Ulcerative Colitis-Related Medical Encounters in Patients Treated With Guselkumab: An Analysis of the QUASAR Phase 3 Induction Study

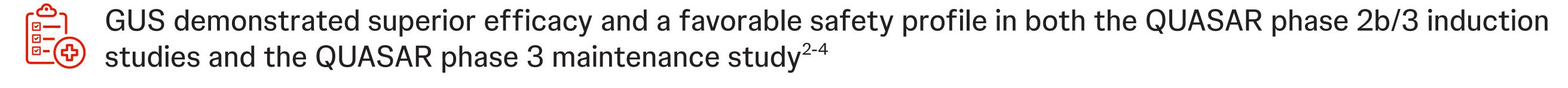
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Endoscopy

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Background

Guselkumab (GUS) is a selective, dual-acting interleukin (IL)-23p19 subunit inhibitor that potently blocks IL-23 and binds to CD64, a receptor on cells that produce IL-23¹



studies and the QUASAR phase 3 maintenance study²⁻⁴ Patients with ulcerative colitis (UC) have a high frequency of UC-related medical encounters⁵





To evaluate the rate of UC-related medical encounters among participants in the QUASAR phase 3 induction study

Methods

Study Design

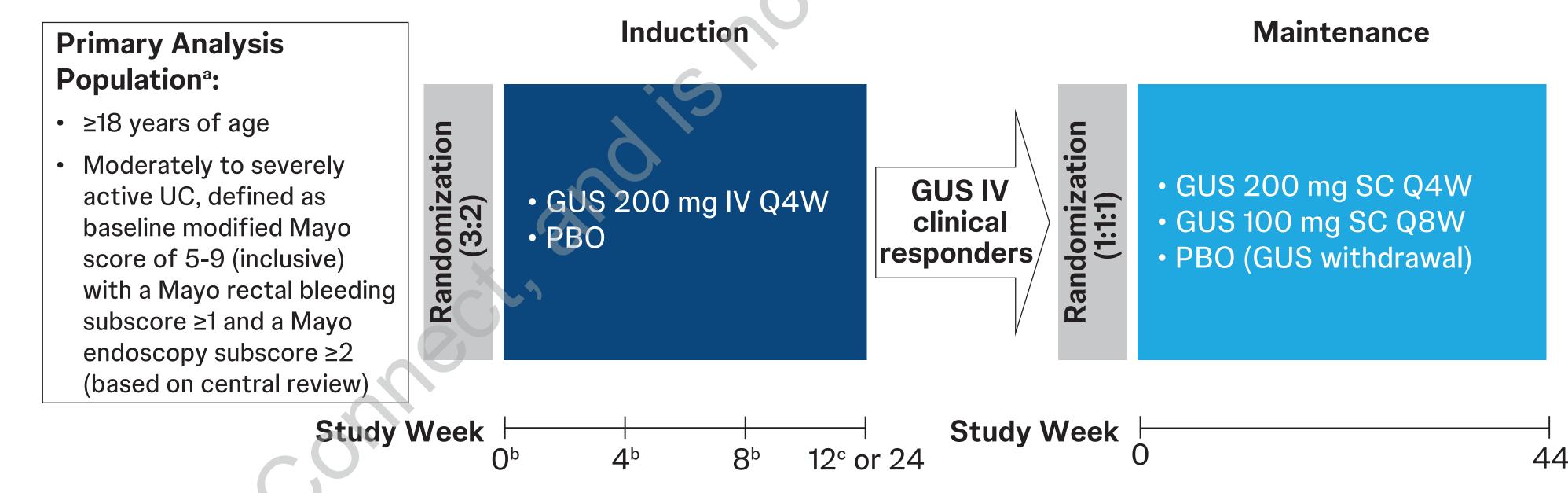
- QUASAR was a randomized, double-blind, placebo (PBO)-controlled, multicenter study
- In the phase 3 induction study (Weeks 0-12), participants were randomized (3:2) to receive either intravenous (IV) GUS 200 mg or PBO at Weeks 0, 4, and 8 (Figure 1)
- Clinical responders to the induction regimen (GUS or PBO) were to be enrolled in the maintenance phase of the study
- The proportions of participants with UC-related medical encounters through Week 12 were compared between the GUS and PBO groups
- Medical encounters were defined as having emergency department (ED) visits, hospitalizations, and/or surgeries (ostomy or colectomy)

Statistical Analysis

• Nominal p values were reported, with statistical significance defined as nominal p<0.05

Figure 1. QUASAR Phase 3 Induction and Maintenance Study Design

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steroids up to 20 mg/day dose of prednisone (or equivalent) were permitted. b. Study treatment administered. GUS=Guselkumab, IV=Intravenous, PBO=Placebo, Q4W=Every 4 weeks, Q8W=Every 8 weeks, R=Randomization, SC=Subcutaneous, UC=Ulcerative colitis.

