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Summary

MIRIKIZUMAB EFFECT ON BOWEL URGENCY RESOLUTION IN A RANDOMISED CONTROLLED PHASE 3 TRIAL OF PARTICIPANTS WITH CROHN'S DISEASE

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In the phase 3 VIVID-1 trial, mirikizumab (an IL-23 p19 inhibitor) demonstrated nominally significantly greater improvements in bowel urgency compared to placebo in adults with moderately-to-severely active Crohn's disease at weeks 12 and 52.

KEY POINTS

- At baseline, 94.5% of 1065 enrolled patients had UNRS ≥3 and 66.0% had UNRS ≥6, with median UNRS of 6.9, indicating high bowel urgency.
- Among patients with baseline UNRS ≥3, mirikizumab achieved clinically meaningful improvement (>3-point reduction in UNRS) in 41.5% at week 12 and 55.0% at week 52, versus 26.9% and 20.4% with placebo (p=0.0004 and p<0.0001, respectively).
- Bowel urgency remission (UNRS ≤2) at week 52 was achieved in 38.2% of mirikizumab-treated patients versus 11.3% of placebo patients among those with baseline UNRS ≥3 (p<0.0001).
- Similar nominally significant benefits were observed in patients with more severe baseline urgency (UNRS ≥6), with week 52 CMI rates of 60.9% for mirikizumab versus 22.6% for placebo (p<0.0001).

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