PSORIASIS

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

K. Reich [1] - K.b. Gordon [2] - S. Tyring [3] - R. Sinvhal [4] - A. Camez [5] - B. Waterhouse [6] - W.c. Valdecantos [7] - K. Papp [8]

Dermatologikum Berlin And Sciderm Research Institute, Na, Hamburg, Germany [1] - Medical College Of Wisconsin, Department Of Dermatology, Milwaukee, United States [2] - University Of Texas Health Science Center And Center For Clinical Studies, Department Of Dematology, Houston, United States [3] - Abbvie Inc., Immunology, Medical Safety Evaluation, North Chicago, United States [4] - Abbvie Deutschland Gmbh & Co Kg, Immunology, Gprd, Ludwigshafen, Germany [5] - Abbvie Inc., Safety Statistics Group, Data And Statistical Sciences, North Chicago, United States [6] - Abbvie Inc., Dermatology Us Medical Affairs, North Chicago, United States [7] - K Papp Clinical Research And Probity Medical Research, Na, Waterloo, Canada [8]

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

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

Materials and Methods: Short-term rate of malignancies was evaluated in a controlled data set (vs adalimumab, ustekinumab, and placebo) through week 16 of risankizumab treatment from 5 completed and ongoing phase 2–3 trials. Longer-term rate of malignancies was evaluated in an all-risankizumab data set from 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]); longer-term (up to 47-month) data included 2471 risankizumab-treated patients (18/90/150/180 mg; [3404.7 PY]). Through week 16, 0.4%, 0.3%, 0%, and 0.3% of risankizumab-, adalimumab-, ustekinumab-, and placebo-treated patients reported any malignant tumors including non-melanoma skin cancers (NMSC); 0.2% and 0.3% of risankizumab- and placebo-treated patients reported NMSC.

Other malignant tumors (excluding NMSC) included invasive lobular breast carcinoma, malignant melanoma in situ, esophageal carcinoma (n=1 each, risankizumab-treated), and gallbladder cancer (n=1, adalimumab-treated). Any malignant tumor events/100PY (95% CI) in risankizumab-treated patients were similar for 16-week (1.4 [0.5–3.0]) and up to 47-month data (1.4 [1.0–1.8]). NMSC events/100PY in risankizumab-treated patients at 16 weeks 0.7 (0.1–2.0) were similar to up to 47-month rates 0.8 (0.5–1.1), as was the rate of other malignant tumors (week-16: 0.7 [0.1–2.0]; up to 47-month: 0.6 [0.4–0.9]). Most frequent non-NMSC malignant tumors with up to 47-month risankizumab treatment were melanoma (n=2, <0.1/100PY), prostate cancer (n=3, <0.1/100PY), and breast cancers (n=6, 0.2/100PY).

Conclusions: NMSC and malignant tumors excluding NMSC rates for risankizumab were relatively low and similar at 16 weeks and up to 47 months of risankizumab treatment.