HEALTH-RELATED QUALITY OF LIFE WITH GUSELKUMAB INDUCTION AND MAINTENANCE THERAPY AS MEASURED BY PROMIS-29: RESULTS THROUGH WEEK 48 OF PHASE 2 GALAXI 1 STUDY

B0367

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BACKGROUND/OBJECTIVE

Patients with moderate to severe Crohn's disease experience GI as well as systemic symptoms that negatively impact their health-related quality of life (HRQOL).

In GALAXI-1, HRQOL was evaluated using the Patient-Reported Outcomes Measurement Information System (PROMIS)-29

Here we report HRQOL outcomes evaluated using the PROMIS-29 scores

METHODS

Definitions of Induction Response

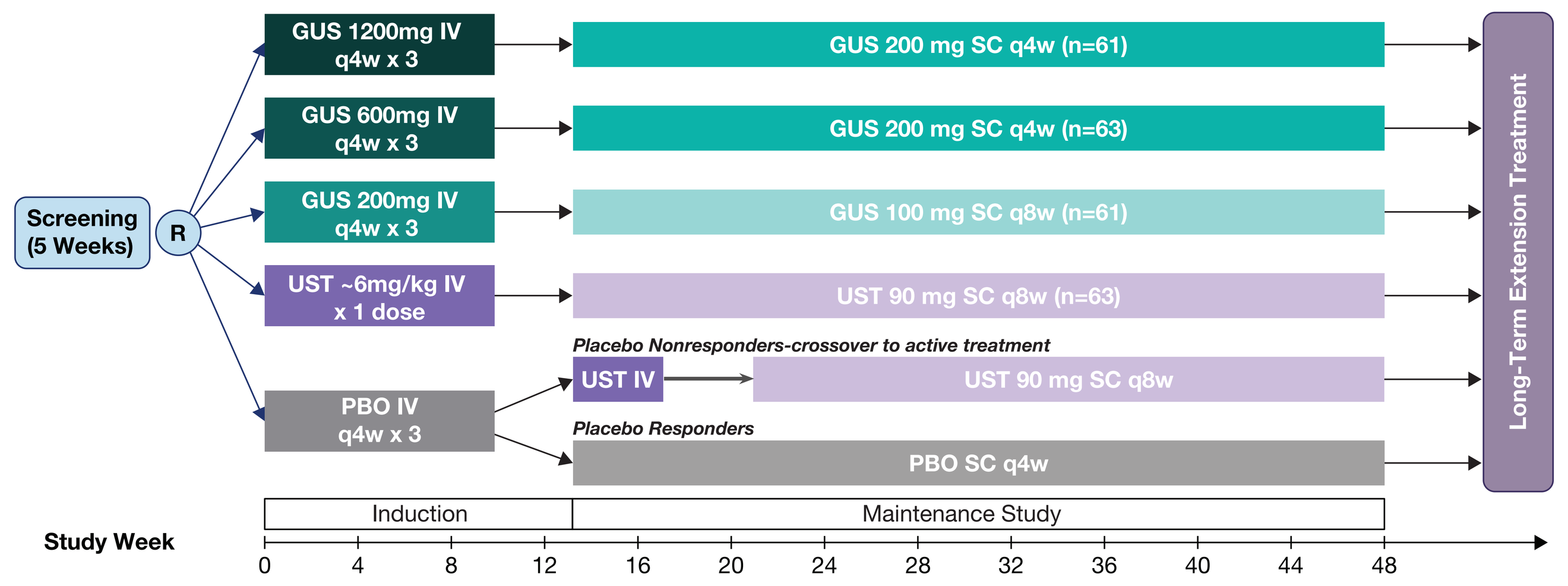
- GALAXI-1 is a phase 2, double-blind, placebo-controlled study of guselkumab (GUS), a selective IL-23 antagonist, for the treatment of patients with moderately to severely active Crohn's disease who had inadequate response or intolerance to conventional therapies (corticosteroid, immunosuppressant) and/or biologics (tumor necrosis factor antagonist, vedolizumab)
- PROMIS-29 consists of 7 domains and a pain intensity 0-10 numeric rating scale:
  1. depression
  2. anxiety
  3. physical function (higher scores indicate better outcomes)
  4. pain interference
  5. fatigue
  6. sleep disturbance
  7. social participation (higher scores indicate better outcomes)
- The raw score of each domain is converted into a standardized T-score with a general population mean of 50 and standard deviation (SD) of 10. Unless otherwise noted, lower scores indicate better outcomes

Clinically meaningful improvement is defined as ≥5-point (or 1/2 SD of population) improvement in each domain T-score and ≥3-point improvement in pain numeric rating scale score.

Statistical Methods

- Least squares (LS) mean changes from baseline were evaluated using two different models:
  - Weeks 8 and 12: LS mean changes from baseline and p-values for GUS vs PBO were based on an mixed-effect model repeated measure (MMRM) analysis of GUS, ustekinumab (UST) and placebo (PBO), including change from baseline in PROMIS-29 domain scores as the response and treatment group, visit, baseline PROMIS-29 domain score, history of inadequate response/intolerance to biologics status (yes, no), baseline CDAI stratification (≤300, >300), an interaction term of visit with treatment group and an interaction term of visit with baseline PROMIS-29 domain score as explanatory variables.
  - Weeks 24 and 48: LS mean changes from baseline were based on an MMRM analysis of GUS and UST including all terms in the model as defined above.
- Patients who had a prohibited change in concomitant Crohn's disease medication, a Crohn's disease-related surgery, or discontinued study agent due to lack of efficacy or an adverse event of worsening Crohn's disease prior to the designated analysis timepoint had their baseline value carried forward from that timepoint onwards (for change from baseline analysis) or were considered not to have achieved the endpoint (for clinically meaningful improvement analysis). Patients who had discontinued study agent due to any other reasons prior to the designated analysis timepoint had their observed data used from that timepoint onwards.
- Patients who had insufficient data to calculate PROMIS-29 domain score at the designated analysis timepoint did not have their missing data imputed.
- P-values presented are for GUS vs PBO. UST was included as a reference arm, there were no formal comparisons between UST and PBO or UST and GUS.