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Key Takeaways

multicenter study showed that participants receiving GUS IV induction treatment had lower rates of UC-related ED visits and hospitalizations through Week 12 compared to those who received PBO

This randomized, double-blind, PBO-controlled,

These findings suggest that GUS may effectively reduce the occurrence of UC-related medical encounters in the short term, thereby potentially improving patient outcomes and reducing health care resource utilization in the long term

Results

Baseline demographic and disease characteristics were similar between the GUS and PBO groups

- The mean duration and severity of UC were similar between the GUS and PBO groups (Table 1)
- At baseline, a substantial proportion of participants were receiving oral corticosteroids, immunomodulatory drugs, or oral aminosalicylates at similar proportions in the GUS and PBO groups (Table 2)
- Nearly half of patients had a history of inadequate response or intolerance to biologics and/or Janus kinase (JAK) inhibitors

Through Week 12, UC-related ED visits and hospitalizations were reported in fewer participants in the GUS group than in the PBO group (Figure 2)

- UC-related surgeries were observed at a similar rate in the GUS and PBO groups (2 [0.5%] and 2 [0.7%] participants, respectively; p=0.653)
- Overall, fewer participants in the GUS group experienced either a UC-related hospitalization or surgery compared with participants in the PBO group through Week 12

Table 1. Sociodemographic and Clinical Characteristics of Participants

Characteristics	GUS 200 mg (n = 421)	PBO (n = 280)	Total (N = 701)
Age (years), mean (SD)	41.0 (13.9)	39.8 (13.4)	40.5 (13.7)
Male, n (%)	238 (56.5)	161 (57.5)	399 (56.9)
Region, n (%)			
Asia	84 (20.0)	58 (20.7)	142 (20.3)
Eastern Europe	179 (42.5)	117 (41.8)	296 (42.2)
Rest of world	158 (37.5)	105 (37.5)	263 (37.5)
UC disease duration (years), mean (SD)	7.8 (7.7)	7.1 (6.5)	7.5 (7.3)
Extensive disease, n (%)	188 (44.7)	147 (52.5)	335 (47.8)
Modified Mayo score (0-9), mean (SD)	6.9 (1.1)	6.9 (1.1)	6.9 (1.1)
Modified Mayo score of 7-9 (severe), n (%)	274 (65.1)	178 (63.6)	452 (64.5)
Mayo endoscopy subscore of 3 (severe), n (%)	296 (70.3)	180 (64.3)	476 (67.9)
CRP, n	416	278	694
Median (IQR) in mg/L	4.3 (1.5-11.2)	3.8 (1.6-9.1)	4.2 (1.5-10.1)
Abnormal CRP (>3 mg/L), n (%)	248 (59.6)	160 (57.6)	408 (58.8)
Fecal calprotectin (mg/kg), n	370	253	623
Median (IQR) in mg/kg	1651.0 (647.0-3479.0)	1606.0 (654.0-3077.0)	1641.0 (647.0-3304.0)
Abnormal fecal calprotectin (>250 mg/kg), n (%)	333 (90.0)	225 (88.9)	558 (89.6)

