COMPARATIVE PHARMACOKINETICS, SAFETY, AND TOLERABILITY OF A SINGLE DOSE OF CENDAKIMAB IN HEALTHY CHINESE AND US PARTICIPANTS

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UEG Week Vienna 2024 | Poster

Oesophagus

October 13, 2024

Two phase 1 trials in healthy Chinese and US participants demonstrated that single-dose subcutaneous cendakimab (360 mg or 720 mg), an IL-13 monoclonal antibody under development for eosinophilic esophagitis, was safe and well tolerated with dose-proportional pharmacokinetics and consistent profiles across populations.

KEY POINTS

- Cendakimab is a humanized monoclonal antibody that blocks IL-13 interaction with its receptors and is in clinical development for eosinophilic esophagitis, a chronic Type 2 inflammatory disease
- In the China study (NCT05638282), geometric mean Cmax, AUC□, and AUC0-T increased in a dose-proportional manner between 360 mg and 720 mg doses, with slow absorption (median Tmax 96 and 143 hours) and mean half-life of approximately 535–565 hours
- The 360 mg dose produced consistent pharmacokinetic, safety, and tolerability profiles in both the Chinese and US populations, supporting use of similar doses across both groups
- Antidrug antibodies were detected in 50% of Chinese participants and 16% of US participants, mostly with low titer, and did not impact safety or pharmacokinetics
- No deaths, serious adverse events, or discontinuations due to adverse events occurred in either study

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