Phase 2 GALAXI-1 Study Design


Screening (5 Weeks)
R
GUS 1200mg IV q4w x 3
GUS 600mg IV q4w x 3
GUS 200mg IV q4w x 3
UST ~6mg/kg IV x 1 dose
PBO IV q4w x 3
GUS 200 mg SC q4w (n=61)
GUS 200 mg SC q4w (n=63)
GUS 100 mg SC q8w (n=61)
UST 90 mg SC q8w (n=63)
Placebo Nonresponders-crossover to active treatment
UST IV
UST 90 mg SC q8w
Placebo Responders
PBO SC q4w
Long-Term Extension Treatment
Induction
Maintenance Study
Study Week
0 4 8 12 16 20 24 28 32 36 40 44 48

R= randomization

CONCLUSIONS

- Patients with moderate to severe Crohn's disease experience impaired HRQOL, with PROMIS-29 scores in each domain worse than scores for the general population.
- Induction and maintenance treatment with GUS was effective in improving HRQOL as measured by PROMIS-29 domains in patients with moderately to severely active Crohn's disease.
- Patients treated with GUS had greater improvement in all 7 PROMIS-29 domain scores at Wk12 compared with PBO.
- The improvements in each of the 7 domains, as well as pain severity, at Wk 12 were maintained through Wk 48 in GUS-treated patients.

RESULTS

- Baseline demographics were generally similar among treatment groups
- Mean baseline PROMIS-29 domain scores were similar between treatment groups with functional domain scores <50 and symptom domain scores >50, indicating impaired HRQOL

Baseline Demographics and Disease Characteristics

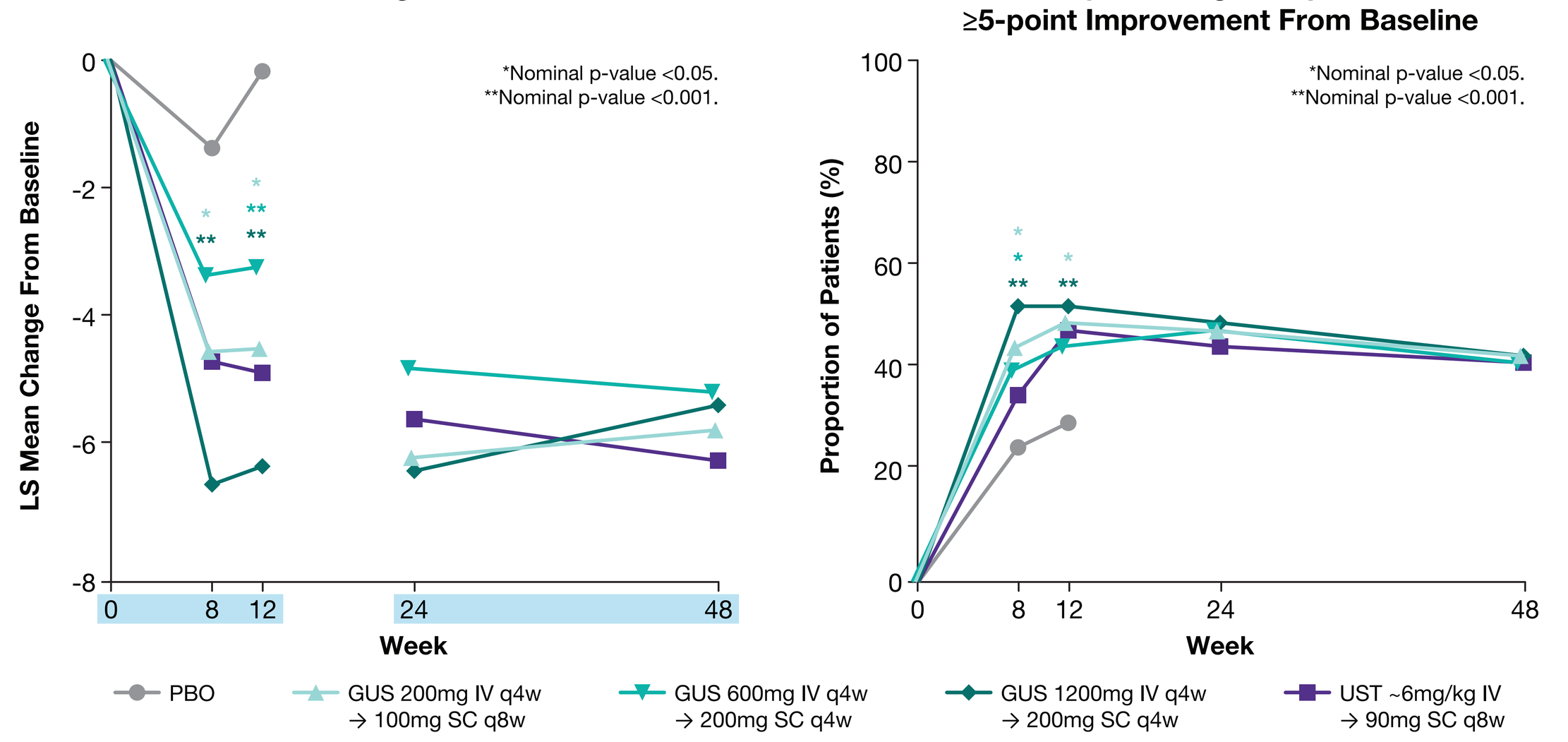
		GUS			
	Placebo	200 mg IV / 100 mg SC	600 mg IV / 200 mg SC	1200 mg IV / 200 mg SC	UST ~6 mg/kg IV / 90 mg SC
Primary efficacy analysis set	61	61	63	61	63
Age, years - mean (SD)	38.9 (12.95)	40.3 (13.67)	39.0 (14.35)	39.6 (13.72)	36.1 (12.02)
Male, n (%)	37 (60.7)	38 (62.3)	36 (57.1)	31 (50.8)	41 (65.1)
Crohn's disease duration, years					
Mean (SD)	8.7 (6.54)	10.7 (12.17)	10.4 (9.74)	6.7 (6.91)	7.4 (6.17)
Median (IQ range)	7.3 (3.5; 12.4)	6.1 (2.3; 14.3)	7.6 (2.9; 16.2)	4.6 (2.1; 9.7)	5.9 (2.1; 10.6)
Prior inadequate response or intolerance to biologic therapy,n (%)	30 (49.2)	32 (52.5)	35 (55.6)	34 (55.7)	37 (58.7)
Biologic-naïve, n (%)	19 (31.1)	25 (41.0)	24 (38.1)	25 (41.0)	19 (30.2)
CDAI score, mean (SD)	300.8 (49.91)	304.6 (57.24)	305.8 (58.77)	305.8 (54.46)	313.3 (61.30)
Stool frequency count >3, n (%)	49 (80.3)	47 (77.0)	52 (82.5)	48 (78.7)	56 (88.9)
Abdominal pain score >1, n (%)	58 (95.1)	57 (93.4)	58 (92.1)	59 (96.7)	60 (95.2)

