Guselkumab Shows Better Long-Term Effectiveness and Drug Survival Compared to Secukinumab Through 84 Weeks in Patients With Moderate-to-Severe Plaque Psoriasis – Results From the German Non-Interventional G-REAL Study

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Key Takeaways

- **Among moderate-to-severe Pso patients treated with GUS or SEC in a real-world setting in the G-REAL study**
  - ✓ **GUS-treated patients achieved higher complete skin clearance and PASI <2 (new German treat-to-target threshold in Pso)[3] rates versus SEC-treated patients from W28 through W84**
  - ✓ **Higher proportions of GUS-treated patients reported no impact of Pso on quality of life (DLQI 0/1) versus SEC-treated patients at W84**
  - ✓ **GUS-treated patients showed higher drug survival rates than SEC-treated patients through 18 months**
- **The highest PASI response and drug survival rates were observed in bionaïve patients treated with GUS**
- **Overall, these findings highlight the benefits of GUS as a first-line biologic therapy in routine practice**

Background

Psoriasis (Pso) is a chronic immune-mediated disease characterized by erythematous, scaly plaques, driven by the interleukin (IL)-23/IL-17 inflammatory pathway[1]

Guselkumab (GUS), a selective p19 subunit-targeted IL-23 inhibitor, demonstrated superior long-term efficacy compared to secukinumab (SEC), an IL-17A inhibitor, in patients with Pso in the Phase 3 ECLIPSE trial[2]

G-REAL is a prospective, non-interventional, multicenter study evaluating the long-term effectiveness of GUS and SEC and their impact on health-related quality of life in patients with moderate-to-severe Pso across different treatment lines in routine practice in Germany

Objective

This analysis of the overall G-REAL patient population assessed effectiveness, patient-reported outcomes (PROs), and drug survival with GUS and SEC over 84 weeks (W)

Study Design & Analyses

- The G-REAL study included adults with moderate-to-severe Pso and baseline PASI >5 treated with GUS Q8W or SEC Q4W per routine care
- Data were collected at W0, W4, W12, W20, W28, W52, and W84
- A total of 669 patients were enrolled; 661 (GUS: 502; SEC: 159) had analyzable data at baseline and ≥1 post-baseline visit; patients were stratified by biologic treatment history: bionaïve (GUS: 259; SEC: 95) and ≥1 prior biologic (GUS: 243; SEC: 64)
- PASI/DLQI were analyzed using NRI after applying treatment failure rules[a]
- Drug survival was analyzed using Kaplan-Meier methodology[b]
- Nominal p-values are reported

[a]*Patients were considered treatment failures when (1) GUS or SEC was discontinued due to lack of effectiveness, loss of effectiveness, or an AE of psoriasis worsening, or (2) a new therapy other than the therapy at baseline was started.* [b]*In the absence of confirmation of treatment discontinuation (including patients lost to follow-up), the time to event was censored on the last documented study date* ***DLQI****=Dermatology Life Quality Index,* ***NRI****=non-responder imputation,* ***PASI****=Psoriasis Area and Severity Index,* ***Q4W****=every 4 weeks,* ***Q8W****=every 8 weeks.*

Results

Baseline patient and disease characteristics were generally well balanced between treatment cohorts

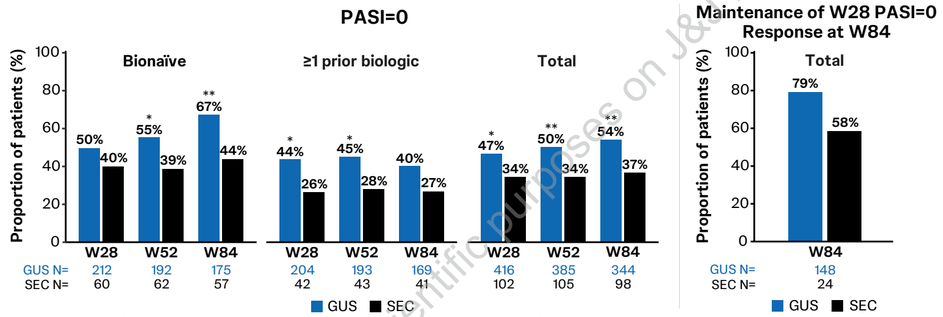
- PsA and depression were less prevalent in the GUS cohort

Baseline Characteristics of Full G-REAL Study Population	GUS (N = 502)	SEC (N = 159)
Demographics		
Mean age, years (SD)	47.5 (14.1)	48.3 (13.2)
Male, n (%)	306 (61.0)	103 (64.8)
Mean BMI, kg/m^2 (SD)	29.2 (6.2)	29.6 (6.1)
Disease Characteristics		
Mean Pso duration, years (SD)	16.4 (12.8)[a]	15.0 (13.9)
Mean DLQI (0-30) (SD)	14.0 (7.5)[b]	14.1 (7.9)[c]
Mean PASI (0-72) (SD)	15.1 (8.5)	14.3 (7.3)
Concomitant Diseases[d], n (%)		
Hypertension	142 (28.3)	42 (26.4)
PsA	121 (24.1)	49 (30.8)
Hyperlipidaemia	58 (11.6)	17 (10.7)
Diabetes	48 (9.6)	18 (11.3)
Depression	31 (6.2)	18 (11.3)
Prior csDMARDs Use, n (%)		
Methotrexate	205 (40.8)	67 (42.1)
Cyclosporine	30 (6.0)	7 (4.4)

