



PRURITUS

EFFECTS OF SERLOPITANT ON PRURITUS ASSOCIATED WITH PSORIASIS: RESULTS OF A PHASE 2 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL

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Introduction: Pruritus is a significant symptom of psoriasis that negatively impacts quality of life. Treatments for psoriatic lesions often do not alleviate psoriatic pruritus. Thus, there remains an unmet medical need for effective treatment of psoriatic pruritus.

Objective: To study the effects of serlopitant, an oral, once-daily neurokinin-1 receptor antagonist on psoriatic pruritus in a phase 2, randomized, double-blind, placebo-controlled trial (NCT03343639).

Materials and Methods: Patients were randomized to serlopitant 5 mg (n=102) or placebo (n=102) daily for 8 weeks. Adult patients with plaque psoriasis covering $\leq 10\%$ of body surface area, pruritus ≥ 4 weeks, and mean worst-itch numerical rating scale (WI-NRS) score ≥ 6.0 over the week prior to randomization were eligible to participate. WI-NRS 4-point and 3-point improvement responder rates were evaluated. The primary and key secondary efficacy endpoints included the WI-NRS 4-point responder rate at week 8 and at week 4.

Results: Mean age of participants was 47.5 years, 54.2% were female, and 85.2% were white. Mean baseline WI-NRS scores were similar for serlopitant (8.3) and placebo (8.1). At week 8, WI-NRS 4-point responder rates were 33.3% for serlopitant vs 21.1% for placebo ($P=0.028$), and at week 4, the rates were 20.8% for serlopitant vs 11.5% for placebo ($P=0.039$). At corresponding timepoints, the WI-NRS 3-point responder rates for serlopitant were 42.1% and 31.9%. At every assessed time point in the trial, the serlopitant group demonstrated greater numerical improvement than the placebo group in the WI-NRS 4-point and 3-point responder analyses. Treatment-related adverse events were reported for 4.9% and 4.0% of serlopitant and placebo patients, respectively.

Conclusions: Serlopitant reduced psoriatic pruritus, as demonstrated by consistent WI-NRS





4- and 3-point improvements. These results represent a clinically meaningful improvement in itch and support the ongoing development of serlopitant for this patient population.

