P2219

Super Response to Guselkumab Treatment in Chinese Patients With Moderate-to-Severe Psoriasis: A Post-Hoc Analysis From a Phase 4 RCT

Min Zheng[1], Kun Huang[2], Songmei Geng[3], Xiaohua Tao[4], Liangdan Sun[5], Chao Ji[6], Bin Yang[7], Yan Lu[8], Xiaoxue Di[9], Weilong Zhao[9], Rui Wang[9]

[1]Department of Dermatology, The Second Affiliated Hospital of Zhejiang University, Hangzhou, China; [2]Department of Dermatology, The First Affiliated Hospital of Chongqing Medical University, Chongqing, China; [3]Department of Dermatology, The Second Affiliated Hospital of Xi'an Jiaotong University, Xi'an, China; [4]Department of Dermatology, Zhejiang Provincial People's Hospital, Hangzhou, China; [5]Department of Dermatology, The Affiliated Hospital of Anhui Medical University, Hefei, China; [6]Department of Dermatology, The First Affiliated Hospital of Fujian Medical University, Fuzhou, China; [7]Department of Dermatology, Dermatology Hospital of Southern Medical University, Guangzhou, China; [8]Department of Dermatology, Jiangsu Provincial People's Hospital, Nanjing, China; [9]Johnson & Johnson, Beijing, China

Key Takeaways

- **A substantial proportion (45.2%) of Chinese patients with moderate-to-severe psoriasis in the PAC study achieved super response with guselkumab treatment**
- **Super responders tended to be younger, have lower body weight, have never used non-biologic systemic treatment, and have moderate psoriasis at baseline**
- **Having never used non-biologic systemic treatment was identified as a significant predictor of achieving super response**

Background

Psoriasis is a chronic immune-mediated inflammatory skin disease.[1] The advent of effective biologics has greatly improved outcomes of patients with psoriasis. Treatment goals have shifted toward achieving near or complete clearance of the skin with highly effective biologics[2]

Guselkumab is a fully human monoclonal antibody that targets the p19 subunit of interleukin-23 and is approved for the treatment of moderate-to-severe psoriasis.[3] In previous global phase 3 studies (VOYAGE 1 and 2), 40.8% of patients treated with guselkumab achieved super response, defined as achieving an absolute Psoriasis Area and Severity Index (PASI) of 0 at both Weeks 20 and 28[2]

A recent Chinese randomized, double-blind, placebo-controlled, phase 4 study showed that guselkumab has high effectiveness and good tolerance in Chinese patients with moderate-to-severe psoriasis.[4] However, characteristics of super responders in Chinese patients remain unclear

Objectives

To report post-hoc analysis results of the proportion of patients who achieved super response and baseline characteristics of guselkumab-treated super responders and non-super responders in the Chinese post-approval commitment (PAC) study

Methods

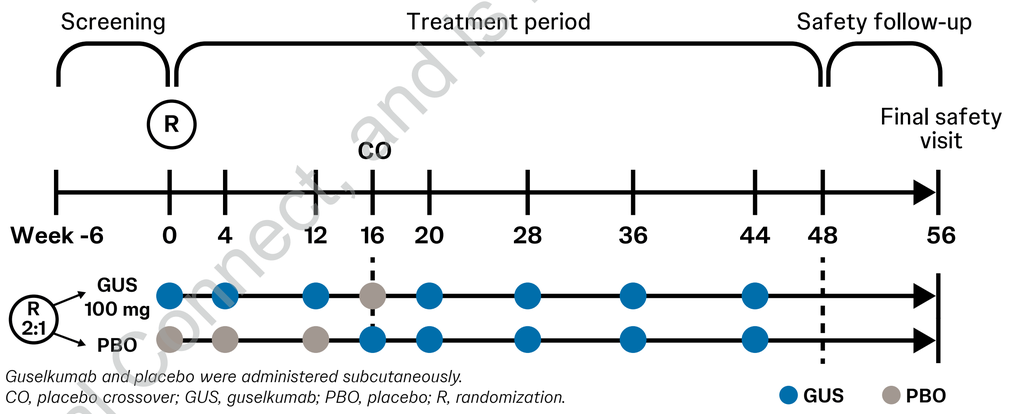
Study Design

- This randomized, double-blind, placebo-controlled, phase 4 study (NCT04914429) enrolled patients from 26 sites in China
- Eligible patients had a diagnosis of moderate-to-severe plaque psoriasis, defined by an Investigator's Global Assessment (IGA) score ≥3, PASI ≥12, and involved body surface area (BSA) ≥10%, and had to be eligible for either systemic therapy or phototherapy
- At Week 0, patients were randomized in a 2:1 ratio to receive guselkumab 100 mg or placebo. At Week 16, patients in the placebo group crossed over to receive guselkumab. Guselkumab and placebo were administered by subcutaneous injection according to the predetermined dosing schedule (Figure 1)

