



FUZION Phase 3 results support Tremfya for the treatment of perianal fistulizing Crohn's disease

Market Event Summary

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Tremfya breaks new ground in fistulizing Crohn's disease with Phase 3 success

Background

- Perianal fistulizing Crohn's disease is a severe, high-burden manifestation affecting ~25% of Crohn's disease patients; it is characterized by pain, persistent drainage, recurrent abscesses, and frequent surgical interventions, with limited durable treatment options and substantial impact on quality of life.
- Infliximab is the only biologic specifically approved for fistulizing Crohn's disease; however, durable fistula closure remains challenging, highlighting a significant unmet need for more effective therapies.

Event

- Johnson & Johnson Innovative Medicine, on May 5, 2026, presented Phase 3 FUZION (NCT05347095)—the first randomized controlled trial demonstrating efficacy of an IL-23p19 antagonist in perianal fistulizing Crohn's disease—at DDW 2026, with Tremfya demonstrating significantly higher week 24 combined fistula remission vs. placebo.
- Combined fistula remission (complete closure of draining fistulas with no MRI-detected fluid collections) was achieved in 28.3% of patients with Tremfya 100 mg Q8W and 27.0% with 200 mg Q4W vs. 10.3% for placebo; safety findings aligned with the established Tremfya profile in Crohn's disease.

Clarivate's takeaways

IL-23 challenges anti-TNF dominance

- Perianal fistulizing Crohn's disease represents a distinct, high-unmet-need subset in which anti-TNFs remain the primary biologic option despite suboptimal long-term outcomes. By demonstrating efficacy in this underserved population, Tremfya can extend beyond luminal Crohn's disease into a niche segment with limited competition and high clinical demand.
- TREMFYA's Phase 3 success introduces IL-23 inhibition as a mechanism in this setting, with FUZION marking the first positive randomized dataset in ~20 years and potentially expanding treatment options and influencing future therapeutic strategies.
- Fistulizing Crohn's disease remains difficult to treat, particularly in patients who have failed or are refractory to anti-TNFs, creating demand for therapies with novel mechanisms such as IL-23 inhibitors. The positive FUZION data may increase clinician interest in IL-23 inhibitors as potential alternatives in this setting; however, broader adoption will depend on demonstrating sustained long-term remission, consistent real-world effectiveness, and clear differentiation vs. established biologics in terms of efficacy, safety, and treatment convenience.

About the author



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In her role at Clarivate, Ms. Aarushe brings nearly five years of experience in market research. Prior to joining Clarivate, she worked at a market research and consulting firm, where she gained experience in delivering client-focused insights and strategic analyses. She has expertise in competitive intelligence, clinical trial analysis, pipeline assessment, secondary research, and competitive landscape evaluation. She holds both a master's and a bachelor's degree in Pharmacy from Amity University.

Clarivate coverage of Crohn's disease

- Disease Landscape & Forecast: Crohn's disease (G7), providing comprehensive market insights
- Epidemiology: Total and diagnosed prevalence data for various population segments of Crohn's disease across the mature markets
- Access & Reimbursement (US): Evaluates payer coverage, restriction policies, and reimbursement dynamics shaping market access for Crohn's disease therapies
- Unmet Need: Crohn's disease (US / EU), including an Excel-based target product profile simulator
- Current Treatment: Physician Insights (US): Explores the current prescribing trends of gastroenterologists treating Crohn's disease



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