Maintenance of Response After Guselkumab Withdrawal: Findings From an Observational Study in Chinese Patients With Moderate-to-Severe Plaque Psoriasis

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P2163

Key Takeaways

- **In this population of Chinese patients with moderate-to-severe plaque psoriasis, the median OTD after guselkumab withdrawal was 350 days**
- **The long OTD observed may be related, in part, to the high proportion of bio-naive patients in this study (only 5% previously received biologic treatment)**
- **Mean DLQI scores increased significantly from 2.5 at the index date to 9.1 at Week 48 ($P < 0.001$), indicating a worsening of quality of life after treatment withdrawal**
- **These findings support the benefits of continued maintenance dosing of guselkumab for sustaining real-world effectiveness in psoriasis**

Background

Psoriasis is a common inflammatory skin disease that is characterized by altered immune function.[1] In patients with moderate-to-severe psoriasis, maintenance of clinical response and potential for relapse after treatment withdrawal (which occurs frequently in clinical practice) are critical points of consideration when initiating biologic treatment[2,3]

Guselkumab is a fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin-23.[4] Guselkumab has received conditional approval in China for the treatment of moderate-to-severe plaque psoriasis based on results from global studies[5,6]

The efficacy of guselkumab in Chinese patients has been studied in a post-approval commitment (PAC) study (NCT04914429);[7] however, data following guselkumab discontinuation in this population are limited

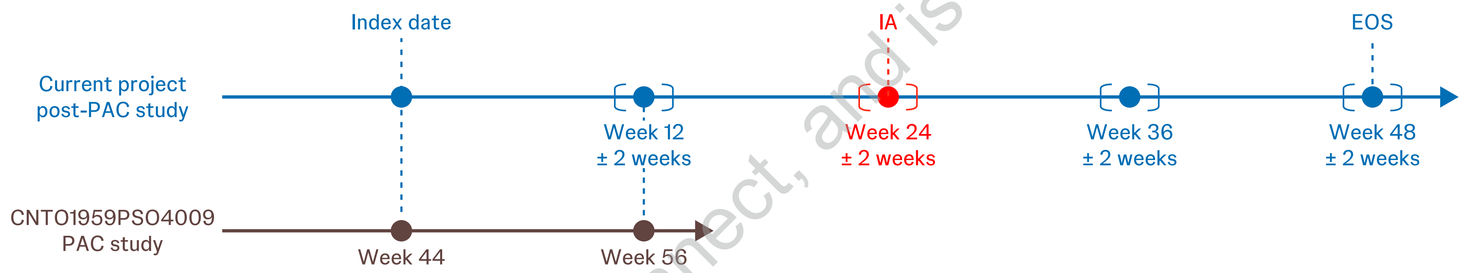
Objective

This prospective, observational, post-PAC study was conducted to evaluate maintenance of response after withdrawal of guselkumab treatment in Chinese patients with moderate-to-severe plaque psoriasis

Methods

- This post-PAC, prospective, observational real-world study included Chinese adult patients with moderate-to-severe plaque psoriasis who achieved a Psoriasis Area and Severity Index (PASI) 75 response at the time of receiving the last scheduled dose of guselkumab (Week 44) in the preceding PAC study (index date; **Figure 1**) and subsequently withdrew from guselkumab treatment
- Patients utilized a decentralized electronic system to self-report data at the index date and every 12 weeks thereafter during the 48-week post-PAC follow-up period
- The primary endpoint was off-treatment duration (OTD), defined from the index date of guselkumab withdrawal to the date of starting any systemic treatment for psoriasis (i.e., relapse)
- Secondary endpoints included change in Dermatology Life Quality Index (DLQI) score during the study follow-up period

Figure 1: Study design



EOS, end of study; IA, interim analysis; PAC, post-approval commitment.

Results

Demographic and disease characteristics at the index date

- A total of 243 eligible patients were enrolled in this post-PAC study (**Table 1**)
  - The mean (range) age was 41.2 (19–74) years
  - A majority of patients:
    - were male (n = 194; 79.8%)
    - were overweight (24 ≤ BMI < 28 kg/m^2; n = 89; 36.6%) or of normal weight (18.5 ≤ BMI < 24 kg/m^2; n = 87; 35.8%)
    - had a PASI score < 3, consistent with mild disease (n = 229; 94.2%)
    - had an Investigator Global Assessment (IGA) score of 0 (n = 146; 60.1%)
  - Prior to enrollment in the initial PAC study, all patients had received previous psoriasis treatments, including phototherapy (n = 129; 53.1%), systemic treatments (n = 147; 60.5%), and biologics (n = 12; 4.9%)

Patient disposition

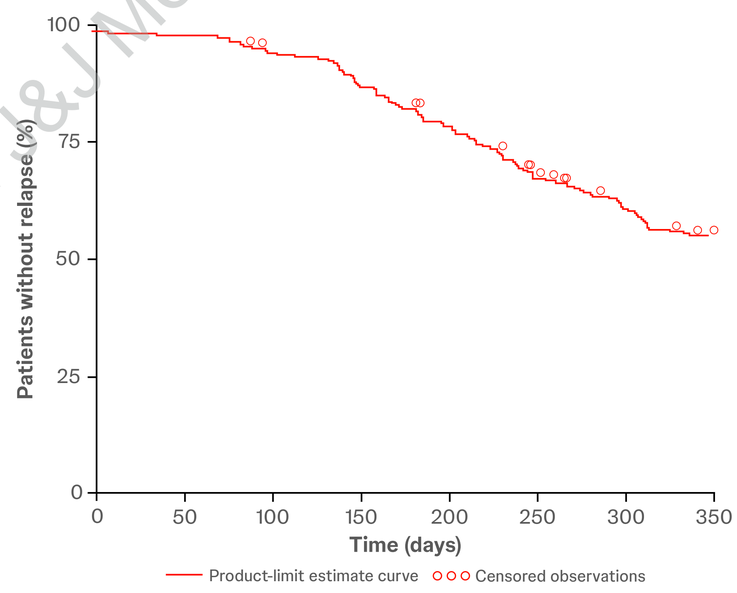
- Patient retention was 93.8% (n = 228) through Week 48 in the post-PAC study
- Discontinuations (n = 15; 6.2%) were due to:
  - loss to follow-up (n = 10)
  - withdrawal of consent (n = 3)
  - participation in other clinical trials (n = 2)

