PSORIASIS

RISANKIZUMAB IS ASSOCIATED WITH LOW AND CONSISTENT INFECTION RATES IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS: ANALYSIS OF SHORT-TERM AND LONG-TERM POOLED CLINICAL TRIAL DATA

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Background: Risankizumab inhibits interleukin-23, a key cytokine in the immunopathogenesis of psoriasis, by binding to its p19 subunit.

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

Materials and Methods: Short-term infection rates were evaluated (vs adalimumab, ustekinumab, and placebo) through week 16 of risankizumab treatment from 5 completed and ongoing phase 2–3 trials. Long-term infection rates were evaluated in a risankizumab data set of 11 phase 1–3 completed double-blind trials, and unblinded or open-label ongoing 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, infections were reported in 22.5%, 24.3%, 20.9%, and 14.7% of risankizumab-, adalimumab-, ustekinumab-, and placebo-treated patients. Week-16 infection events/100PY (95% CI) were 92.0 (83.2–101.6), 104.2 (84.7–126.9), 87.0 (67.3–110.6), and 56.5 (42.2–74.1) with risankizumab, adalimumab, ustekinumab, and placebo. Upper respiratory infections were the most frequent infections with risankizumab. Week-16,

serious infection (SI) events/100PY (95% CI) 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). The only SI with >1 event with risankizumab was cellulitis (0.5/100PY). Long-term events/100PY (95% CI) were 72.1 (69.3–75.0), all infections, and 1.4 (1.1–1.9), SIs. Most common SIs (≥5 events) with long-term risankizumab were sepsis (0.2/100PY), cellulitis (0.1/100PY), and pneumonia (0.1/100PY); 8 patients had latent tuberculosis (0.3/100PY). Long-term, 3.8% patients reported fungal infections (3.2/100PY), predominantly superficial tinea infections, all mildly-to-moderately severe. There were no cases of systemic candidiasis.

Conclusions: Overall infection rates with risankizumab were higher than placebo, comparable with ustekinumab, and numerically lower than adalimumab. Serious infection rates were low and remained consistent with long-term exposure.