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Topic: Psoriasis

A Multicenter, Randomized, Open-label, Phase 3 Study to Evaluate the Efficacy and Safety of SSGJ-608 in patients with moderate-to-severe plaque psoriasis

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Introduction
SSGJ-608 is an anti-interleukin-17A monoclonal antibody with high specificity and high affinity. This is a multicenter, randomized, open-label, phase 3 study with the primary objective of demonstrating efficacy and safety of SSGJ-608 in patients with moderate-to-severe plaque psoriasis.

Materials and Methods
This study composed of a 12-week open label treatment period and a 8-week safety follow-up period. Patients with moderate-to-severe plaque psoriasis were randomly assigned (1:1) to receive subcutaneous injections of 80mg of SSGJ-608 every two weeks (Q2W) after a starting dose of 160mg at week 0 (608A group), or 160mg of SSGJ-608 every four weeks (Q4W) (608 B group) for 12 weeks. Efficacy was assessed by ≥75% improvement from baseline in the Psoriasis Area and Severity Index score (PASI75) and a static Physicians Global Assessment score of 0/1 (sPGA 0/1) response rates at week 12 as co-primary endpoints, and proportion of patients who achieved PASI90, PASI100 or sPGA score of 0 at week 12 as key secondary endpoints. The safety profile was also evaluated.

Results
A total of 770 Chinese patients were enrolled and randomized to 608A group (n=385) or 608B group (n=385). At week12, the proportions of patients achieving PASI75 (92.7% vs. 95.1%) and sPGA 0/1 (80.3% vs. 79.0%) were comparable between the two SSGJ-608 dose regimens; 81.0% of patients in the 608A group and 82.3% in the 608B group achieved PASI90, respectively; 49.4% and 47.5% in each group achieved PASI100, respectively; sPGA score of 0 was achieved by 49.4% of patients and 47.3% in each group, respectively. PASI 90 response rate was 26.2% in the 608A group and 22.9% in the 608B group at week 4; this rate increased to 66.2% and 66.0% at week 8, and further improved to 77.4% and 79.7% by week 20, respectively. PASI100 response rate was 10.4% in the 608A group and 4.2% in the 608B group at week 4; this rate increased to 32.7% and 28.8% at week 8, and further improved to 48.3% and 48.6% by week 20, respectively. The proportions of patients achieving sPGA 0 in the two groups (49.4% and 47.3%) were comparable to the PASI100 response rates, with both endpoints signifying complete skin clearance. Besides, of the patients who had a NRS

score ≥4 at baseline, 82.3% of patients in the 608A group and 78.9% in the 608B group achieved a reduction in NRS score of ≥4 at week 12. In the subgroup of patients who had received IL-17 targeted therapy before, 77.8% (42/54) of patients in the 608A group and 74.0% (37/50) in the 608B group achieved PASI90, respectively; 55.6% (30/54) and 44.0% (22/50) in each group achieved PASI100, respectively; sPGA 0 was achieved by 55.6% (30/54) and 44.0% (22/54) in each group, respectively. The most common TEAEs were hypertriglyceridemia (5.2%), upper respiratory tract infection (4.9%), hyperuricemia (4.4%), alanine aminotransferase increased (4.3%) and hypercholesterolemia (3.6%). Both treatment groups demonstrated a favorable safety profile, with no increase in risk observed with longer drug exposure.

Conclusions

SSGJ-608 showed rapid, substantial, and durable levels of skin clearance in patients with moderate to severe psoriasis at both 80mg Q2W (with a 160mg starting dose at Week 0) and 160mg Q4W in a larger population, which was reflected in high proportions of complete skin clearance. SSGJ-608 also achieved high clinical response rates in patients previously treated with anti-IL-17 therapy in both dosing schedules. Safety findings in this patient population were consistent with other same-target drugs, and no new risk signals were found for SSGJ-608. This study featured a large sample size and sufficient exposure, further validating both the efficacy and safety profile of SSGJ-608. These findings suggest that SSGJ-608 has the potential to ensure long-term therapeutic success and improve patient quality of life, while also presenting a lower risk of certain significant complications.