Long-Term Effectiveness of Guselkumab vs. Other Biologic Therapies Among Plaque Psoriasis Patients in the CorEvitas Psoriasis Registry

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Introduction

- Guselkumab (GUS), an interleukin (IL)-23 p19-subunit inhibitor, is approved for psoriasis, psoriatic arthritis, and ulcerative colitis
- The efficacy and real-world treatment persistence of GUS have been shown to be superior to several other advanced treatment options for psoriasis [1,2]
- However, long-term real-world effectiveness vs. other biologic therapies warrants further study

Objective

- **To compare the long-term effectiveness of GUS with adalimumab (ADA), ixekizumab (IXE), secukinumab (SEC), and ustekinumab (UST) in patients with psoriasis using real-world registry data**
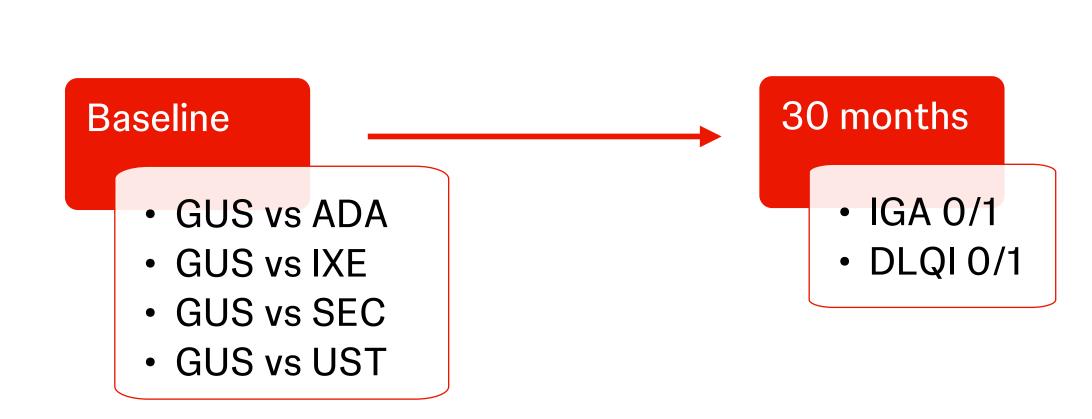
Methods

Study setting

- The CorEvitas Psoriasis Registry is a prospective, multicenter, non-interventional registry, launched in April 2015, for patients with psoriasis under the care of a dermatologist in the US and Canada
- The Registry collects data from both clinicians and patients at the time of outpatient clinical dermatological encounters
- Registry inclusion criteria include age ≥18 years, written informed consent for participation, and start or switch to an FDA-approved systemic psoriasis treatment at or within the previous 12 months of the date of enrollment

Study design and population

- An active comparator design was used to compare initiators of GUS to initiators of ADA, IXE, SEC, and UST in separate analyses
- Inclusion criteria for the study were:
  - Plaque psoriasis
  - Investigators Global Assessment (IGA) score ≥2
  - At least 30 months of follow-up prior to the data cutoff (June 2024)
- For each comparison, patients with a prior history of GUS or the comparator therapy were excluded

Outcomes

- The primary outcome was achievement of IGA 0/1 (clear or almost clear) at 30 months
- Dermatology Life Quality Index (DLQI) 0/1 (no impact on quality of life) at 30 months was assessed as a secondary outcome among patients with DLQI>1 at baseline

Baseline	→	30 months
• GUS vs ADA • GUS vs IXE • GUS vs SEC • GUS vs UST		• IGA 0/1 • DLQI 0/1

ADA=adalimumab, DLQI=Dermatologic Life Quality Index, GUS=guselkumab, IGA=Investigator's Global Assessment, IXE=ixekizumab, SEC=secukinumab, UST=ustekizumab