Baseline PROMIS-29 Demographics and Disease Characteristics

		GUS			
	Placebo	200 mg IV / 100 mg SC	600 mg IV / 200 mg SC	1200 mg IV / 200 mg SC	UST ~6 mg/kg IV / 90 mg SC
Primary efficacy analysis set	61	61	63	61	63
PROMIS-29 subset	57	60	63	61	63
Anxiety score (T-score), mean (SD)	57.68 (10.004)	56.43 (9.344)	56.94 (9.843)	57.29 (9.455)	54.25 (9.068)
Depression score (T-score), mean (SD)	54.99 (9.386)	54.33 (9.306)	53.64 (10.567)	54.07 (9.499)	52.20 (8.619)
Fatigue score (T-score), mean (SD)	57.80 (9.128)	56.36 (9.193)	56.74 (10.097)	58.35 (9.361)	56.03 (8.991)
Pain interference score (T-score), mean (SD)	62.25 (6.625)	60.26 (8.550)	62.26 (6.337)	60.69 (7.418)	60.37 (8.431)
Physical function score (T-score), mean (SD)	42.70 (7.491)	44.71 (8.391)	45.24 (7.888)	43.16 (8.275)	45.72 (8.056)
Sleep disturbance score (T-score), mean (SD)	55.06 (8.418)	54.19 (8.062)	54.84 (7.181)	53.23 (7.447)	52.55 (7.408)
Ability to participate in social roles and activities score (T-score), mean (SD)	45.50 (7.990)	46.25 (9.278)	46.80 (8.705)	45.40 (9.329)	47.99 (8.827)
Pain intensity score, mean (SD)	5.53 (2.122)	5.13 (2.012)	5.49 (1.925)	5.46 (2.038)	5.37 (2.238)

Anxiety Score (T-Score) Through Week 48

LS Mean Change From Baseline | Clinically Meaningful Improvement: ≥5-point Improvement From Baseline

