PSORIASIS

SAFETY OF RISANKIZUMAB IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS: ANALYSIS OF POOLED SHORT-TERM AND LONG-TERM CLINICAL TRIAL DATA

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Background: Risankizumab inhibits interleukin-23, a key cytokine associated with psoriatic lesions, by binding to its p19 subunit.

Objective: To report short- and long-term safety in patients with moderate-to-severe psoriasis treated with risankizumab.

Materials and Methods: Short-term safety was evaluated (vs adalimumab, ustekinumab, and placebo) through week-16 of risankizumab treatment from 5 phase 2–3 trials. Long-term safety was evaluated in an all-risankizumab data set from 11 phase 1–3 trials.

Results: Week-16 data included 2232 patients (risankizumab 90/150/180-mg doses, n=41/1306/42; adalimumab, n=304; ustekinumab, n=239; placebo, n=300), representing 432.4, 95.0, 75.9, and 92.0 patient-years [PY]); long-term (up to 47-month) data included 2471 risankizumab-treated patients (18/90/150/180 mg; [3404.7 PY]). Through week-16, adverse events (AEs) occurred in 49.0%, 56.9%, 52.3%, and 48.3% of patients receiving risankizumab, adalimumab, ustekinumab, and placebo, and serious AEs/100PY per treatment were 9.3, 14.7, 18.4, and 17.4, respectively. At week-16, events (E)/100PY (95% CI) per treatment for serious infection (SI) were risankizumab: 1.6 (0.7–3.3), adalimumab: 2.1 (0.3–7.6), ustekinumab: 5.3 (1.4–13.5), and placebo: 1.1 (<0.1–6.1); for malignancies excluding non-melanoma skin cancer (NMSC) were risankizumab: 0.7 (0.1–2.0), adalimumab: 1.1 (<0.1–5.9), ustekinumab: 0 (0–4.0), and placebo: 0 (0–3.3); and for adjudicated major adverse cardiac events (MACE) were risankizumab: 0.2 (<0.1–1.3),

adalimumab: 0 (0–3.2), ustekinumab: 0 (0–4.0), and placebo: 1.1 (<0.1–6.1). E/100PY (95% CI) with up to 47-month risankizumab for SI (1.4 [1.1–1.9]), malignancy excluding NMSC (0.6 [0.4–0.9]), and MACE (0.4 [0.3–0.7]) were consistent with week-16 data as were up to 47-month E/100PY (95% CI) for depression (0.9 [0.3–2.4], 0.9 [0.6–1.3]) and hypersensitivity reactions (10.4 [7.6–13.9], 7.1 [6.3–8.1]).

Conclusions: Week-16 AE rates with risankizumab were low and similar to comparator groups and to AE rates with long-term risankizumab treatment up to 47 months.