Statistical analysis

- Stabilized standardized mortality ratio (SMR) weights were used to balance all baseline characteristics between each GUS group and each comparator
- Non-responder imputation was used for all patients who discontinued GUS or the comparator prior to the 30-month visit
- Absolute differences (Δ) in the proportions achieving responses in the GUS vs. comparator groups were reported after incorporating the SMR weights
- For all comparisons, p<0.05 was considered statistically significant and Bonferroni-Holm adjustments were made for multiple testing
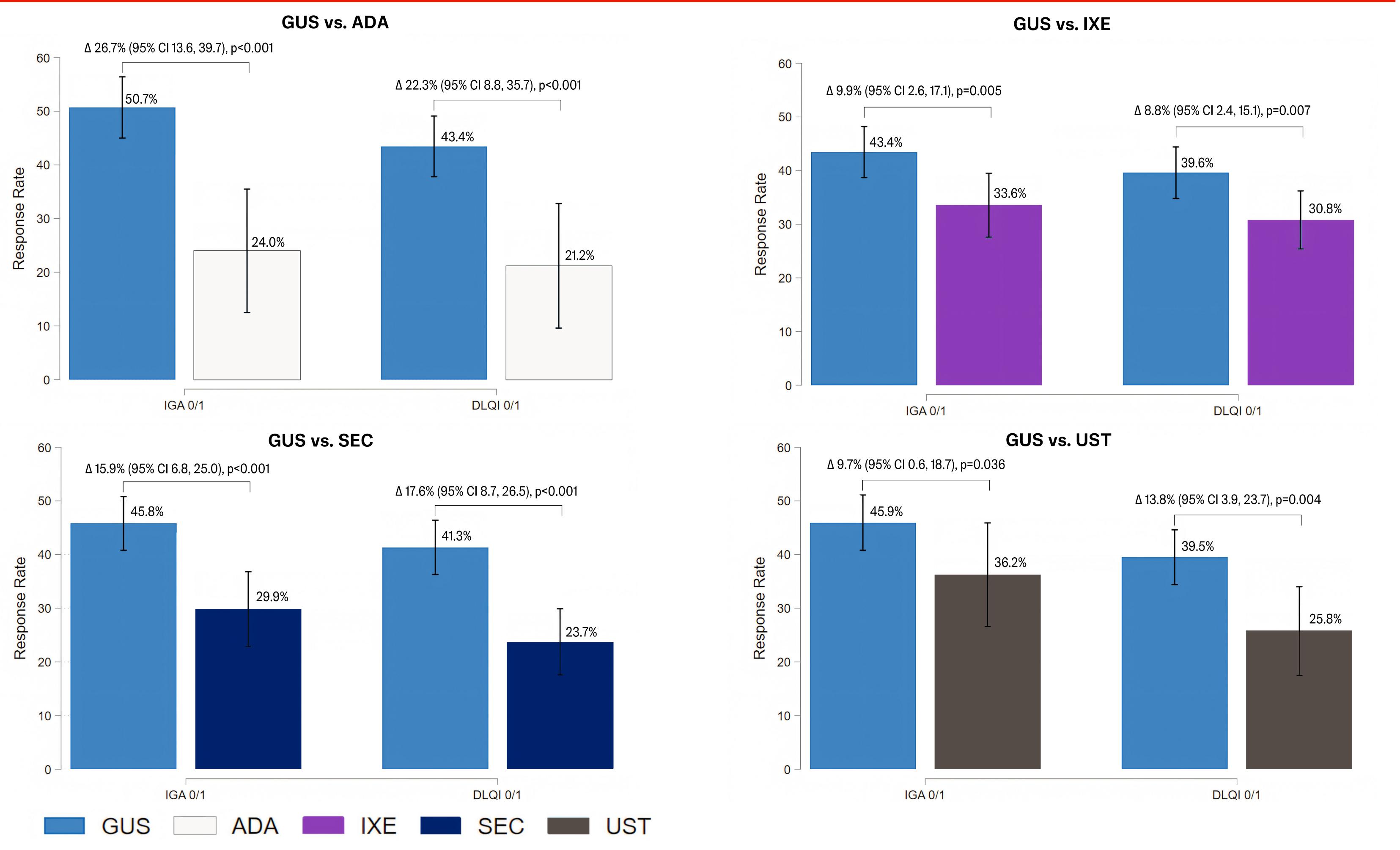
Key Takeaways

- ✓ Our findings support that GUS was superior to ADA, IXE, SEC, and UST in achieving clear or almost clear skin and no impact of psoriasis on quality of life at 30 months
- ✓ This is among the largest and longest real-world comparative effectiveness studies of GUS vs. ADA, IXE, SEC, and UST in patients with psoriasis
- ✓ Additional studies with longer follow-up and inclusion of emerging therapies could provide data to further inform clinical treatment considerations

Results

Patient demographics and disease characteristics at baseline

	GUS vs ADA		GUS vs IXE	
	GUS N=431	**ADA** N=309	**GUS** N=590	**IXE** N=580
Patient characteristics				
Age, years	49.7 (14.8)	49.0 (14.6)	49.5 (14.4)	50.4 (13.5)
Sex – male, %	52.4	47.6	53.4	54.5
Race/ethnicity – Non-Hispanic White, %	72.9	68.0	74.1	71.6
BMI, kg/m²	31.3 (7.8)	31.1 (8.0)	31.5 (7.4)	31.7 (7.8)
≥ 1 comorbidity, %	23.2	24.9	22.9	27.1
Disease characteristics				
PsO duration >2 years, %	79.1	66.7	83.9	82.6
Previous use of biologic, %	39.4	19.7	57.8	62.9
BSA (% involvement)	14.2 (13.7)	15.6 (15.9)	13.5 (13.9)	13.9 (15.3)
PASI	9.6 (7.7)	8.9 (7.1)	9.1 (7.7)	8.9 (7.7)
IGA – moderate or severe (3/4), %	84.2	86.4	83.1	79.5
Psoriatic arthritis, %	25.3	47.9	32.9	46.4
DLQI	8.4 (5.9)	8.8 (5.7)	8.0 (5.9)	8.1 (6.0)
Patient skin pain assessment	35.2 (32.1)	37.2 (31.5)	35.1 (32.8)	36.7 (32.2)
Patient itch assessment	56.2 (32.1)	55.9 (30.8)	55.3 (32.6)	55.7 (32.5)