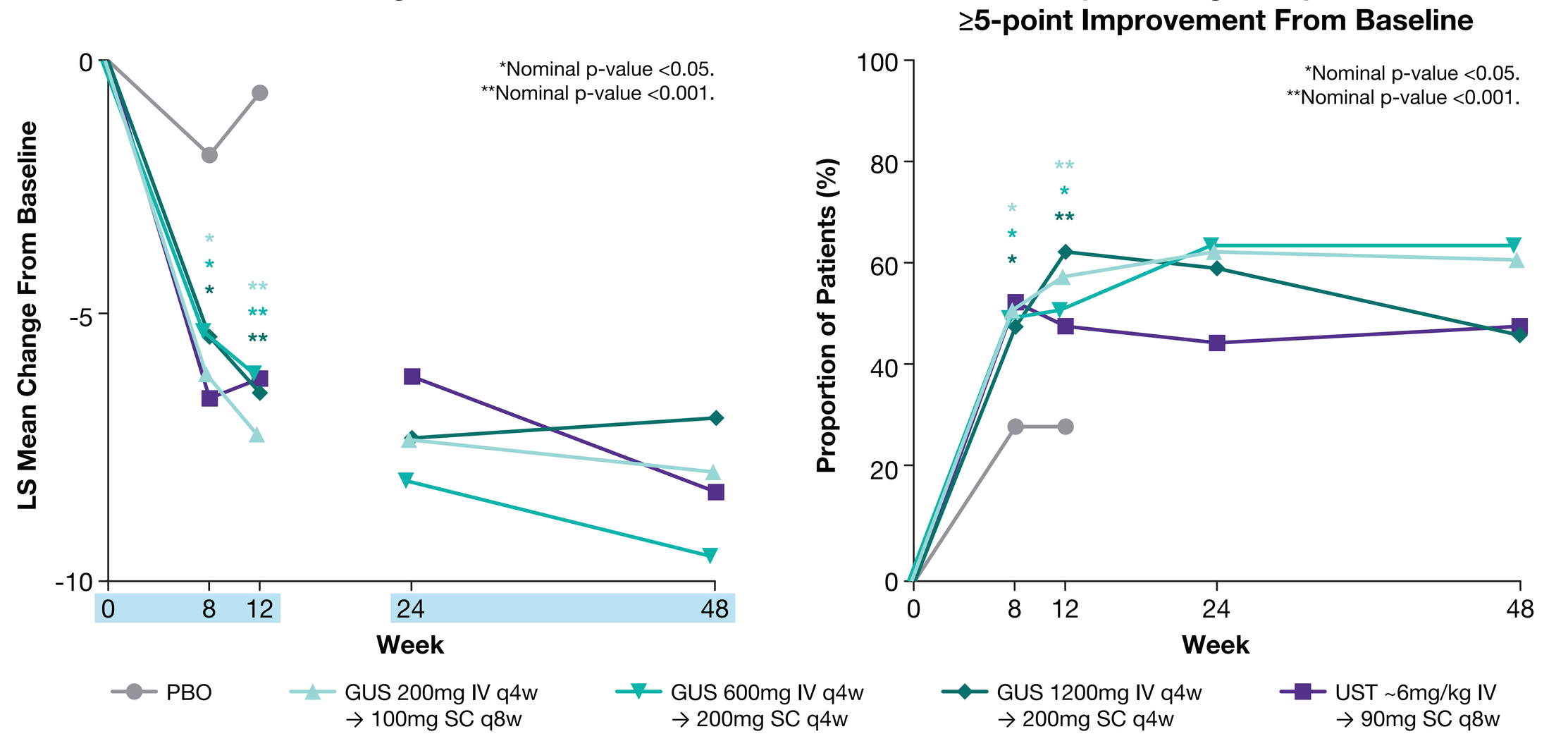


	PBO	GUS 200mg IV q4w → 100mg SC q8w	GUS 600mg IV q4w → 200mg SC q4w	GUS 1200mg IV q4w → 200mg SC q4w	UST ~6mg/kg IV → 90mg SC q8w
Wk 12 N=	56	58	61	57	63
Wk 48 N=		56	58	49	59

Week 0-12 analyses compare GUS vs PBO. Week 24-48 analyses did not include comparison of GUS vs PBO.

Fatigue Score (T-Score) Through Week 48

LS Mean Change From Baseline | Clinically Meaningful Improvement: ≥5-point Improvement From Baseline