Statistical Analysis

- This analysis included only patients randomized to the guselkumab group at Week 0
- Super response was defined as achieving a PASI 100 response (i.e., absolute PASI=0) at both Weeks 20 and 28. Patients with missing PASI results at Weeks 20 or 28 were counted as not having achieved super response
- Baseline demographics and disease characteristics for super responders and non-super responders were summarized descriptively
- A multivariable logistic regression analysis was conducted to explore factors associated with achieving super response

Figure 1: Study design



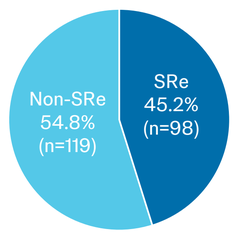
Guselkumab and placebo were administered subcutaneously.
CO, placebo crossover; GUS, guselkumab; PBO, placebo; R, randomization.

Results

Identification of Super Responders

- Of 327 patients who were randomized in the PAC study, 217 patients were assigned to the guselkumab group and included in this post-hoc analysis
- The PASI 100 response rates in the guselkumab group were 53.6% at Week 20 and 58.9% at Week 28
- Overall, 98 guselkumab-treated patients (45.2%) were identified as having achieved super response (PASI 100 response at both Weeks 20 and 28; Figure 2)

Figure 2: Proportion of super responders



SRe, super responder.

Patient Demographics and Medical History of Super Responders and Non-Super Responders

- Patient demographics and medical history at baseline are summarized in Table 1
- Guselkumab-treated patients who achieved super response, compared with those who did not, respectively, were:
  - slightly younger (<45 years: 64.3% vs 59.7%; 45 to <65 years: 34.7% vs 32.8%; ≥65 years: 1.0% vs 7.6%)
  - of lower body weight (≤90 kg: 93.8% vs 85.7%)
  - more likely to be overweight (body mass index 24 to <28 kg/m^2: 43.3% vs 29.4%) but less likely to be obese (body mass index ≥28 kg/m^2: 17.5% vs 27.7%)
  - less likely to have a comorbidity of hyperlipidemia (19.4% vs 25.2%) or hyperuricemia (7.1% vs 15.1%)

Table 1: Patient demographics and medical history at baseline

	Super Responder (N=98)	Non-Super Responder (N=119)	Total (N=217)
Baseline characteristics			
Age, years			
<45	64.3 (63/98)	59.7 (71/119)	61.8 (134/217)
45 to <65	34.7 (34/98)	32.8 (39/119)	33.6 (73/217)
≥65	1.0 (1/98)	7.6 (9/119)	4.6 (10/217)
Gender			
Female	23.5 (23/98)	20.2 (24/119)	21.7 (47/217)
Male	76.5 (75/98)	79.8 (95/119)	78.3 (170/217)
Body weight, kg			
≤90	93.8 (91/97)	85.7 (102/119)	89.4 (193/216)
>90	6.2 (6/97)	14.3 (17/119)	10.7 (23/216)
Body mass index, kg/m^2			
Underweight (<18.5)	2.1 (2/97)	3.4 (4/119)	2.8 (6/216)
Normal (18.5 to <24)	37.1 (36/97)	39.5 (47/119)	38.4 (83/216)
Overweight (24 to <28)	43.3 (42/97)	29.4 (35/119)	35.7 (77/216)
Obese (≥28)	17.5 (17/97)	27.7 (33/119)	23.2 (50/216)
Medical history			
Hyperlipidemia	19.4 (19/98)	25.2 (30/119)	22.6 (49/217)
Hypertension	20.4 (20/98)	21.9 (26/119)	21.2 (46/217)
Hyperuricemia	7.1 (7/98)	15.1 (18/119)	11.5 (25/217)

Data are presented as % (n/N).

