

CENDAKIMAB EFFICACY AND SAFETY IN ADULT AND ADOLESCENT PATIENTS WITH EOSINOPHILIC ESOPHAGITIS: 24-WEEK RESULTS FROM THE RANDOMIZED, PLACEBO-CONTROLLED, PHASE 3 STUDY

Yasuhiko Abe

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Presentation

Endoscopy

IBD

Mechanisms & Personalised Medicine

Oesophagus

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Phase 3 trial demonstrates that cendakimab 360 mg weekly significantly improved dysphagia, eosinophil counts, and endoscopic features in adults and adolescents with active eosinophilic esophagitis at 24 weeks.

KEY POINTS

- Cendakimab 360 mg weekly reduced dysphagia days by 6.1 versus 4.2 with placebo (difference ± 1.9 days, 95% CI ± 3.0 to ± 0.8 , $P=0.0005$) and achieved histologic response (≤ 6 eosinophils/hpf) in 28.6% versus 2.2% with placebo (difference 26.4%, 95% CI 20.6 to 32.2, $P<0.0001$).
- Histologic response below 15 eosinophils/hpf was achieved in 43.1% of cendakimab-treated patients versus 3.1% with placebo ($P<0.0001$), and endoscopic severity (EREFS score) improved by ± 5.2 versus ± 1.2 with placebo ($P<0.0001$).
- Efficacy in the steroid inadequate responder or intolerant subgroup (approximately 65% of patients) was comparable to the overall population.
- Adverse events related to study drug occurred in 30.3% with cendakimab and 18.9% with placebo, with discontinuations due to adverse events in 1.4% and 0.7%, respectively, and no deaths.
- Cendakimab is a monoclonal antibody that neutralizes IL-13 by blocking binding to both IL-13R α 1 and IL-13R α 2 receptors.

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