

**Darvadstrocel in Patients With Crohn's Disease With Complex Perianal Fistulas: The ADMIRE CD II Phase 3 Randomized Trial**

Multicenter double-blind, randomized, placebo-controlled phase 3 trial.

Adult patients with CD and complex perianal fistulas with  $\leq 2$  internal openings and  $\leq 3$  external openings and inadequate response to immunosuppressants/biologics were randomized 1:1 to receive darvadstrocel ( $120 \times 10^6$  stem cells in 24 mL sterile buffered solution) or placebo.

Both groups underwent curettage and seton placement 2-3 weeks before treatment administration followed by a further fistula curettage, seton removal and closure of the internal opening.

Primary endpoint: Combined remission (closure of all treated external openings and absence of  $>3$ cm collections) at week 24

**Results: N=568**

- At week 24, combined remission was achieved in 48.8% darvadstrocel vs 46.3% placebo,  $p=0.571$ .
- No differences were found in clinical remission or time to clinical remission between groups.

Conclusion: This trial did not meet its primary endpoint of combined remission at week 24. No new safety signals were identified for darvadstrocel

**Combined remission at week 24**