PSORIASIS

LONG-TERM SAFETY OF TILDRAKIZUMAB IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS: INCIDENCE OF MALIGNANCIES THROUGH 3 YEARS (148 WEEKS) FROM RESURFACE 1 AND RESURFACE 2 PHASE 3 TRIALS

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Introduction: Tildrakizumab (TIL) is a high-affinity anti-IL-23p19 monoclonal antibody FDA-approved for treating moderate-to-severe plaque psoriasis in the US.

Objective: To evaluate malignancies in two phase3 trials: reSURFACE1/2 (NCT01722331/NCT01729754).

Materials and Methods: Pooled analysis of adult patients with moderate-to-severe plaque psoriasis from two 3-part, parallel-group, double-blinded, randomized controlled trials: reSURFACE1 (64week) and reSURFACE2 (52week). Detailed methodology has been previously published (Reich et al., Lancet, 2017). Safety data over 148 weeks pooled across trials and treatment groups were included. Groups were defined as placebo, etanercept (until week 28), TIL 100mg (100mg-only in at least one part of the study), TIL 200mg (200mg-only in at least one part of the study), continuous TIL 100mg (100mg throughout the 3 double-blind parts plus open-label extension), continuous 200mg (200mg throughout all parts), TIL100/200mg (any TIL dose in at least one part) and continuous TIL 100/200mg (consistently exposed but dose could change throughout all parts). Exposure-adjusted incidence rates (EAIR) for malignancies (excluding non-melanoma skin cancer [NMSC]) and for NMSC were reported.

Results: Overall, 928 patients on TIL 200mg, 872 on TIL 100mg, 316 on continuous TIL 200mg, 352 on continuous TIL 100mg, 543 on placebo, 1646 on TIL 100/200mg, 808 on continuous TIL 100/200mg, and 313 on etanercept were included. The EAIR of malignancies was 0.39/100 subject-years of exposure among TIL 200mg, 0.45 (TIL 100mg), 0.69 (continuous TIL 200mg), 0.45 (continuous TIL 100mg), 0.0 (placebo), 0.42 (TIL 100/200mg), 0.47 (continuous TIL 100/200mg), and 0.65 (etanercept). The EAIR of NMSC was 0.49/100 subject-years of exposure among TIL 200mg, 0.50 (TIL 100mg), 0.59 (continuous TIL 200mg), 0.27
(continuous TIL 100mg), 0.97 (placebo), 0.49 (TIL 100/200mg), 0.35 (continuous TIL 100/200mg), and 1.30 (etanercept).

Conclusions: Tildrakizumab had a favourable long-term safety profile as demonstrated by a low rate of malignancies (comparable to etanercept and placebo) in patients with moderate-to-severe plaque psoriasis.