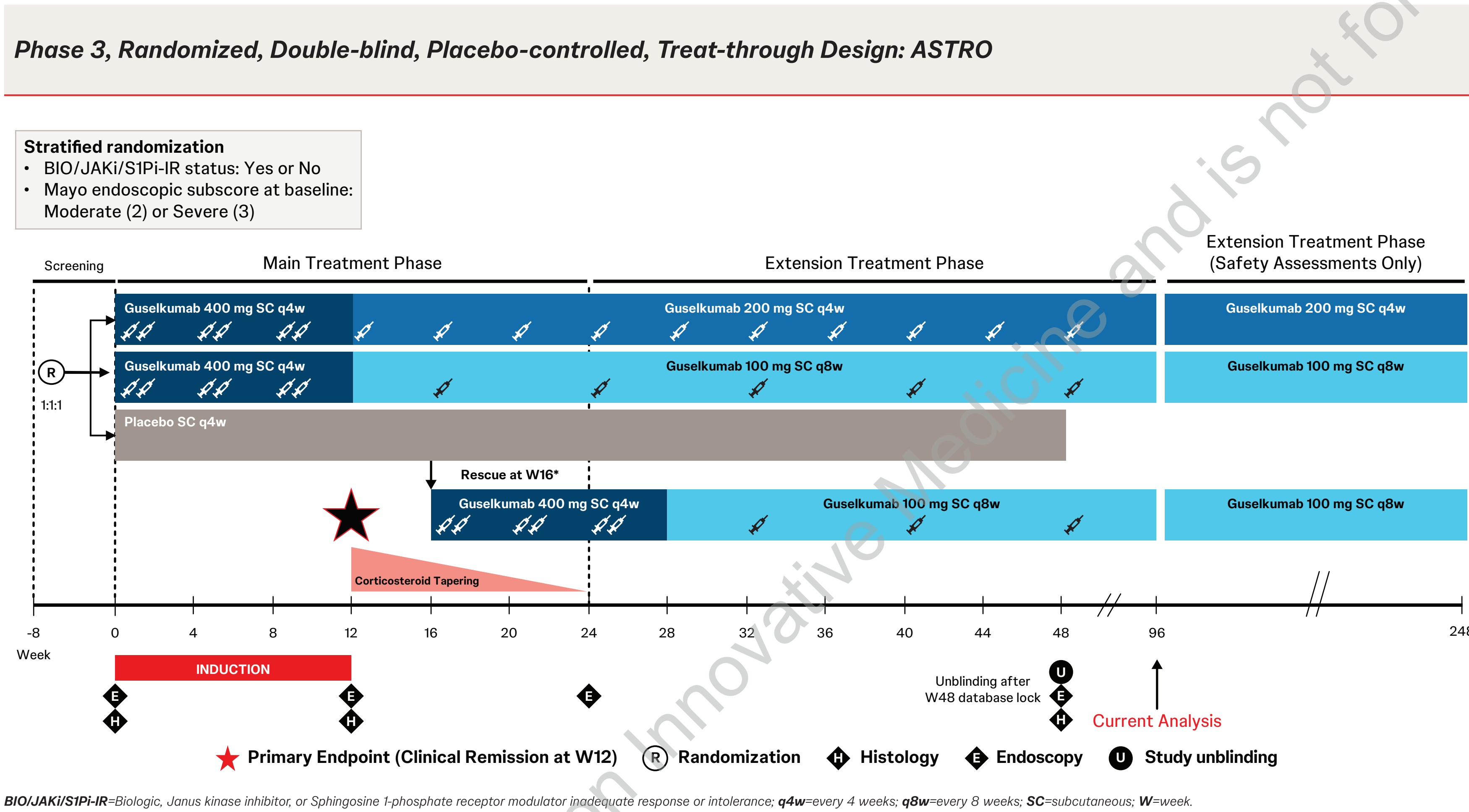


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Methods

- Patients (Pts) were randomized at W0 to receive GUS 400 mg SC q4w (x3)→GUS 100 mg SC q8w, GUS 400 mg SC q4w (x3)→GUS 200 mg SC q4w, or placebo SC
- Starting from W16, pts meeting the following rescue criteria at W12 received blinded GUS SC treatment*:
 - No improvement in Mayo endoscopic subscore at W12 compared with baseline **AND**
 - <2 point improvement in partial Mayo score at W12 and W16 compared with baseline
- * Rescue treatment for GUS arms:**
Sham rescue with matching placebo SC to maintain the blind at W16, W20, and W24. Efficacy and safety data from rescue pts are not reported here.
- Pts who benefited from treatment at W24 were eligible for the study extension with treatment to be continued through W248
- Upon study unblinding after W48, placebo pts who were not rescued with GUS discontinued treatment; therefore, placebo efficacy data are not reported
- Symptomatic remission, Ulcerative Colitis-Patient-reported outcomes Signs and Symptoms (UC-PRO/SS) assessments of bowel urgency and abdominal pain, and levels of inflammatory biomarkers C-reactive protein (CRP) and fecal calprotectin were assessed through W96 in pts who continued treatment beyond W48. No endoscopic or histologic outcomes were assessed at W96.
 - Symptomatic remission is defined as a stool frequency subscore of 0 or 1 and not increased from baseline, and a rectal bleeding subscore of 0 as assessed by two PRO questions from Mayo Score
 - No bowel urgency is defined as a rounded daily average (within 1 week) score of 0 in question Q7 of the UC-PRO/SS. Q7: In the past 24 hours, did you feel the need to have a bowel movement right away?
 - No abdominal pain is defined as a rounded daily average (within 1 week) score of 0 in question Q8 of the UC-PRO/SS. Q8: In the past 24 hours, did you feel pain in your belly?
- Statistical Analysis
 - Efficacy analyses were based on pts who were randomized to GUS and continued treatment after W48
 - "As observed" analyses included pts who had data available at the analysis timepoint (no imputation for intercurrent events and missing data)
