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Summary

DURABILITY OF SYMPTOMATIC AND CLINICAL OUTCOMES IN OZANIMOD-TREATED PATIENTS BY ENDPOINTS OF INCREASING OBJECTIVITY AT TRUE NORTH WEEK 52: INTERIM ANALYSIS OF THE TRUE NORTH OPEN-LABEL EXTENSION STUDY

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Interim analysis of the True North open-label extension study found that symptomatic and clinical outcomes with ozanimod in ulcerative colitis were sustained up to 94 weeks regardless of which endpoint of increasing objectivity was achieved at week 52.

KEY POINTS

- Among 131 ozanimod clinical responders at True North week 52 who continued in the open-label extension, 87% completed week 46 and 72% completed week 94.
- Partial and total Mayo scores, symptomatic clinical responses, and maintenance of clinical response were similar and sustained over 94 weeks regardless of the endpoint achieved at week 52.
- Achievement of clinical remission at week 52 provided incremental benefit over clinical response for maintaining clinical remission and corticosteroid-free remission at week 94, but more objective endpoints such as complete endoscopic healing, histologic remission, mucosal healing, or stringent mucosal healing provided no additional benefit.
- Clinical outcomes from week 46 to week 94 remained stable with clinical response rates of 71.4 to 78.4%, clinical remission rates of 65.2 to 70.0%, and corticosteroid-free remission rates of 63.6 to 70.6%.
- This analysis may be most relevant to gastroenterologists managing patients with moderately to severely active ulcerative colitis on long-term ozanimod therapy and considering treatment targets.

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