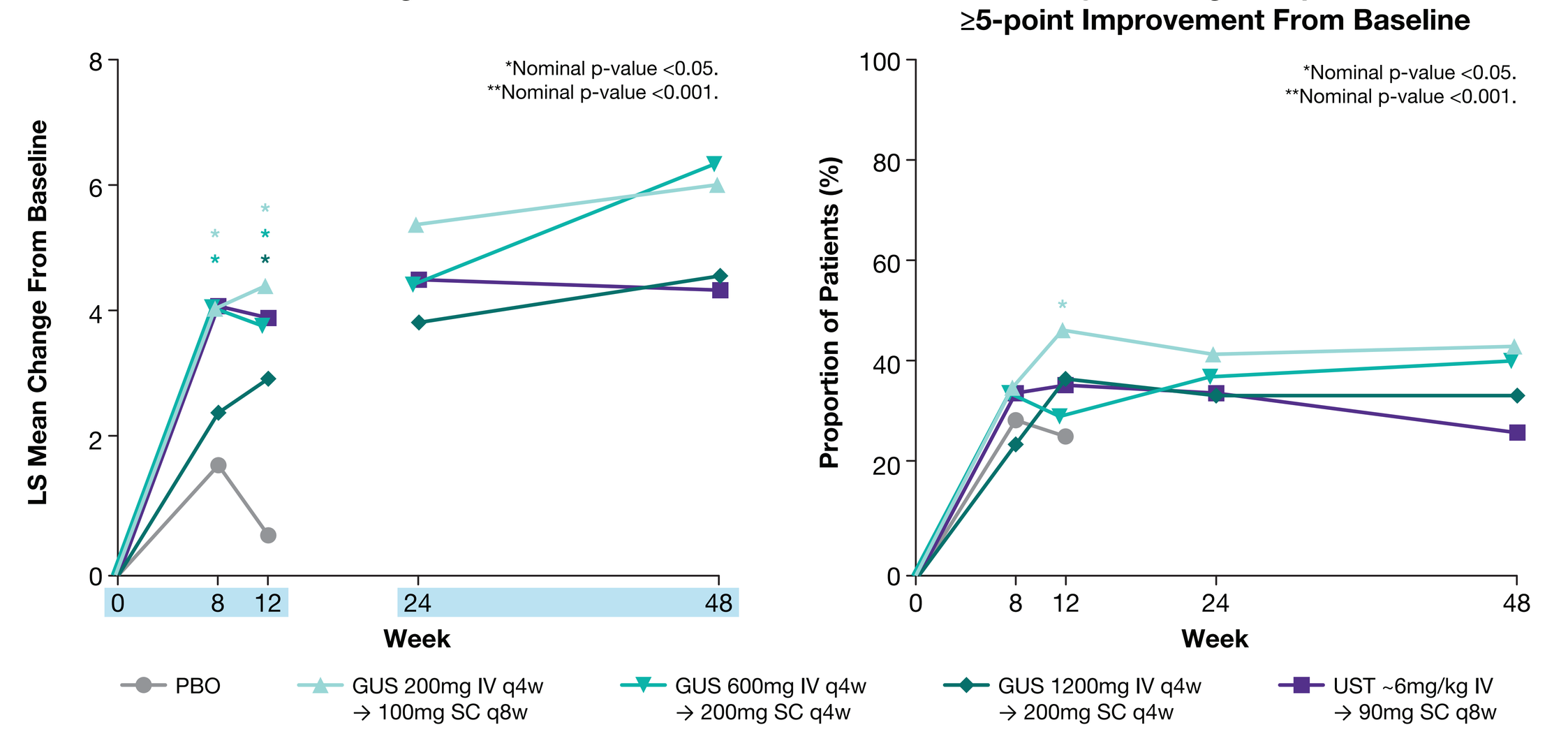


	PBO	GUS 200mg IV q4w → 100mg SC q8w	GUS 600mg IV q4w → 200mg SC q4w	GUS 1200mg IV q4w → 200mg SC q4w	UST ~6mg/kg IV → 90mg SC q8w
Wk 12 N=	56	58	61	57	63
Wk 48 N=		56	58	49	59

Week 0-12 analyses compare GUS vs PBO. Week 24-48 analyses did not include comparison of GUS vs PBO.

Physical Function Score (T-Score) Through Week 48

LS Mean Change From Baseline | Clinically Meaningful Improvement: ≥5-point Improvement From Baseline

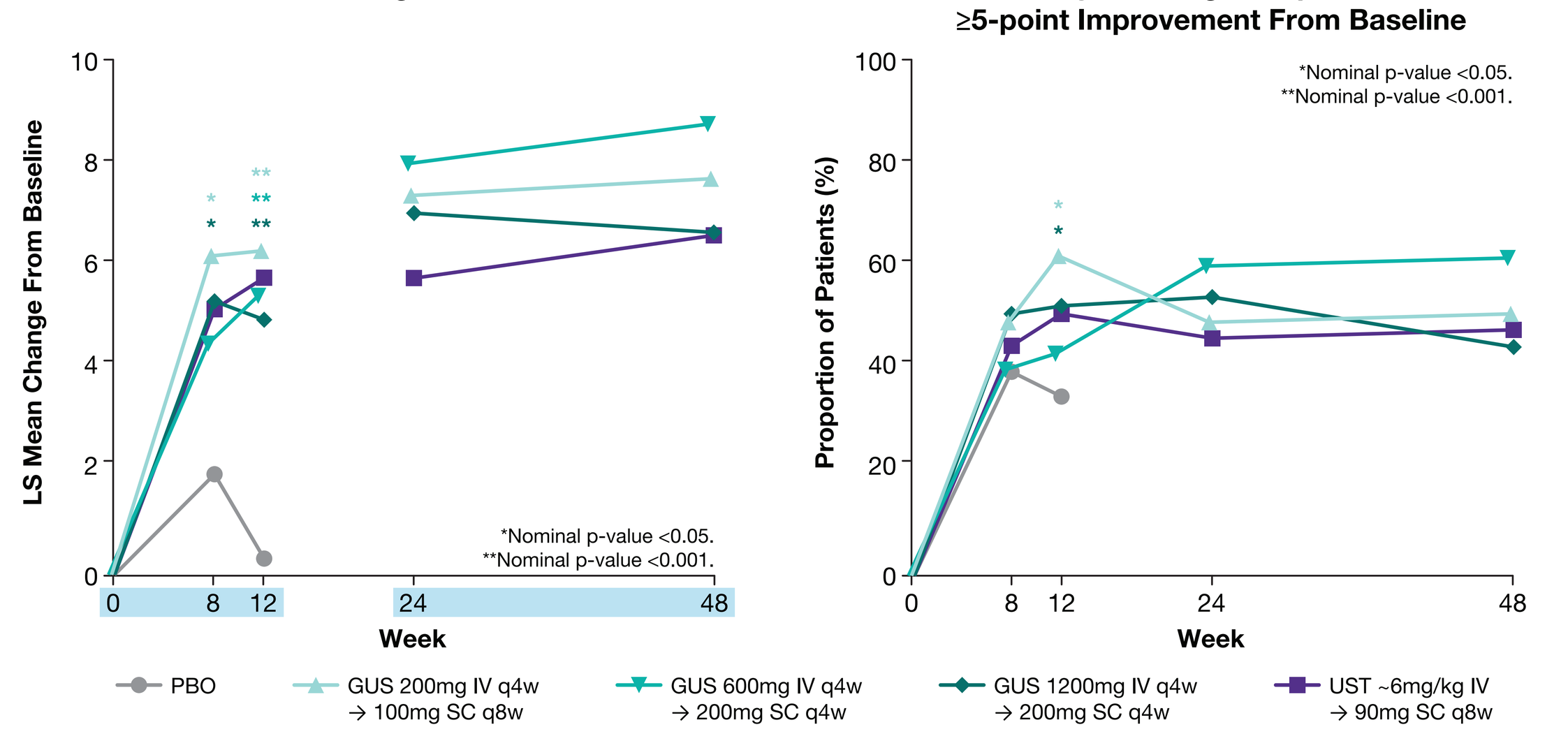


	PBO	GUS 200mg IV q4w → 100mg SC q8w	GUS 600mg IV q4w → 200mg SC q4w	GUS 1200mg IV q4w → 200mg SC q4w	UST ~6mg/kg IV → 90mg SC q8w
Wk 12 N=	56	58	61	57	63
Wk 48 N=		56	58	49	59

Week 0-12 analyses compare GUS vs PBO. Week 24-48 analyses did not include comparison of GUS vs PBO.

