DAS28 were included as predictors of trajectory group membership using multinomial logistic regression.

Results: Baseline characteristics of the cohorts were similar (ERAN vs NOAR: mean age = 57 vs 56 years; female = 70% vs 69%; met ACR criteria = 88% vs 77%; mean DAS28 = 4.7 vs 4.2). For both cohorts, LCGM analysis indicated 4 subgroups provided best fit (Bayesian Information Criterion), with similar shaped trajectories (figure 1). Multinomial logistic regression indicated that older age (ERAN & NOAR, $p < 0.005$), female gender (ERAN & NOAR, $p < 0.01$), meeting ACR criteria (NOAR only, $p < 0.05$), use of DMARD (ERAN & NOAR, $p < 0.01$), and baseline DAS28 (ERAN & NOAR, $p < 0.005$) were related to an increased likelihood of being in a subgroup with higher disability (vs. lowest disability subgroup).

Conclusions: Four disability trajectories were observed in both the ERAN and NOAR cohort of patients with moderate disease activity. Patients on a worse trajectory who may benefit from more intensive treatment could potentially be identified earlier in the disease the group of patients with moderate disease activity.

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SAT0111 EFFICACY OF TOFACITINIB IN PATIENTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS BY BASELINE C-REACTIVE PROTEIN LEVELS AND ERYTHROCYTE SEDIMENTATION RATES

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Background: C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) levels are serum markers of inflammation in rheumatoid arthritis (RA). Tofacitinib is an oral JAK inhibitor for the treatment of RA.

Objectives: To investigate the impact of baseline (BL) inflammation severity, measured by CRP and ESR levels, on tofacitinib efficacy and safety.

Methods: Data were analysed from tofacitinib studies in patients (pts) with RA and prior inadequate response (IR) to conventional synthetic (cs) or biologic (b) DMARDs, who initiated tofacitinib 5 or 10 mg BID as monotherapy or with csDMARDs, mainly methotrexate. Data were pooled from 4 Phase 2 trials (NCT00413660; NCT00550446; NCT00603512; NCT00687193) and 5 Phase 3

randomised, double-blind, placebo-controlled trials (ORAL Scan [NCT00847613]; ORAL Solo [NCT00814307]; ORAL Sync [NCT00856544]; ORAL Standard [NCT00853385]; ORAL Step [NCT00960440]). Analyses were stratified by BL CRP and ESR levels (tertiles) separately. Efficacy analyses at Month 6 (M6) included ACR20/50/70 response rates and changes from BL in CDAL, DAS28-4 (ESR) and SDAI. Summary/descriptive statistics were provided. Adverse events (AEs) to M6 were summarised. Results were not adjusted for multiplicity.

Results: A total of 2161 pts were included in the csDMARD-IR group (grp) and 512 pts in the bDMARD-IR grp. Pt BL characteristics were generally similar between grps and across CRP and ESR tertiles, except that a numerically higher proportion of csDMARD-IR pts were Asian and RA disease duration was numerically shorter for csDMARD-IR pts vs bDMARD-IR pts. In both dose grps, ACR20/50/70 response rates at M6 were generally numerically higher in the highest BL CRP grp for csDMARD-IR and bDMARD-IR pts (figure 1). Generally, a trend for greater improvement from BL in disease activity at M6 was observed with higher BL CRP. Trends across endpoints were less clear when stratified by BL ESR (data not shown). Proportions of pts with AEs, serious AEs, serious infections and discontinuations due to AEs to M6 were generally similar regardless of BL CRP or ESR.

Figure 1. ACR20/50/70 response rates at Month 6 for tofacitinib 5 and 10 mg BID by baseline CRP concentrations (mg/L) in A) csDMARD-IR and B) bDMARD-IR pts

Conclusions: While efficacy outcomes in csDMARD-IR and bDMARD-IR pts with RA were improved after 6 months with tofacitinib 5 and 10 mg BID across all BL CRP/ESR tertiles, this post hoc analysis suggests that ACR response rates and disease activity improvements may be numerically greater in the highest BL CRP tertile, especially in bDMARD-IR RA pts. This trend was less clear with BL ESR. The tofacitinib safety profile was generally similar regardless of BL CRP or ESR, although changes in selected laboratory parameters have previously been associated with BL CRP following tofacitinib treatment.¹ These results suggest that subsets of pts with particularly good responses to therapy may be identified, but need further investigation.

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