

Key Takeaways

- ## Background

 In the Phase 3 ASTRO study, GUS SC induction → SC maintenance was also efficacious in UC⁵

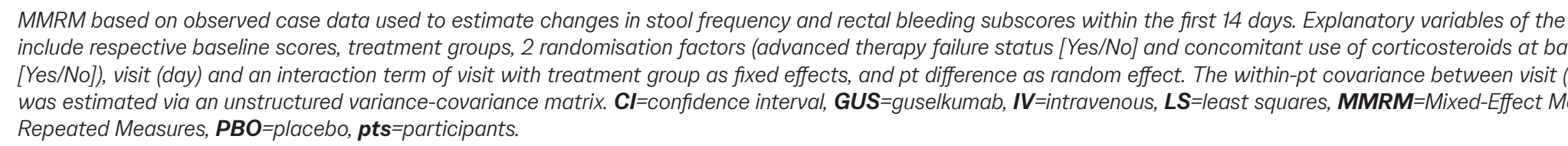
 We evaluated early symptomatic improvement and remission following IV GUS induction in participants (pts) with moderately to severely active UC from the Phase 3 QUASAR induction study

QUASAR Phase 3 Induction Study Design (Through Week 12)³

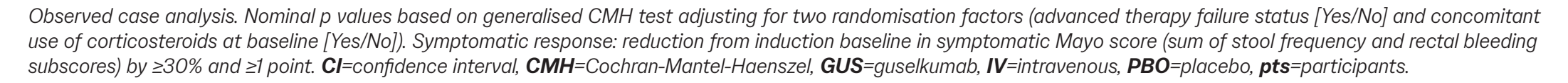
^aDefined as modified Mayo score of 5–9 with a Mayo rectal bleeding subscore ≥ 1 and a Mayo endoscopic subscore ≥ 2 based on central review. **GUS**=guselkumab, **IV**=intravenous, **LS**=least squares, **PBO**=placebo, **PRO-2**=patient-reported outcome-2, **pts**=participants, **R**=randomized, **SC**=subcutaneous, **UC**=ulcerative colitis

Data shown are mean (SD) unless otherwise noted. *N=416; *N=278; *N=370; *N=253. *Denominator is pts without a history of BtO/JAK-IR. BtO/JAK-IR=inadequate response or intolerance to biologic and/or Janus kinase inhibitor, CRP=C-reactive protein, GUS=guselkumab, IQR=interquartile range, IV=intravenous, pts=participants, PBO=placebo, q4w=every 4 weeks, SD=standard deviation, UC=ulcerative colitis.

- By Day 6, pts receiving GUS had greater improvements in stool frequency and rectal bleeding compared with PBO

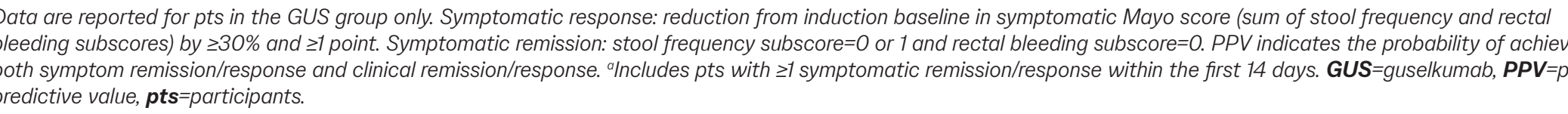


- By Day 6, significantly greater proportions of pts receiving GUS vs PBO achieved symptomatic response



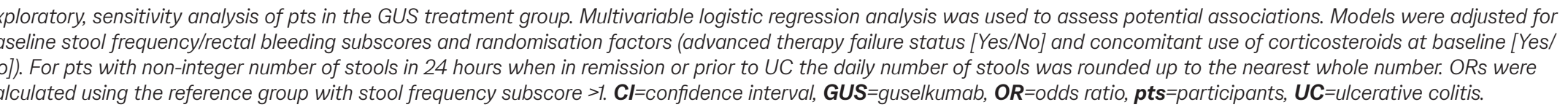
Observed case analysis. Nominal *p* values based on generalised CMH test adjusting for two randomisation factors (advanced therapy failure status [Yes/No] and concomitant use of corticosteroids at baseline [Yes/No]). CI=confidence interval, CMH=Cochran-Mantel-Haenszel, GUS=guselkumab, IV=intravenous, PBO=placebo, pts=participants.

- Day 14 symptomatic response and remission predict Week 12 clinical response with high accuracy



Data are reported for pts in the GUS group only. Symptomatic response: reduction from induction baseline in symptomatic Mayo score (sum of stool frequency and rectal bleeding subscores) by $\geq 30\%$ and ≥ 1 point. Symptomatic remission: stool frequency subscore=0 or 1 and rectal bleeding subscore=0. PPV indicates the probability of achieving both symptom remission/response and the indicated Week 44 endpoint. *Includes pts with ≥ 1 symptomatic remission/response within the first 14 days. GUS=guselkumab, BDQ=Inflammatory Bowel Disease Questionnaire, PPV=positive predictive value, pts=participants, QoL=quality of life.

- Day 3 normalisation of stool frequency (stool frequency subscore ≤ 1) is associated with achieving long-term outcomes



- At Week 2, rates of symptomatic response and remission were similar with IV (QUASAR) and SC (ASTRO) GUS induction