[a]*N=501.* [b]*N=490.* [c]*N=152.* [d]*Top 5 most frequent concomitant diseases are shown.* ***BMI****=body mass index,* ***csDMARD****=conventional synthetic disease-modifying antirheumatic drug,* ***PsA****=psoriatic arthritis,* ***SD****=standard deviation.*

GUS demonstrated higher rates of complete skin clearance versus SEC through W84 across treatment lines

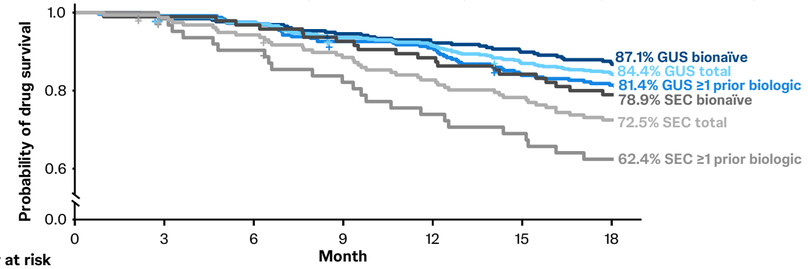
- GUS demonstrated the highest PASI=0 response rate in bionaïve patients, with higher rates than SEC from W28 to W84 (left-hand figure)
- Among patients who achieved PASI=0 at W28 in the overall population, a higher PASI=0 response rate was observed with GUS compared to SEC treatment at W84 (right-hand figure)
- The treatment failure[a] rate with GUS (5.4%) was lower than that for SEC (17.0%) through W84 (data not shown)



Nominal ****p<0.05, **p<0.01 vs SEC.*** *[a]Patients were considered treatment failures when (1) GUS or SEC was discontinued due to lack of effectiveness, loss of effectiveness, or an adverse event of psoriasis worsening, or (2) a new therapy other than the therapy at baseline was started.*

Patients treated with GUS showed higher drug survival rates versus those treated with SEC across treatment lines through 18 months

- Bionaïve patients treated with GUS showed the highest drug survival rate through 18 months
- Higher drug survival rates were observed across all GUS treatment lines (81.4-87.1%) versus all SEC treatment lines (62.4-78.9%) through 18 months
- The primary reasons for treatment discontinuation were AEs (GUS: 5.0%; SEC: 10.1%) and loss of effect (GUS: 2.2%; SEC: 8.8%)



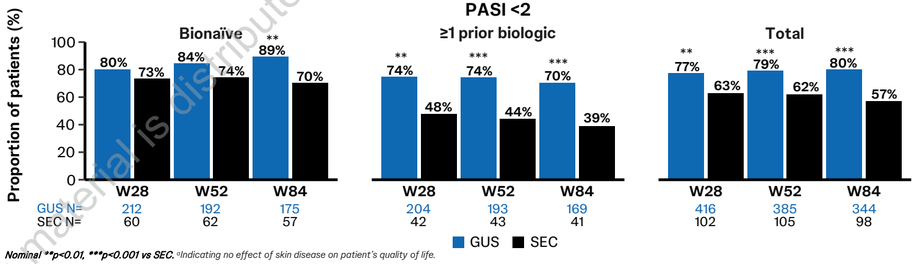
Number at risk

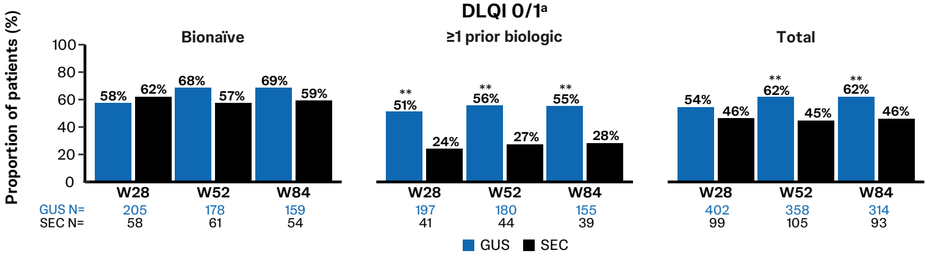
GUS bionaïve N=	259	254	250	242	236	230	223
GUS ≥1 prior biologic N=	243	241	237	224	220	202	196
GUS total N=	502	495	487	466	456	432	419
SEC bionaïve N=	95	94	92	88	84	80	75
SEC ≥1 prior biologic N=	64	61	56	50	45	42	38
SEC total N=	159	155	148	138	129	122	113

Cross symbol (+) indicates censored patients. ***AE****=adverse event.*

GUS demonstrated generally higher PASI <2 and DLQI 0/1 response rates versus SEC through W84 across treatment lines

- Higher proportions of patients achieved PASI <2 with GUS compared with SEC through W84 across treatment lines
- GUS-treated patients achieved higher DLQI 0/1[a] response rates versus SEC at all assessed time point across treatment lines (except at W28 in bionaïve patients)





Nominal *****p<0.01, ***p<0.001 vs SEC.*** *[a]Indicating no effect of skin disease on patient's quality of life.*

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