Ability to Participate in Social Roles and Activities Score (T-Score) Through Week 48

LS Mean Change From Baseline | Clinically Meaningful Improvement: ≥5-point Improvement From Baseline

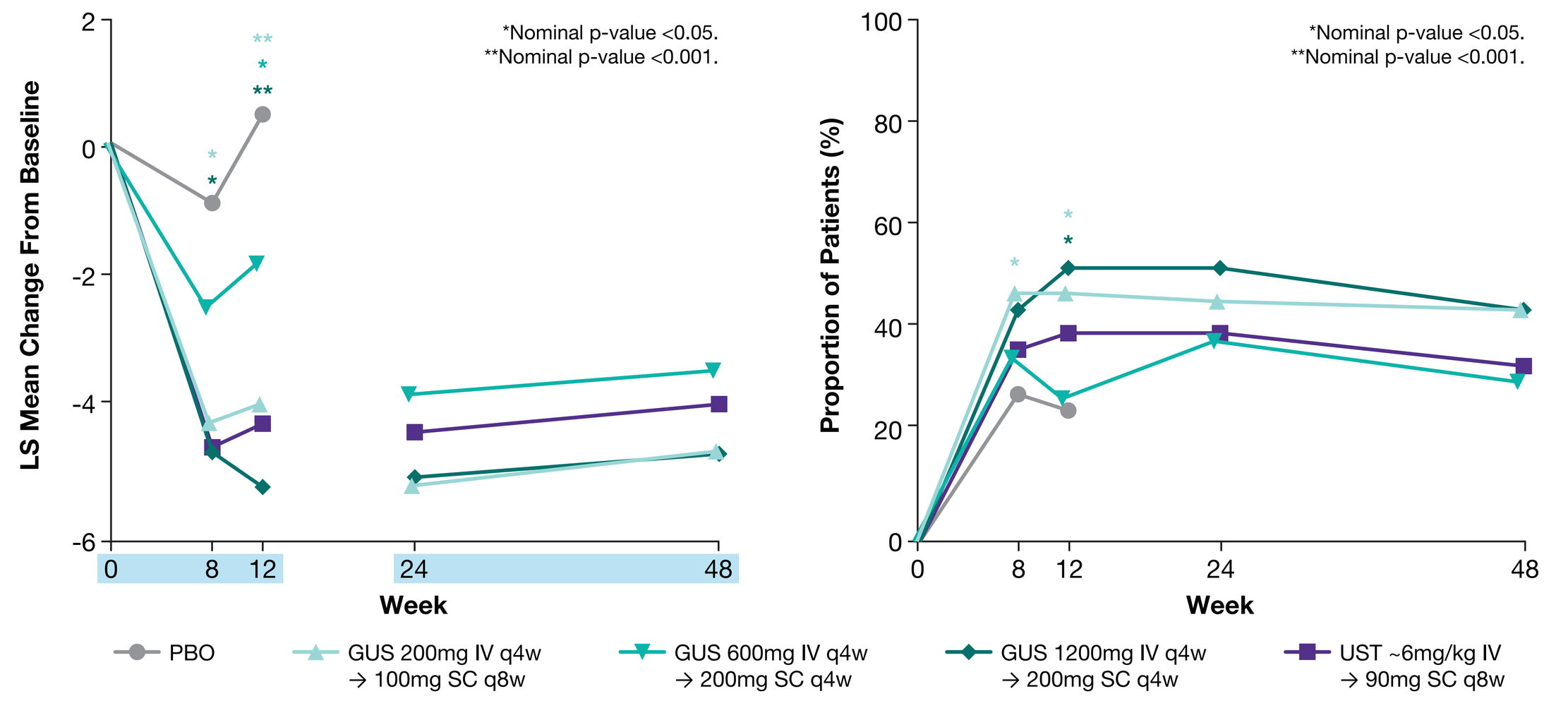


	PBO	GUS 200mg IV q4w → 100mg SC q8w	GUS 600mg IV q4w → 200mg SC q4w	GUS 1200mg IV q4w → 200mg SC q4w	UST ~6mg/kg IV → 90mg SC q8w
Wk 12 N=	56	58	61	57	63
Wk 48 N=		56	58	49	59

Week 0-12 analyses compare GUS vs PBO. Week 24-48 analyses did not include comparison of GUS vs PBO.

Depression Score (T-Score) Through Week 48

LS Mean Change From Baseline | Clinically Meaningful Improvement: ≥5-point Improvement From Baseline

