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Summary

DEEP REMISSION IN GUSELKUMAB-TREATED PARTICIPANTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE THROUGH 3 YEARS: RESULTS FROM THE GALAXI 2 & 3 STUDIES

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In the pooled GALAXI 2 & 3 phase 3 studies, guselkumab maintained deep remission (clinical remission plus endoscopic remission) through 3 years in participants with moderately to severely active Crohn's disease, with 63.6% of those in deep remission at Week 48 sustaining it at Week 144.

KEY POINTS

- Among 184 participants (31.6%) achieving deep remission at Week 48, 57.1% maintained it at Week 96 and 63.6% at Week 144, with similar rates across bionaive and biologic-experienced subgroups.
- Deep remission was defined as CDAI less than 150 plus SES-CD 4 or less with at least a 2-point reduction from baseline and no subscore greater than 1, a stringent endoscopic threshold.
- Participants in deep remission at Week 48 had higher IBDQ remission rates at Weeks 96 and 144 (68.5%, 67.4%) compared to those not in deep remission (40.5%, 40.2%).
- Rates of CD-related hospitalizations or surgeries through Weeks 96 and 144 were lower in participants in deep remission at Week 48 (2.2%, 2.7%) versus those not in deep remission (10.8%, 14.6%).
- Two guselkumab maintenance regimens were evaluated: 200mg IV q4w then 100mg SC q8w (N=286) and 200mg IV q4w then 200mg SC q4w (N=296), with numerically similar deep remission maintenance rates.
- The study used non-responder imputation as the primary analysis, treating missing data or discontinuation for any reason as treatment failure.

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