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Efficacy and safety of vunakizumab in patients with moderate-to-severe plaque psoriasis with different disease durations: a post-hoc analysis of a phase III, randomized controlled trial

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Introduction & Objectives:

The psoriasis treatment landscape has evolved with the advent of targeted biologic therapies and a proactive treatment approach. Vunakizumab, a novel interleukin 17A inhibitor, has shown promising results in both efficacy and safety in preliminary data from phase III studies. This study aims to conduct a post-hoc analysis to evaluate the efficacy and safety of vunakizumab in patients with moderate-to-severe plaque psoriasis with different disease durations.

Materials & Methods:

Post-hoc analysis was conducted on data from a phase 3, randomized, double-blind, multicenter clinical study (NCT04839016). Patients treated with vunakizumab were divided into short disease duration (SDD, ≤ 2 years) or long disease duration (LDD, > 2 years) groups. Efficacy analysis included Psoriasis Area and Severity Index (PASI) 75, PASI90, and PASI100 response rates in both groups of intention-to-treat (ITT) population, with 95% confidence intervals (CI) estimated by Clopper-Pearson method. Safety analysis involved summarization by system organ class and preferred term, along with severity grading.

Results:

A total of 461 patients were included (SDD:67; LDD: 394). Baseline characteristics were shown in Table 1. From w0 to w12, the total response rates of PASI 75 were 97.0% (95% CI: 89.6-99.6), 93.4% (95% CI: 90.5-95.6); PASI 90 were 85.1% (95% CI: 74.3-92.6), 76.9% (95% CI: 72.4-81.0); PASI 100 were 40.3% (95% CI: 28.5-53.0), 38.3% (95% CI: 33.5-43.3) in the SDD and LDD groups, respectively (Table 2). From w0 to w52, the total response rates of PASI 75 were 100.0% (95% CI: 94.6-100.0), 99.2% (95% CI: 97.8-99.8); PASI 90 were 97.0% (95% CI: 89.6-99.6), 97.0% (95% CI: 94.7-98.4); PASI 100 were 86.6% (95% CI: 76.0-93.7), 81.9% (95% CI: 77.8-85.6) in the SDD and LDD groups, respectively (Table 3). Regarding safety, the incidence of treatment related adverse events within w52 was 62.7% (serious in 1.5%) in the SDD group; 64.1% (serious in 0.8%) in the LDD group, with an overall incidence of 63.9% (serious in 0.9%).

Conclusion:

Vunakizumab demonstrates favorable efficacy and safety for moderate-to-severe plaque psoriasis patients with different disease durations. Compared to patients with longer disease duration, those with shorter disease duration showed higher PASI75, 90, and 100 response rates within both w12 and w52.

Table 1. Baseline characteristics

Characteristic	SDD (N=67)	LDD (N=394)	Overall (N=461)
Age (years)			
< 65	65 (97.0)	367 (93.1)	432 (93.7)
≥ 65	2 (3.0)	27 (6.9)	29 (6.3)
Sex, n (%)			
Male	51 (76.1)	301 (76.4)	352 (76.4)
Female	16 (23.9)	93 (23.6)	109 (23.6)
Weight (kg)			
< 90kg	59 (88.1)	342 (86.8)	401 (87.0)
≥ 90kg	8 (11.9)	52 (13.2)	60 (13.0)
BMI (kg/m ²)			
< 24kg/m ²	27 (40.3)	152 (38.6)	179 (38.8)
≥ 24kg/m ²	40 (59.7)	242 (61.4)	282 (61.2)
Baseline BSA (%)			
Mean (SD)	29.0 (15.9)	35.4 (17.4)	34.5 (17.3)
Median	26.5	32.0	31.0
Min, max	10.1, 74.4	10.1, 89.5	10.1, 89.5
Baseline PASI			
Mean (SD)	19.6 (6.9)	22.7 (9.161)	22.2 (8.9)
Median	17.4	21.0	20.1
Min, max	12.0, 40.0	12.0, 60.0	12.0, 60.0
Baseline sPGA, n (%)			
3	31 (46.3)	157 (39.8)	188 (40.8)
4	33 (49.3)	198 (50.3)	231 (50.1)
5	3 (4.5)	39 (9.9)	42 (9.1)

SDD: short disease duration; LDD: long disease duration; SD: Standard Deviation; BSA: Body Surface Area; PASI: Psoriasis Area and Severity Index; sPGA: static Physician's Global Assessment

Table 2. PASI response from week0 to week12

Characteristic	SDD (N=67)	LDD (N=394)
PASI 75		
Response, n (%) ^[1]	65 (97.0)	368 (93.4)
Response rate (95% CI) ^[2]	97.0 (89.6-99.6)	93.4 (90.5-95.6)
PASI 90		
Response, n (%)	57 (85.1)	303 (76.9)
Response rate (95% CI)	85.1 (74.3-92.6)	76.9 (72.4-81.0)
PASI 100		
Response, n (%)	27 (40.3)	151 (38.3)
Response rate (95% CI)	40.3 (28.5-53.0)	38.3 (33.5-43.3)

N: number of patients in treatment group of ITT; n: number of subjects in specific category;

[1] Percentage are calculated using the subjects in ITT count as denominator.

[2] Clopper-Pearson method used.

Table 3. PASI response from week0 to week52

Characteristic	SDD (N=67)	LDD (N=394)
PASI 75		
Response, n (%) ^[1]	67 (100.0)	390 (99.2)
Response rate (95% CI) ^[2]	100.0 (94.6-100.0)	99.2 (97.8-99.8)
PASI 90		
Response, n (%)	65 (97.0)	381 (97.0)
Response rate (95% CI)	97.0 (89.6-99.6)	96.95 (94.7-98.4)
PASI 100		
Response, n (%)	58 (86.6)	322 (81.9)
Response rate (95% CI)	86.6 (76.0-93.7)	81.9 (77.8-85.6)

N: number of patients in treatment group of ITT; n: number of subjects in specific category;

[1] Percentage are calculated using the subjects in ITT count as denominator.

[2] Clopper-Pearson method used.

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