 - NRI (nonresponder imputation) analyses: pts who, prior to a/the designated timepoint, had an ostomy or colectomy or discontinued study agent due to lack of efficacy or an AE or worsening of UC were considered not to have achieved any of the binary efficacy endpoints at W96. For patients who discontinued study agent due to COVID-19-related reasons (excluding COVID-19 infection) or regional crisis, their observed values were used, if available. Pts who discontinued study agent prior to W96 due to other reasons were considered not to have achieved any of the binary efficacy endpoints at W96. Pts with insufficient data to calculate a binary efficacy endpoint at W96 were considered not to have achieved the endpoint at W96.
 - A cumulative safety analysis W0 through W96 included all treated pts



	Placebo	GUS 400 mg SC → 100 mg SC q8w	GUS 400 mg SC → 200 mg SC q4w
Full analysis set^a, N	139	139	140
Age in years, mean (SD)	39.5 (13.6)	42.1 (14.6)	43.6 (14.3)
Male, n (%)	90 (64.7%)	79 (56.8%)	87 (62.1%)
UC disease duration in years, mean (SD)	6.61 (6.2)	8.39 (7.3)	7.69 (6.4)
Modified Mayo score^b (0–9), mean (SD)	6.8 (11) ^c	6.8 (12)	6.6 (12)
Modified Mayo score of 7–9 (severe), n (%)	87 (63.0%) ^c	95 (68.3%)	77 (55.0%)
Mayo endoscopic subscore of 3 (severe), n (%)	78 (56.1%)	78 (56.1%)	78 (55.7%)
Extensive UC, n (%)	73 (52.5%)	69 (49.6%)	82 (58.6%)
C-reactive protein^d, median in mg/L (IQR)	3.8 (1.2; 10.9)	3.7 (1.3; 7.2)	4.7 (1.7; 9.1)
C-reactive protein^d >3 mg/L, n (%)	77 (55.4%)	75 (55.1%)	86 (61.4%)
Fecal calprotectin^e, median in mg/kg (IQR)	1749.0	1351.5	1594.0
Fecal calprotectin^e >250 mg/kg, n (%)	(617.0; 3202.0)	(609.0; 2805.0)	(838.0; 3336.0)
	119 (90.8%)	107 (84.9%)	119 (93.0%)

^aAll randomized pts who received at least 1 (partial or complete) dose of study intervention. ^bModified Mayo score, 3-component [stool frequency, rectal bleeding, and endoscopy subscores] Mayo score without the physician's global assessment. ^cBased on N=138. ^dBased on N=136 for placebo, N=136 for GUS 400 mg SC→100 mg SC q8w, N=140 for GUS 400 mg SC→200 mg SC q4w. ^eBased on N=131 for placebo, N=126 for GUS 400 mg SC→100 mg SC q8w, N=136 for GUS 400 mg SC→200 mg SC q4w. IQR=interquartile range. q4w=every 4 weeks; q8w=every 8 weeks. SC=subcutaneous. SD=standard deviation.

