EFFICACY AND SAFETY OF GUSELKUMAB IN PERIANAL FISTULIZING CROHN'S DISEASE: WEEK 48 RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED FUZION TRIAL

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The Phase 3 FUZION trial demonstrated that guselkumab, an IL-23p19 inhibitor, achieved sustained combined clinical and radiological fistula remission in 31% of patients with perianal fistulizing Crohn's disease at week 48, maintaining efficacy from the primary week 24 endpoint.

KEY POINTS

- Guselkumab met the primary endpoint at week 24 with combined fistula remission rates of 28% versus 10% for placebo (p=0.007 for 100mg Q8W, p=0.013 for 200mg Q4W), and this efficacy was sustained at week 48 with 31% achieving combined remission.
- Clinically assessed fistula response rates improved from 34% at week 24 to 41% at week 48 in the combined guselkumab group.
- Through week 48, adverse events occurred in 71% to 77% of guselkumab-treated patients versus 83% on placebo, with serious adverse events in 8% to 16% and no new safety signals identified.
- The study enrolled 286 patients with at least one active draining perianal fistula confirmed by MRI, CDAI less than 350, and prior inadequate response to conventional or advanced therapies; 90% completed treatment through week 48.
- Efficacy was maintained or improved across all endpoints at week 48, supporting continued use of guselkumab for durable fistula remission in this difficult-to-treat phenotype.

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