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Topic: Psoriasis

Efficacy and Safety of SSGJ-608 in Moderate-to-Severe Plaque Psoriasis: a Pivotal Multicenter, Randomized, Double-blind, Placebo-Controlled, Phase 3 Clinical Trial

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Introduction
SSGJ-608 is a recombinant humanized IgG1 monoclonal antibody that targets human IL-17A with high specificity and high affinity, and it has shown promising efficacy with a longer dosing interval of every 4 or 8 weeks in treatment of moderate-to-severe psoriasis in preliminary trials. This pivotal multicenter, randomized, double-blind, placebo-controlled, phase 3 clinical trial aims to evaluate the efficacy and safety of SSGJ-608 in patients with moderate-to-severe psoriasis.

Materials and Methods
The study consisted of four time periods: screening (week -4 to week 0), double-blind induction period (week 0 to 12), double-blind maintenance period (weeks 12 to 52), and follow-up (weeks 52 to 60). Adults (≥18 years) with moderate-to-severe plaque psoriasis were randomized (2:2:1) to receive placebo, SSGJ-608 80 mg Q2W (with a 160 mg loading dose at Week 0; 608A group), or SSGJ-608 160 mg Q4W (608B group). At Week 12, the 608A group switched to 80 mg Q4W, the 608B group to 160 mg Q8W, and patients received placebo were re-randomized (1:1) to receive either the 608A or 608B maintenance regimen (with a 160 mg loading dose for those entering the 608A regimen). Treatment continued for all patients until Week 48. The co-primary endpoints were the achievement of Psoriasis Area and Severity Index score 75 (PASI75) and sPGA 0/1 at Week 12. Key secondary endpoints included PASI90, PASI100, and sPGA 0 at Week 12, as well as the maintenance of PASI75, PASI90, PASI100, sPGA 0/1, and sPGA 0 responses through Week 52. Safety was assessed throughout the study.

Results
A total of 458 Chinese patients were randomly assigned to either the 608 A group (n=184), the 608B group (n=183), or the placebo group (n=91). PASI75 response was observed as early as week 2, and 48.4% and 44.3% of patients in the 608A and 608B groups, respectively, achieved PASI75 versus no patient in the placebo group ($P < 0.0001$) by week 4. Similarly, sPGA 0/1 response emerged at Week 2, with 26.6% (608A) and 21.3% (608B) of patients achieving this endpoint at Week 4, compared to none in the placebo group ($P < 0.0001$). At week 12, a greater proportion of patients in the 608A group and in the 608B group achieved the primary endpoints of PASI75 (95.1% vs. 93.4% vs. 8.8%) and sPGA of 0 or 1(76.1% vs. 67.2% vs. 1.1%) compared with placebo; PASI90 was achieved by 80.4% of patients in the 608A group and 72.7% in the 608B group compared with 1.1% in the placebo group; PASI100 was achieved by 42.9% of patients in the 608A group and 33.9% in the 608B group compared with none in the placebo group; sPGA of 0 was achieved by the same proportion as PASI100. During the maintenance period, PASI75 and sPGA 0/1 response rates were sustained in 91.8% to 95.7% and 73.8% to 87.5% of patients in the 608A and 608B groups, respectively. At Week 52, maintenance rates were 93.7% for PASI75, 89.3% for sPGA 0/1, and 92.6% for PASI90 in the 608A group, compared with 93.6%, 89.4%, and 92.5% in the 608B group, respectively. Immunogenicity analysis revealed pre-existing anti-drug antibodies (ADA) in 1.6% (608A) and 0.5% (608B) of patients prior to the first dose. Treatment-induced ADA occurred in 2.7% (608A) and 1.6% (608B) of patients, all of which were treatment-related. Persistent ADA was observed in 0.5% (608A) and 1.6% (608B) of patients; all tested negative for neutralizing antibodies. During all treatment period, the most common TEAEs were upper respiratory tract infection, hypertriglyceridemia and hyperuricemia. Both treatment groups demonstrated a favorable safety profile, with no increase in risk observed with longer drug exposure.

Conclusions
SSGJ-608 demonstrated rapid, substantial, and durable skin clearance in Chinese patients with moderate-to-severe plaque psoriasis, even with an extended dosing interval of every 8 weeks. The safety profile was consistent with other drugs sharing the same target, with no new safety signals identified. These findings support SSGJ-608 as a promising new treatment option for this patient population.