

EFFECTS OF SUBCUTANEOUS GUSELKUMAB INDUCTION AND MAINTENANCE ON HISTOLOGIC OUTCOMES IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE IN GRAVITI, A PHASE 3 DOUBLE-BLIND, PLACEBO-CONTROLLED, TREAT-THROUGH STUDY

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Poster

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Subcutaneous guselkumab induction and maintenance therapy demonstrated significantly higher rates of histologic response and remission compared to placebo at weeks 12 and 48 in the GRAVITI trial of patients with moderately to severely active Crohn's disease.

KEY POINTS

- At week 12, guselkumab 400 mg subcutaneous induction achieved histologic response in 52.0% versus 34.0% for placebo (treatment difference 17.7%, 95% CI 6.2-29.2, $p=0.003$) and histo-endoscopic response in 30.9% versus 12.0% (treatment difference 18.9%, 95% CI 10.7-27.2, $p<0.001$).
- At week 48, guselkumab maintenance with 100 mg every 8 weeks or 200 mg every 4 weeks achieved histologic response in 49.5% and 63.6% respectively versus 10.6% for placebo (both $p<0.001$).
- Histologic remission at week 48 was achieved in 44.3% of patients in both guselkumab maintenance groups compared to 10.3% for placebo (both treatment differences approximately 34%, $p<0.001$).
- Histologic outcomes were assessed using Robarts Histopathology Index, Global Histologic Activity Score, and Geboes scoring with comparable results across scoring systems; endpoints were exploratory with nominal p-values not controlled for multiple comparisons.
- Gastroenterologists and researchers evaluating treatment options and endpoints for moderately to severely active Crohn's disease would benefit from this data on histologic and composite histo-endoscopic outcomes.

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