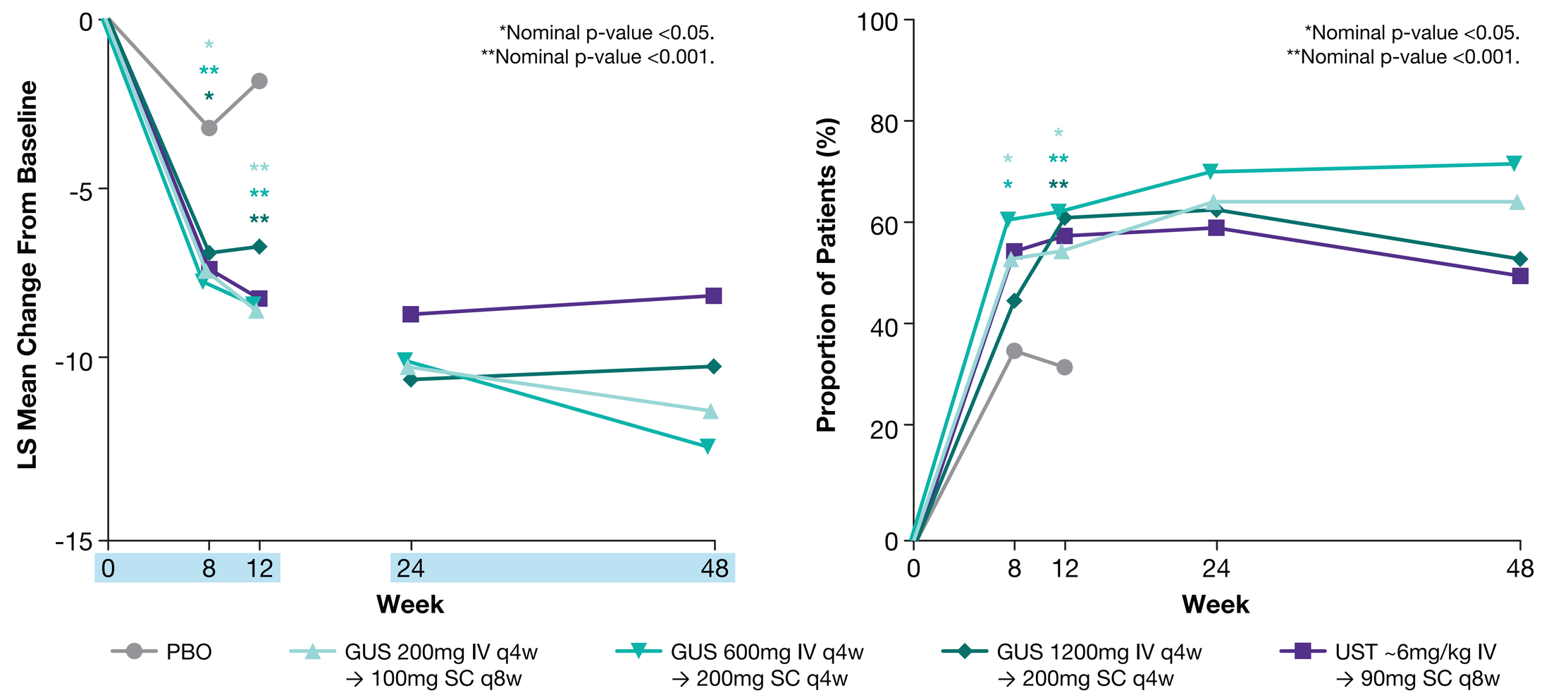


	PBO	GUS 200mg IV q4w → 100mg SC q8w	GUS 600mg IV q4w → 200mg SC q4w	GUS 1200mg IV q4w → 200mg SC q4w	UST ~6mg/kg IV → 90mg SC q8w
Wk 12 N=	56	58	61	57	63
Wk 48 N=		56	58	49	59

Week 0-12 analyses compare GUS vs PBO. Week 24-48 analyses did not include comparison of GUS vs PBO.

Pain Interference Score (T-Score) Through Week 48

LS Mean Change From Baseline | Clinically Meaningful Improvement: ≥5-point Improvement From Baseline

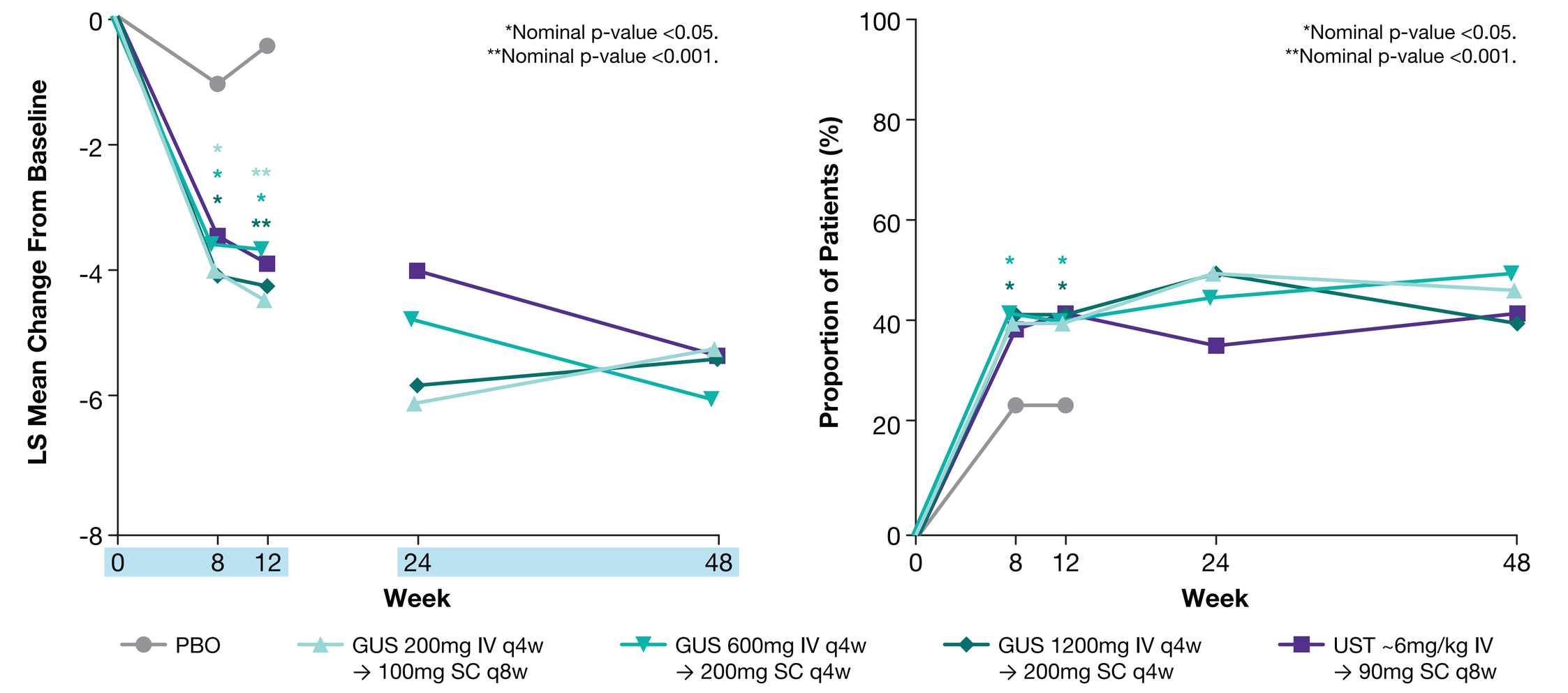


	PBO	GUS 200mg IV q4w → 100mg SC q8w	GUS 600mg IV q4w → 200mg SC q4w	GUS 1200mg IV q4w → 200mg SC q4w	UST ~6mg/kg IV → 90mg SC q8w
Wk 12 N=	56	58	61	57	63
Wk 48 N=		56	58	49	59