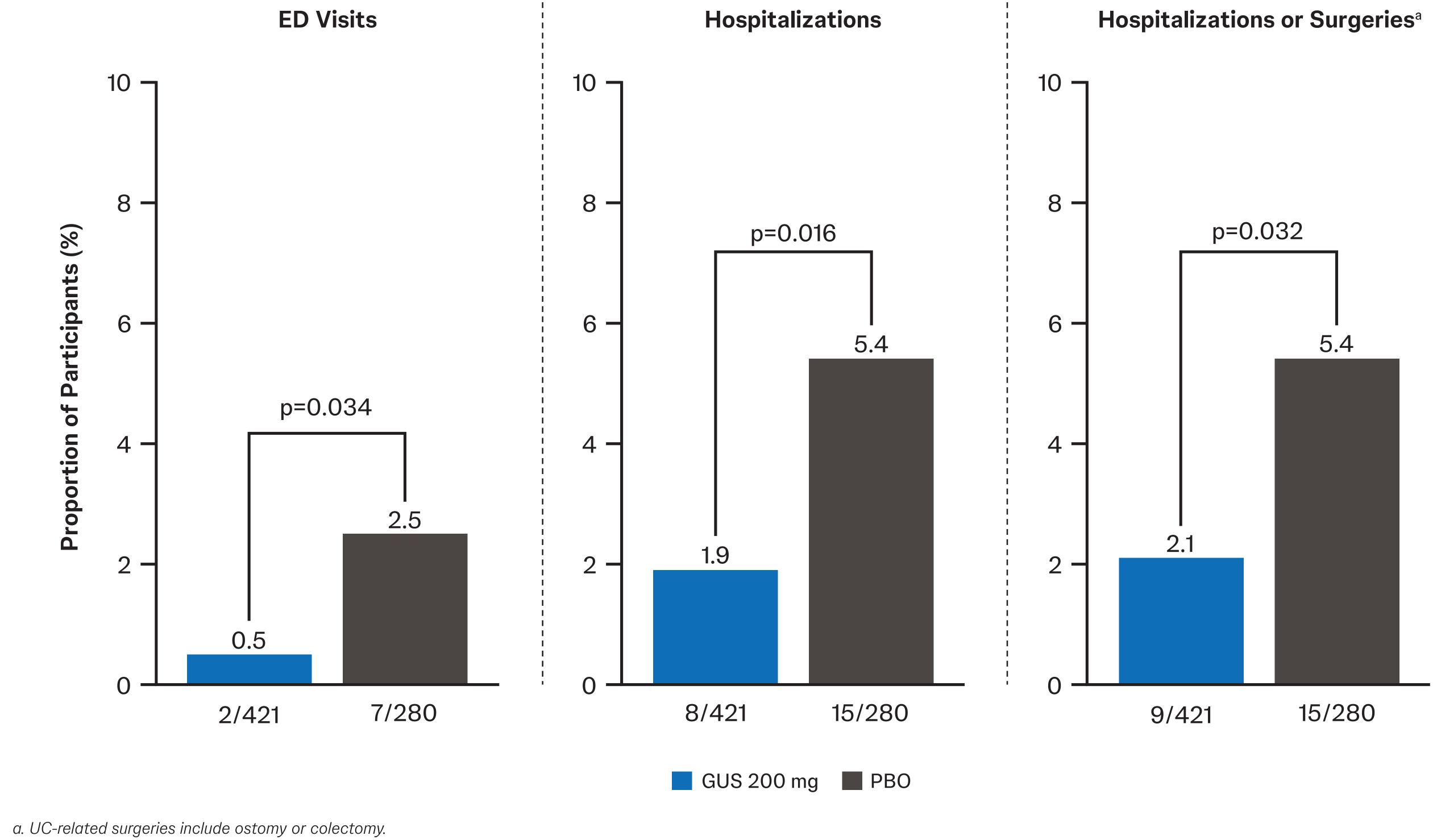
CRP=C-reactive protein, GUS=Guselkumab, IQR=Interguartile range, PBO=Placebo, SD=Standard deviation, UC=Ulcerative colitis

Table 2. UC-Related Treatments

Treatment type, n (%)	GUS 200 mg (n = 421)	PBO (n = 280)	Total (N = 701)
Baseline oral corticosteroid use	182 (43.2)	120 (42.9)	302 (43.1)
Baseline immunosuppressant use ^a	92 (21.9)	54 (19.3)	146 (20.8)
Baseline oral aminosalicylate use	304 (72.2)	204 (72.9)	508 (72.5)
No prior inadequate response or intolerance to a biologic ^b and/or JAK inhibitor	213 (50.6)	144 (51.4)	357 (50.9)
Biologic and/or JAK inhibitor naive	202 (94.8)	137 (95.1)	339 (95.0)
Prior inadequate response or intolerance to a biologic and/or JAK inhibitor	208 (49.4)	136 (48.6)	344 (49.1)
≥2 biologic and/or JAK inhibitor classes	99 (47.6)	64 (47.1)	163 (47.4)
2 biologic and/or JAK inhibitor classes	72 (34.6)	49 (36.0)	121 (35.2)
3 biologic and/or JAK inhibitor classes	27 (13.0)	15 (11.0)	42 (12.2)
By specific class			
Anti-TNF°	182 (87.5)	119 (87.5)	301 (87.5)
Integrin receptor antagonist (vedolizumab)°	112 (53.8)	74 (54.4)	186 (54.1)
JAK inhibitor (tofacitinib)°	40 (19.2)	22 (16.2)	62 (18.0)

sants included azathioprine, 6-mercaptopurine, and methotrexate. b. Biologic therapy included TNF-a antagonists and vedolizumab. c. Regardless of exposure, response, or intolerance status to other biologic and/or JAK inhibitor class(es)

Figure 2. Proportion of Participants With UC-Related Medical Encounters Through Week 12



ED=Emergency department, **GUS**=Guselkumab, **PBO**=Placebo, **UC**=Ulcerative colitis.

GUS=Guselkumab, JAK=Janus kinase, PBO=Placebo, TNF=Tumor necrosis factor, UC=Ulcerative colitis.