Secukinumab treatment demonstrated high efficacy and safety in pediatric patients with moderate to severe plaque psoriasis: 52-week results from a randomized trial

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INTRODUCTION

• Psoriasis in children (<18 years) and adolescents (18–25 years) is the most common variant of psoriasis in pediatric patients.1,2
• Limited treatment options have been approved for pediatric psoriasis, leading to a need for better treatment alternatives in pediatric patients.3

Secukinumab is a fully human monoclonal antibody that selectively neutralizes interleukin-17A, a pro-inflammatory cytokine involved in the development of psoriasis. It has demonstrated sustained, long-term efficacy with a favorable safety profile in various psoriatic disease manifestations in adults.4

Here, we report the efficacy and safety of two SEC dosing regimens (low dose and high dose) in pediatric patients with moderate to severe plaque psoriasis up to 52 weeks.

RESULTS

• A total of 94/92 patients completed the screening phase and were randomized to receive SEC low dose and high dose.
• The mean (standard deviation [SD]) PASI score at baseline was 14.5 (3.2) for low dose and 19.3 (5.7) for the high dose group (Table 1). At baseline, 72.6% (81) and 27.4% (21) patients had moderate and severe plaque psoriasis, respectively.

Table 1. Demographics and baseline characteristics

| Characteristics | Low dose (N=42) | High dose (N=42) | p-value
|-----------------|----------------|----------------|------
| Age group, n (%) | 2–<12 years | 17 (40.5) | 16 (38.1) | 0.03
| 12 to <18 years | 25 (59.5) | 26 (61.9) |
| Gender, n (%) | Female | 20 (47.6) | 25 (59.5) | 0.23
| Male | 22 (52.4) | 17 (40.5) |
| Weight status, n (%) | <25 kg | 17 (40.5) | 20 (47.6) | 0.61
| 25–<30 kg | 20 (47.6) | 18 (42.9) |
| ≥30 kg | 5 (11.9) | 4 (9.5) |
| Weight status, n (%) | <25 kg | 17 (40.5) | 20 (47.6) | 0.61
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• The quality of life (QoL) of patients (<18 years at the time of assessment) with psoriasis area and severity index (PASI) 75/ Investigator’s Global Assessment (IGA) 0/1 responded to SEC treatment (last observation carried forward), over time up to Week 52.

METHODS

Study Design and Patients

• This is a randomized, open-label, parallel-group, multicenter study (NCT02693881) in pediatric patients aged <18 years at randomization, with moderate to severe chronic plaque psoriasis.

Patients were randomized in a 1:1 ratio to receive low dose (75/75/150mg; N=42) or high dose (150/150/300mg) subcutaneous SEC. Randomization was defined by weight (<30kg/30kg/60kg and ≥30kg/60kg) and disease severity (moderate/severe)(Figure 1).

At baseline, 72.6% (61) and 27.4% (23) patients had moderate and severe plaque psoriasis, respectively.

• The proportion of patients achieving PASI 90 response at Week 4 was significantly higher in the SEC high dose group (90.5%/85.7%) compared with that of the low dose group (92.9%/88.1%) (P = 0.02) (Figure 3A). The proportion of patients achieving PASI 75 response at Week 12 was significantly higher in the SEC high dose group (70.7% in the low dose group and 70.3% in the high dose group, respectively) (Figure 3B).

Efficacy

• The study achieved its primary and key secondary objectives.

• The co-primary (PASI 75 and IGA mod 2011 0/1) response was achieved in 50.0% and 61.9% of patients at Week 12, which increased to 70.3% and 70.7% at Week 52, in the low dose and high dose groups, respectively (Figure 4).

CONCLUSIONS

• SEC is highly effective in rapidly clearing skin (PASI 75/90/100 and IGA mod 2011 0/1), with sustained efficacy with both dose regimens over a 52-week period.

• The safety profile in pediatric patients is consistent with that in the adult population.

• The proportion of patients achieving CDLQI 0/1 continued to increase up to Week 24 and reached 70.3% and 70.7% in the low dose and high dose group, up to Week 52.

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Table 2. TSA effects through Week 52 (Safety set)

| Characteristics | Low dose (N=42) | High dose (N=42) | p-value
|-----------------|----------------|----------------|------
| Any AEs, n (%) | 28 (66.7) | 27 (64.3) | 0.55
| Any non-fatal SAEs, n (%) | 2 (4.8) | 2 (4.8) | 1.00
| Any death, n (%) | 0 | 0 | 1.00
| Most frequent AEs by SOC, n (%) | 45.2% | 50.0% | 0.55
| Most frequent AEs by PT, n (%) | 4.8% | 4.8% | 1.00
| Neutrophilia | 9 (21.4) | 6 (14.3) | 0.55
| Leukopenia | 3 (7.1) | 2 (4.8) | 1.00
| Pancytopenia | 3 (7.1) | 3 (7.1) | 1.00

DISCLOSURE

• No honoraria or personal benefits have been received from any of the commercial organizations.

• The authors have and declare no conflicts of interest.

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• Clinical safety of SEC was evaluated up to Week 52.

• The exploratory endpoints of the study were to evaluate the proportion of responders achieving PASI 75/90 and IGA mod 2011 0/1 scores over time up to Week 52 and absolute and percentage change in PASI, PASI 75/90 scores from baseline, over time up to Week 52.

• The quality of life (QoL) of patients (<18 years at the time of assessment) was evaluated by CDLQI 0/1 response (last observation carried forward), over time up to Week 52.

• Absolute PASI change (mean [SD]) of patients from baseline was evaluated as a measure of treatment effect on Psoriasis Area and Severity Index (CDLQI 0/1 responses) (last observation carried forward), over time up to Week 52.

• Absolute CDLQI 0/1 response was achieved in 50.0% and 61.9% of patients at Week 12, which increased to 70.3% and 70.7% at Week 52, in the low dose and high dose groups, respectively (Figure 4).

• Treatment-emergent adverse events (TEAEs) were consistent with the known safety profile from adult studies with no new safety signals observed (Table 2).