Week 0-12 analyses compare GUS vs PBO. Week 24-48 analyses did not include comparison of GUS vs PBO.

Sleep Disturbance Score (T-Score) Through Week 48

LS Mean Change From Baseline | Clinically Meaningful Improvement: ≥5-point Improvement From Baseline

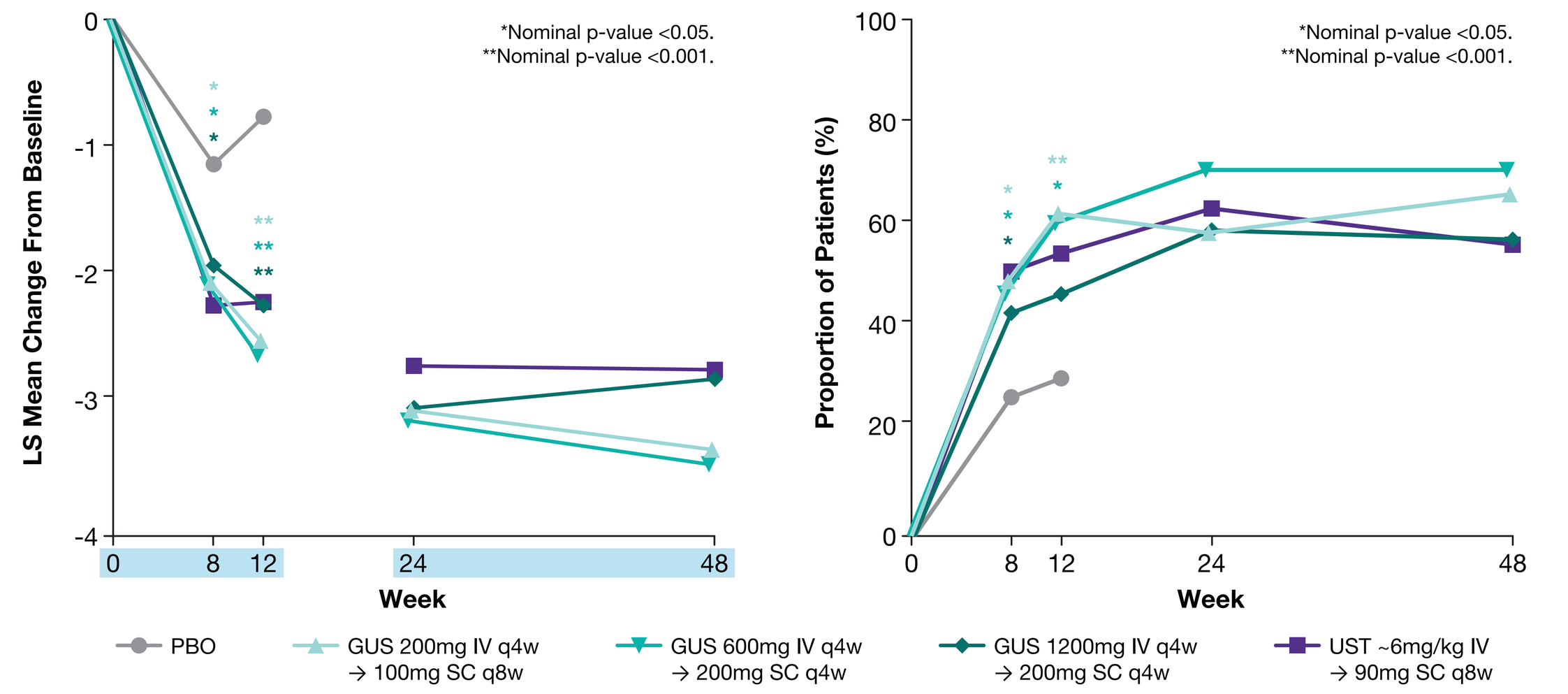


	PBO	GUS 200mg IV q4w → 100mg SC q8w	GUS 600mg IV q4w → 200mg SC q4w	GUS 1200mg IV q4w → 200mg SC q4w	UST ~6mg/kg IV → 90mg SC q8w
Wk 12 N=	56	58	61	57	63
Wk 48 N=		56	58	49	59

Week 0-12 analyses compare GUS vs PBO. Week 24-48 analyses did not include comparison of GUS vs PBO.

Pain Intensity Score (Numeric Rating Score) Through Week 48

LS Mean Change From Baseline | Clinically Meaningful Improvement: ≥3-point Improvement From Baseline



	PBO	GUS 200mg IV q4w → 100mg SC q8w	GUS 600mg IV q4w → 200mg SC q4w	GUS 1200mg IV q4w → 200mg SC q4w	UST ~6mg/kg IV → 90mg SC q8w
Wk 12 N=	56	58	61	57	63
Wk 48 N=		56	58	49	59

Week 0-12 analyses compare GUS vs PBO. Week 24-48 analyses did not include comparison of GUS vs PBO.

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