was previously presented at American College of Allergy, Asthma & Immunology 2021 Annual Scientific Meeting and published in *Ann Allergy Asthma Immunol* 127(5 Suppl):S29.

The HELP OLE study was sponsored by Shire Human Genetic Therapies, Inc., a Takeda company, Lexington, MA, USA.
Disclosures: M.A. Riedl has received research grants from BioCryst, CSL Behring, Pharming, and Takeda; consulting fees from Adverum, Attune, BioCryst, CSL Behring, Ionis, KalVista, Pharming, and Takeda; payments for lectures from CSL Behring, Pharming, and Takeda; and is an advisory board member of the US Hereditary Angioedema Association. J.A. Bernstein has been a clinical investigator for BioCryst, CSL Behring, Pharming, and Takeda; speaker for CSL Behring, Pharming, and Takeda; consultant for BioCryst, CSL Behring, Fresenius Kabi, Kalvista, Pharming, and Takeda; and is an advisory board member of the US Hereditary Angioedema Association. J.T Anderson is a speaker bureau member for CSL Behring, Pharming, and Takeda; and has received consultancy fees from and is a clinical trial investigator for BioCryst, CSL Behring, Pharming, and Takeda. S. Juethner and M. Yu are employees of and hold stock/options in Takeda. J. Rayamajhi is a full-time employee of Phastar Inc., which was contracted by Takeda to conduct the statistical analyses presented in this poster. W.R. Lumry is a member of advisory boards for BioCryst, CSL Behring, and Takeda; has received research grants from BioCryst, CSL Behring, Ionis, and Takeda; consulting fees from BioCryst, CSL Behring, Fresenius Kabi, Pharming, and Takeda; payments for lectures from CSL Behring, Pharming, and Takeda; and is an advisory board member of the US Hereditary Angioedema Association.

Introduction In the HELP OLE (NCT02741596), attack-free periods of ≥6 months and ≥12 months were achieved by 81.8% and 68.9% of patients in the overall population, respectively (regular dosing period for rollovers). Herein we analyze the attack-free status for patients treated for ≥12 months.

Methods Patients ≥12 years old with HAE-1/2 who continued from HELP (NCT02586805) (rollovers) received lanadelumab 300mg on Day 0, then 300mg Q2W after the first attack (regular dosing period). Newly enrolled patients (non-rollovers) received 300mg Q2W from Day 0. Patients were treated for up to 33 months.

Results 212 patients (109 rollovers, 103 non-rollovers) were enrolled. The mean (range) exposure was 29.6 (1.4–34.2) months. Between month 12 to <month 18 of treatment, 69.3% of the patients were attack free (64.9% rollovers [n=97]; 73.7% nonrollovers [n=95]). Between month 18 to <month 24 of treatment, 69.4% of patients were attack-free (69.9% rollovers [n=93]; 68.8% nonrollovers [n=93]). Between month 24 to <month 30 of treatment, 71.4% of patients were attack-free (74.2% rollovers [n=89]; 68.6% nonrollovers [n=86]). Among patients treated for ≥12 months (97 rollovers, 95 nonrollovers), 39.6% were attack-free from Day 0 to month 30. From month 12 to end of treatment (n=192), 55.2% of patients were attack-free. The mean maximum duration of the attack-free period was 13.8 months. Patients were attack-free for a mean of 98.6% of days.

Conclusion: In the HELP OLE, a consistent percentage of patients were attack-free within fixed 6-month intervals from Months 12-30, demonstrating sustained efficacy of lanadelumab in long-term prophylactic treatment of HAE.