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Efficacy and Safety of a Selective Oral TYK2/JAK1 Inhibitor, AC-201, in Patients with Plaque Psoriasis: A Phase II, Randomized, Double-blinded, Placebo-Controlled Trial

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Introduction

AC-201 is a novel, oral TYK2/JAK1 Inhibitor under investigation as a potential treatment for plaque psoriasis.

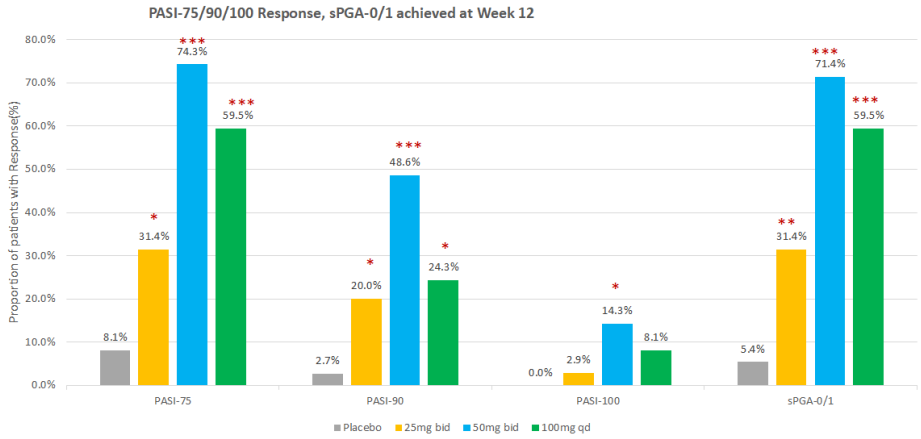
Materials and Methods

This Phase 2 study (AC201-003, NCT06972888) aimed to characterize the efficacy, safety and pharmacokinetic profile of AC-201 vs. placebo in Chinese patients with moderate-to-severe plaque psoriasis.
One hundred and forty-five patients were randomized to receive AC-201 25mg BID, 50mg BID,100mg QD, or placebo over 12 weeks. The primary endpoint was the proportion of patients achieving a ≥ 75%reduction in the Psoriasis Area and Severity Index (PASI-75) score at week 12.

Results

At week 12, PASI-75 response rates were significantly higher for all AC-201 dose groups: 31.4% (25mg BID; P=0.012), 74.3% (50mg BID; P<0.001), and 59.5% (100mg QD; P<0.001), compared with placebo (8.1%). PASI-90 and static Physician's Global Assessment (sPGA)-0/1 (score of 0 ‘clear’ or 1 ‘almost clear’)response rates were also significantly higher for AC-201 vs. placebo. The PASI-90 response rate was 2.7% for placebo, 20% for 25mg BID (P=0.02), 48.6% for 50mg BID (P<0.001), and 24.3% for 100mg QD (P=0.007). The percent of patients achieved sPGA-0/1 were 5.4% for placebo, 71.4% for 50mg BID (P<0.001), 59.5% for100mg QD (P<0.001), and 31.4% for 25mg BID (P=0.004). There was no serious adverse event (SAE) or AE leading to permanent discontinuation reported in the study. The most common Treatment-Emergent Adverse Events (TEAEs) reported were upper respiratory tract infection (8.6% for 25mg BID, 34.3% for 50mg BID,13.5% for 100mg QD and 10.8% for placebo) and hypertriglyceridemia (8.6% for 25mg BID, 17.1% for 50mgBID, 8.1% for 100mg QD and 18.9% for placebo).

PASI-75/90/100 response, sPGA 0/1 at Week 12-FAS population



*p<0.05; **p< 0.005; ***p<0.001 . P-value is comparing proportion in each AC-201 dose group vs placebo using the Cochran-Mantel-Haenszel (CMH) test. NRI (non-responder imputation) was applied for subjects who discontinued study

Conclusion

12-week treatment with oral AC-201 results in significant clinical improvement in patients with moderate-to-severe plaque psoriasis and is generally well tolerated.