PSORIASIS

EFFICACY AND SAFETY OF CONTINUOUS Q12W RISANKIZUMAB VERSUS TREATMENT WITHDRAWAL: 104-WEEK RESULTS FROM THE PHASE 3 IMMHANCE TRIAL

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Background: Risankizumab (RZB) is a humanized IgG1 monoclonal antibody that selectively inhibits IL-23 through binding p19. IMMhance was a two-part Phase 3 multinational, double-blind study in patients with moderate-to-severe plaque psoriasis. In Part A1, RZB met all primary and ranked secondary efficacy endpoints compared with placebo (PBO) at week 16.

Objectives: To evaluate the impact of RZB withdrawal and re-treatment on safety and efficacy in patients with moderate-to-severe plaque psoriasis.

Materials and Methods: In Part A1, patients initially randomized to RZB received 150mg at weeks 0 and 4. In Part A2, all patients received RZB at week 16. In Part B, responders to initial RZB treatment (Static Physician Global Assessment [sPGA] 0/1) at week 28 were stratified by weight and prior TNF inhibitor exposure, and re-randomized 1:2 to continuous RZB every 12-week treatment (RZB/RZB) or to withdrawal (RZB/PBO). After week 32, patients who relapsed (sPGA ≥3) were re-treated with open-label RZB 150mg. The primary

and ranked secondary efficacy endpoints in Part B were the proportion of re-randomized patients at week 28 who maintained sPGA 0/1 at weeks 52 and 104, respectively, using non-responder imputation. Safety was assessed in all patients.

Results: In part B, 87.4% (97/111) and 81.1% (90/111) of patients re-randomized to continuous RZB (RZB/RZB) maintained sPGA 0/1 at weeks 52 and 104, respectively, compared with 61.3% (138/225) and 7.1% (16/225) of patients re-randomized to withdrawal (RZB/PBO; P<.001 at both weeks). Overall, 153 responders at Week 28 who were re-randomized to PBO experienced relapse. After 16 weeks of RZB re-treatment, 83.7% (128/153) regained sPGA 0/1. RZB was well-tolerated; safety was generally comparable in Part B between patients re-randomized to continuous RZB or withdrawal.

Conclusions: RZB provides durable maintenance of efficacy and its safety profile was generally comparable with that of PBO in patients with moderate-to-severe plaque psoriasis.