Baseline Disease Characteristics and Laboratory Data of Super Responders and Non-Super Responders

- Disease characteristics and laboratory assessment results at baseline are presented in Table 2
- Guselkumab-treated patients who achieved super response, compared with those who did not, respectively:
  - had somewhat lower disease severity (PASI ≥20: 54.1% vs 58.0%; BSA ≥20%: 69.4% vs 79.8%; IGA score of 4: 19.4% vs 26.9%)
  - were more likely to have never used non-biologic systemic treatment for psoriasis (67.4% vs 51.3%)

Logistic Regression Analysis for Factors Associated With Achieving Super Response

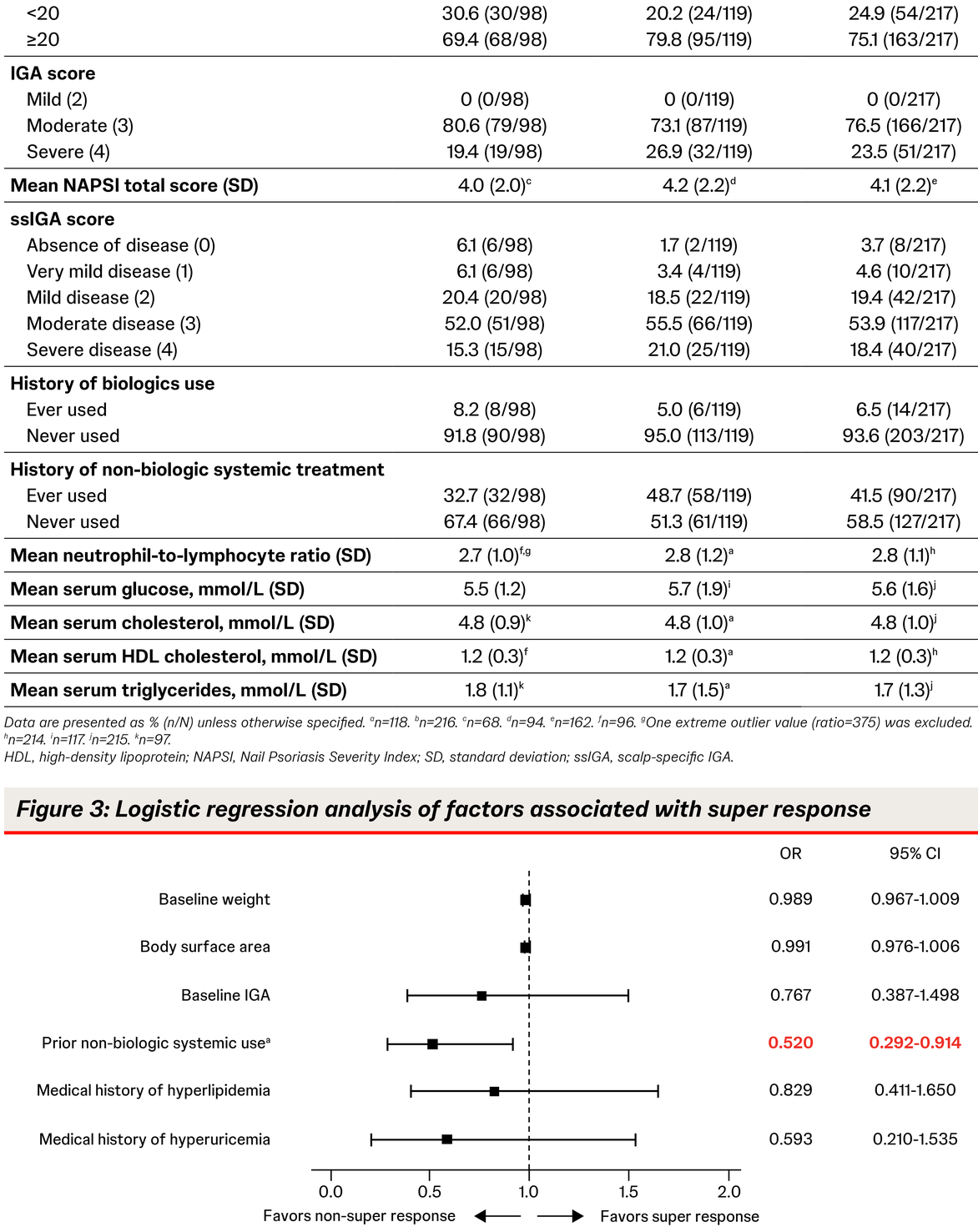
- Logistic regression analysis showed that having never used non-biologic systemic treatment was associated with achieving super response (Figure 3)

