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RC001 - GLUCOCORTICOID DOSE IS PROGRESSIVELY REDUCED IN PATIENTS WITH RHEUMATOID ARTHRITIS RECEIVING SARILUMAB: RESULTS FROM THE OPEN-LABEL EXTEND STUDY

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Resumen

Objectives: This post hoc analysis assessed changes in oral glucocorticoid (OGC) use over time in patients with rheumatoid arthritis (RA) receiving sarilumab 200 mg (dose reduction to 150 mg for laboratory abnormalities or per investigator's discretion) every 2 weeks (q2w) plus conventional synthetic disease-modifying antirheumatic drugs (csDMARD) in EXTEND (NCT01146652), a long-term, open-label extension (OLE) study of sarilumab in RA.

Methods: Patients who had completed placebo-controlled Phase 3 studies of sarilumab +csDMARD (NCT01061736 and NCT01709578) and received sarilumab in EXTEND were included. Reported total daily OGC doses were converted to prednisone equivalent daily doses (PED). Patients were grouped by PED dose at enrollment into the OLE: 0- < 5, 5- < 10, and ≥ 10 mg/day (PED < 1 mg/day imputed to 0). PED doses were analyzed over 12-week intervals to Week 216. Change from baseline for average PED was tested (Wilcoxon-Pratt-Lehman).

Results: In total, 891/1,353 patients (65.9%) had ≥ 1 record of OGC use. Of these, 137 (15.4%) received baseline PED of 0- < 5 mg/day, 515 (57.8%) 5- < 10 mg/day, and 239 (26.8%) ≥ 10 mg/day. Mean (± SD) PED was 6.3 (± 3.1) mg/day at baseline and decreased over time (21.3% mean reduction at 4 years; nominal $p < 0.0001$). By Weeks 49-60, 660/776 patients (85.1%) had stable PED, 90/776 patients (11.6%) had decreased PED, and 26/776 (3.4%) had increased PED. This difference increased during follow-up: at Weeks 205-216, 109/236 patients (46.2%) had decreased PED and 18/236 (7.6%) had increased PED. Patients with PED ≥ 5 mg/day were more likely than patients with PED < 5 mg/day to decrease their dose. Efficacy (Clinical Disease Activity Index and Disease Activity Score (28 joints) using C-reactive protein) was maintained with sarilumab irrespective of OGC tapering.

Conclusions: Long-term RA treatment with sarilumab was associated with sustained efficacy and decreased OGC dose. The proportion of patients who reduced their OGC dose increased with time and reductions were more common among patients with baseline PED ≥ 5 mg/day.

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