	GUS vs SEC		GUS vs UST	
	GUS N=549	**SEC** N=617	**GUS** N=467	**UST** N=224
Patient characteristics				
Age, years	49.7 (14.5)	50.5 (14.7)	49.9 (14.8)	48.2 (16.0)
Sex – male, %	54.5	50.1	54.2	53.6
Race/ethnicity – Non-Hispanic White, %	73.2	71.0	75.8	75.4
BMI, kg/m²	31.3 (7.5)	31.5 (7.7)	31.6 (7.7)	30.6 (7.1)
≥ 1 comorbidity, %	22.0	26.4	24.4	28.6
Disease characteristics				
PsO duration >2 years, %	82.7	74.2	79.4	77.2
Previous use of biologic, %	53.7	56.7	45.6	42.9
BSA (% involvement)	13.2 (13.0)	15.5 (15.8)	14.3 (13.8)	17.8 (17.5)
PASI	9.0 (7.5)	8.2 (7.1)	9.8 (7.7)	9.9 (7.9)
IGA – moderate or severe (3/4), %	82.1	78.3	84.6	80.8
Psoriatic arthritis, %	29.5	50.6	30.6	29.9
DLQI	8.0 (5.8)	8.3 (5.7)	8.6 (5.8)	8.8 (5.7)
Patient skin pain assessment	34.4 (31.8)	35.4 (31.7)	38.1 (32.9)	35.4 (31.3)
Patient itch assessment	54.7 (32.7)	54.5 (32.4)	58.1 (31.9)	59.6 (30.7)

Data shown before balancing, presented as mean (SD) unless otherwise noted. Skin pain and itch assessments were collected on a visual analog scale, range 0-100, where 0=no pain/itch and 100=worst pain/itch
Comorbidities include history of myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease (stroke or transient ischemic attack), chronic obstructive pulmonary disease, peptic ulcer disease, diabetes mellitus, lymphoma, solid tumor cancer (excluding non-melanoma), and liver disease
Abbreviations: ADA=adalimumab, BMI=body mass index, BSA=body surface area, DLQI=Dermatology Life Quality Index, GUS=guselkumab, IGA=Investigator's Global Assessment, IXE=ixekizumab, PASI=Psoriasis Area and Severity Index, PsO=psoriasis, SD=standard deviation, SEC=secukinumab, UST=ustekizumab

GUS initiators achieved significantly higher rates of skin clearance (IGA 0/1) and patient-reported improvements in quality of life (DLQI 0/1) than each of the comparators after incorporating the SMR weights

GUS vs. ADA
- Δ 26.7% (95% CI 13.6, 39.7), p<0.001 — IGA 0/1: GUS 50.7%, ADA 24.0%
- Δ 22.3% (95% CI 8.8, 35.7), p<0.001 — DLQI 0/1: GUS 43.4%, ADA 21.2%

GUS vs. IXE
- Δ 9.9% (95% CI 2.6, 17.1), p=0.005 — IGA 0/1: GUS 43.4%, IXE 33.6%
- Δ 8.8% (95% CI 2.4, 15.1), p=0.007 — DLQI 0/1: GUS 39.6%, IXE 30.8%

GUS vs. SEC
- Δ 15.9% (95% CI 6.8, 25.0), p<0.001 — IGA 0/1: GUS 45.8%, SEC 29.9%
- Δ 17.6% (95% CI 8.7, 26.5), p<0.001 — DLQI 0/1: GUS 41.3%, SEC 23.7%

GUS vs. UST
- Δ 9.7% (95% CI 0.6, 18.7), p=0.036 — IGA 0/1: GUS 45.9%, UST 36.2%
- Δ 13.8% (95% CI 3.9, 23.7), p=0.004 — DLQI 0/1: GUS 39.5%, UST 25.8%

Legend: GUS, ADA, IXE, SEC, UST

Error bars represent 95% CIs. ADA=adalimumab, CI=confidence interval, DLQI=Dermatology Life Quality Index, GUS=guselkumab, IGA=Investigator's Global Assessment, IXE=ixekizumab, SEC=secukinumab, UST=ustekizumab

Strengths and Limitations

Strengths

- The CorEvitas Psoriasis Registry provides a unique resource with a large sample size and longitudinal follow-up to study the real-world use of psoriasis treatments in the US and Canada
- The Registry collects clinical data (e.g., disease activity scores, patient-reported outcomes) that are not commonly available in claims databases
- The methodological approach utilized allowed assessment of outcomes for patients who discontinued therapy in addition to those who persisted on therapy
- This study's 30-month follow-up period highlights its focus on long-term outcomes in comparisons between GUS and other biologics in a real-world setting

Limitations

- The new-user design of this study resulted in distinct GUS and comparator initiator cohorts for each comparison. Therefore, a patient may have been classified as a GUS initiator for one comparison and as a comparator for another comparison. Inferences should be made within and not across different GUS vs. comparator assessments
- Due to the timing of the study, the registry did not have enough patients using risankizumab or bimekizumab to allow comparisons between these and GUS
- Results may be subject to channeling bias and residual confounding if dermatologists preferentially prescribed GUS, the most recently approved of the included therapies, for patients with more severe signs and symptoms not reflected in baseline disease scores