PSORIASIS

LONG-TERM SAFETY OF TILDRAKIZUMAB IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS: INCIDENCE OF SEVERE INFECTIONS 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 severe infections in two phase 3 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 (64 week) and reSURFACE2 (52 week). 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), TIL100mg (100mg-only in at least one part of the study), TIL200mg (200mg-only in at least one part of the study), continuous TIL100mg (100mg throughout the 3 double-blind parts plus open-label extension), continuous TIL200mg (200mg throughout all parts), TIL100/200mg (any TIL dose in at least one part) and continuous TIL100/200mg (consistently exposed but dose could change throughout all parts). Severe infections were defined as any infection meeting the regulatory definition of a serious adverse event (SAE), or requiring intravenous antibiotics, irrespective of whether it

was reported as a SAE. Exposure-adjusted incidence rates (EAIR) were reported.

Results: Overall, 928 patients on TIL200mg, 872 on TIL100mg, 316 on continuous TIL200mg, 352 on continuous TIL100mg, 543 on placebo, 1646 on TIL100/200mg, 808 on continuous TIL100/200mg, and 313 on etanercept were included. The EAIR of severe infections was 1.12/100 subject-years of exposure among TIL200mg, 1.14 (TIL100mg), 0.88 (continuous TIL200mg), 0.64 (continuous TIL100mg), 0.97 (placebo), 1.11 (TIL100/200mg), 0.86 (continuous TIL100/200mg), and 1.96 (etanercept). Most commonly reported types of severe infections included appendicitis, cellulitis, diverticulitis, and sinusitis.

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