Table 2: Patient disease characteristics and laboratory assessments at baseline

	Super Responder (N=98)	Non-Super Responder (N=119)	Total (N=217)
Baseline characteristics			
Mean psoriasis disease duration, years (SD)	12.4 (9.1)	12.4 (10.4)[a]	12.4 (9.8)[b]
Mean PASI score (SD)	22.6 (9.7)	24.9 (11.2)	23.9 (10.6)
<20	45.9 (45/98)	42.0 (50/119)	43.8 (95/217)
≥20	54.1 (53/98)	58.0 (69/119)	56.2 (122/217)
Mean BSA, % (SD)	32.7 (18.8)	36.9 (20.3)	35.0 (19.7)
<20	30.6 (30/98)	20.2 (24/119)	24.9 (54/217)
≥20	69.4 (68/98)	79.8 (95/119)	75.1 (163/217)
IGA score			
Mild (2)	0 (0/98)	0 (0/119)	0 (0/217)
Moderate (3)	80.6 (79/98)	73.1 (87/119)	76.5 (166/217)
Severe (4)	19.4 (19/98)	26.9 (32/119)	23.5 (51/217)
Mean NAPSI total score (SD)	4.0 (2.0)[c]	4.2 (2.2)[d]	4.1 (2.2)[e]
ssIGA score			
Absence of disease (0)	6.1 (6/98)	1.7 (2/119)	3.7 (8/217)
Very mild disease (1)	6.1 (6/98)	3.4 (4/119)	4.6 (10/217)
Mild disease (2)	20.4 (20/98)	18.5 (22/119)	19.4 (42/217)
Moderate disease (3)	52.0 (51/98)	55.5 (66/119)	53.9 (117/217)
Severe disease (4)	15.3 (15/98)	21.0 (25/119)	18.4 (40/217)
History of biologics use			
Ever used	8.2 (8/98)	5.0 (6/119)	6.5 (14/217)
Never used	91.8 (90/98)	95.0 (113/119)	93.6 (203/217)
History of non-biologic systemic treatment			
Ever used	32.7 (32/98)	48.7 (58/119)	41.5 (90/217)
Never used	67.4 (66/98)	51.3 (61/119)	58.5 (127/217)
Mean neutrophil-to-lymphocyte ratio (SD)	2.7 (1.0)[f,g]	2.8 (1.2)[a]	2.8 (1.1)[h]
Mean serum glucose, mmol/L (SD)	5.5 (1.2)	5.7 (1.9)[i]	5.6 (1.6)[j]
Mean serum cholesterol, mmol/L (SD)	4.8 (0.9)[k]	4.8 (1.0)[a]	4.8 (1.0)[j]
Mean serum HDL cholesterol, mmol/L (SD)	1.2 (0.3)[f]	1.2 (0.3)[a]	1.2 (0.3)[h]
Mean serum triglycerides, mmol/L (SD)	1.8 (1.1)[k]	1.7 (1.5)[a]	1.7 (1.3)[j]

Data are presented as % (n/N) unless otherwise specified. [a]n=118. [b]n=216. [c]n=68. [d]n=94. [e]n=162. [f]n=96. [g]One extreme outlier value (ratio=375) was excluded. [h]n=214. [i]n=117. [j]n=215. [k]n=97.
HDL, high-density lipoprotein; NAPSI, Nail Psoriasis Severity Index; SD, standard deviation; ssIGA, scalp-specific IGA.

Figure 3: Logistic regression analysis of factors associated with super response



[a]Included psoralen and ultraviolet A light therapy, methotrexate, cyclosporine, and acitretin. CI, confidence interval; OR, odds ratio.

PRESENTED AT: EADV Congress 2025; September 17-20, 2025; Paris, France, by M Zheng. **REFERENCES:** 1. Girolomoni G, et al. *Dermatol Ther (Heidelb).* 2023;13:2171-2185. 2. Reich K, et al. *J Eur Acad Dermatol Venereol.* 2022;36:2393-2400. 3. Eyerich K, et al. *JAMA Dermatol.* 2024;160:953-963. 4. Zheng M, et al. *Free Communication.* The 29th Annual Meeting of the Chinese Society of Dermatology; June 13-16, 2024; Qingdao, China. **ACKNOWLEDGMENTS:** Medical writing support was provided by Shao-Hua Chin of Parexel International, which was funded by Johnson & Johnson, under the direction of the authors in accordance with Good Publication Practice guidelines (DeTora LM, et al. *Ann Intern Med.* 2022;175:1298-1304). This presentation was sponsored by Johnson & Johnson. **DISCLOSURES:** This study was funded by Johnson & Johnson. **Xiaoxue Di**, **Weilong Zhao**, and **Rui Wang** are employees of Johnson & Johnson. Other authors have nothing to disclose.