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Abstract #: 9

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Safety and efficacy of tofacitinib, an oral Janus kinase inhibitor, up to 36 months in patients with active psoriatic arthritis: data from the third interim analysis of OPAL Balance, an open-label, long-term extension study

Objective(s): Tofacitinib is an oral Janus kinase inhibitor for the treatment of psoriatic arthritis (PsA). We report the safety and efficacy of tofacitinib in patients with active PsA from an open-label, long-term extension (LTE) study (OPAL Balance, NCT01976364; August 31 2017 data-cut; study ongoing, database not locked; some values may change in final, locked database).

Method(s): Eligible patients from two Phase (P)3 tofacitinib PsA studies (OPAL Broaden, NCT01877668; OPAL Beyond, NCT01882439) entered a 3-year LTE ≤3 months after completing these studies or discontinuing for reasons other than treatment-related AEs. Patients received tofacitinib 5 mg BID to Month (M)1, after which dose adjustments between 5 and 10 mg BID were permitted to improve efficacy, or for safety reasons. Patients receiving a csDMARD at P3 study entry continued the same csDMARD in the LTE. Primary endpoints included incidence and severity of AEs and change from baseline in laboratory values. Safety data are reported up to M36 and efficacy (as a secondary endpoint) to M30 (when N>50).

Result(s): 686 patients were treated in OPAL Balance; 468 (68.2%) remained in the study at data cut-off. Mean (range) LTE tofacitinib treatment duration was 614 (1–1032) days. On Day 1, 675 patients (98.4%) received a csDMARD (86 discontinued; 12.7%). To M36, 2189 AEs were reported in 546 patients (79.6%), 95 patients (13.8%) had serious AEs and 59 (8.6%) AE-related discontinuations. Serious infections occurred in 12 patients (1.7%), herpes zoster in 20 patients (2.9%; 1 serious event), major adverse cardiovascular events in 5 patients (0.7%), malignancies in 24 patients (3.5%; including 12 patients with NMSC) and uveitis in 2 patients (0.3%). There were 5 deaths (not attributed to treatment by the investigator) due to metastatic pancreatic carcinoma, acute cardiac failure/hypertensive heart disease, chronic obstructive pulmonary disease, pulmonary embolism and cardiovascular insufficiency. Four patients reported AEs of latent tuberculosis, whose previously negative QuantiFERON response became positive. ALT was elevated ≥3x ULN in 27 patients (4.0%), and AST ≥3x ULN in 15 patients (2.2%). Changes in laboratory values observed in P3 studies were generally stable in the LTE (7 patients had protocol-mandated discontinuations; 1.0%), except for a modest decrease in absolute lymphocyte count over time. Efficacy was maintained up to M30.

Conclusion(s): Over 36 months in the LTE, the safety profile of tofacitinib in patients with active PsA was generally similar to the two prior P3 studies, with no new safety risks identified. Efficacy across various disease domains was maintained over time.

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