Table 1: Demographic and disease characteristics at the index date

		Total (N = 243)
Demographics		
	Age, years	
	Mean (SD)	41.2 (12.3)
	Range	19–74
	Male, n (%)	194 (79.8)
	BMI, n (%)	
	Underweight (BMI < 18.5 kg/m^2)	9 (3.7)
	Normal (18.5 ≤ BMI < 24 kg/m^2)	87 (35.8)
	Overweight (24 ≤ BMI < 28 kg/m^2)	89 (36.6)
	Obese (BMI ≥ 28 kg/m^2)	58 (23.9)
	Treatment history,[a] n (%)	
	Phototherapy	129 (53.1)
	Systemic treatments	147 (60.5)
	Biologics	12 (4.9)
Characteristics		
	PASI score, mean (SD)	0.68 (1.3)
	Mild (PASI < 3), n (%)	229 (94.2)
	Moderate (3 ≤ PASI < 10), n (%)	14 (5.8)
	IGA scale, n (%)	
	Clear (0)	146 (60.1)
	Almost clear (1)	76 (31.3)
	Mild (2)	19 (7.8)
	Moderate (3)	2 (0.8)
	DLQI score, mean (SD)	2.5 (4.3)
	0 or 1: no effect at all on patient's life, n (%)	117 (62.6)
	2–5: small effect on patient's life, n (%)	44 (23.5)
	6–10: moderate effect on patient's life, n (%)	16 (8.6)
	11–20: very large effect on patient's life, n (%)	8 (4.3)
	21–30: extremely large effect on patient's life, n (%)	2 (1.1)

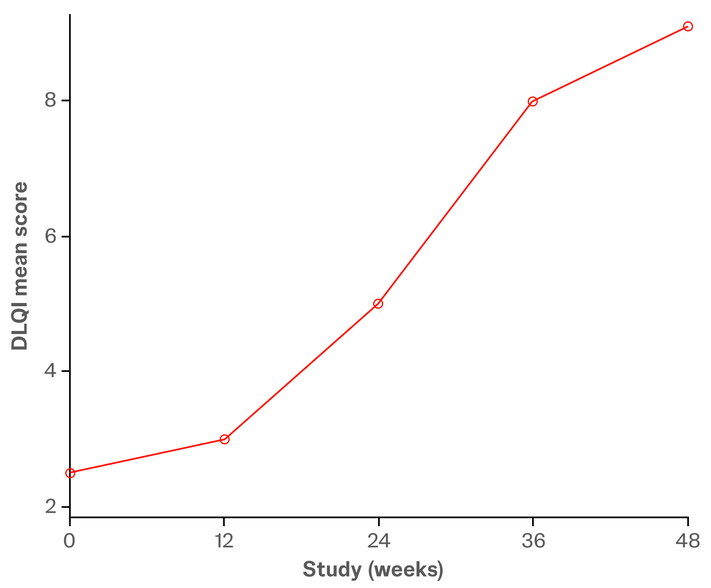
[a]*Treatment history was based on the time of enrollment in the initial PAC study. Patients may have received ≥ 1 type of previous treatment.*
BMI, body mass index; DLQI, Dermatology Life Quality Index; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; SD, standard deviation.

Figure 2: Off-treatment duration



- Median OTD was 350 days (range 9–350 days)
- During the 48-week follow-up period, median time to relapse was not reached (**Figure 2**)

Figure 3: Mean DLQI scores over time after guselkumab withdrawal



DLQI, Dermatology Life Quality Index.

- For the 187 patients with DLQI data at the index date, the mean (SD) change (increase) in DLQI score from the index date was 0.5 (4.50), 2.6 (6.24), 4.9 (7.54), and 6.9 (7.57) at Weeks 12, 24, 36, and 48, respectively (**Figure 3** and **Table 2**)
- Mean (SD) DLQI scores increased significantly after withdrawal of guselkumab, from 2.5 (4.28) at the index date to 9.1 (7.21) at Week 48 in the post-PAC study ($P < 0.001$) (**Table 2**)

Table 2: Summary of DLQI scores over time after guselkumab withdrawal

N = 243	Index date (n = 187)	Week 12 (n = 172)	Week 24 (n = 215)	Week 36 (n = 173)	Week 48 (n = 138)
DLQI					
Mean (SD)	2.5 (4.3)	3.0 (4.4)	5.0 (6.1)	8.0 (7.7)	9.1 (7.2)
Median	1	1	3	7	8
Q1, Q3	0, 3	0, 5	0, 8	1, 12	2, 12
Min, max	0, 26	0, 27	0, 30	0, 30	0, 30
Missing, n (%)	56 (23.0)	71 (29.2)	28 (11.5)	70 (28.8)	105 (43.2)

Percentages are calculated using the number of total patients in the 'Enrolled' set as the denominator.
DLQI, Dermatology Life Quality Index; Q1, first quartile; Q3, third quartile; SD, standard deviation.

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