TOCILIZUMAB IMPROVES HEALTH-RELATED QUALITY OF LIFE IN RA PATIENTS WITH INADEQUATE RESPONSE TO PRIOR ANTI-TNF THERAPY: THE RADIATE STUDY

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Rheumatoid arthritis (RA) impairs patient (pt) quality of life (QoL) through inflammation and progressive joint destruction, resulting in pain, fatigue and physical dysfunction. The effect of tocilizumab (TCZ), an IL-6 receptor inhibitor, on QoL outcomes in pts with inadequate response to previous anti-TNF agents was investigated in a phase 3, randomized, double-blind, placebo-controlled study, RADIATE.

Methodology

Adult pts with moderate/severe active RA received TCZ 4 mg/kg, TCZ 8 mg/kg or placebo (control) every 4 wks and MTX wkly for 24 wks. QoL outcomes (SF-36, HAQ-DI, FACIT-fatigue, pt pain VAS and pt global VAS) were assessed for 24 wks.

Results

There were 489 pts in the ITT population. Pts who received TCZ experienced clinically relevant improvements in the SF-36 physical and mental component summary (PCS, MCS) scores and in 5 SF-36 domains (Figure). Pts in the TCZ8 group had significant improvement in PCS score from baseline (BL) to wk 24 (p=0.0003 vs control). Clinically relevant improvement in mean PCS score (>5.0) was observed from wk 8 in the TCZ8 group but not for control at any time. The following data are presented for the TCZ8/TCZ4/control groups, respectively. HAQ-DI changes from BL to wk 24 were -0.39/-0.31/-0.05 (p<0.0001, TCZ8 vs control). Percentages of pts with improved physical function (HAQ-DI change ≥0.3) were 55/42/24. Mean changes from BL to wk 24 were: pain VAS, 32.5/21.0/8.6 (p<0.0001, TCZ8 vs control); global VAS, 32.8/25.4/15.4 (p=0.0011, TCZ8 vs control); FACIT-fatigue, 8.8/6.7/4.2 (p=0.015, TCZ8 vs control). Pts in the TCZ8 group achieved at least 5-point increases in FACIT-fatigue s!
core by wk 8; pts in the TCZ4 group achieved increases by wk 12 and pts in the control group by wk 20.

Conclusion

Il-6 receptor inhibition with TCZ was associated with rapid, clinically relevant and statistically significant improvements in pt-reported outcomes related to physical health (SF-36) and fatigue (FACIT-fatigue), which were sustained throughout the TCZ treatment period.

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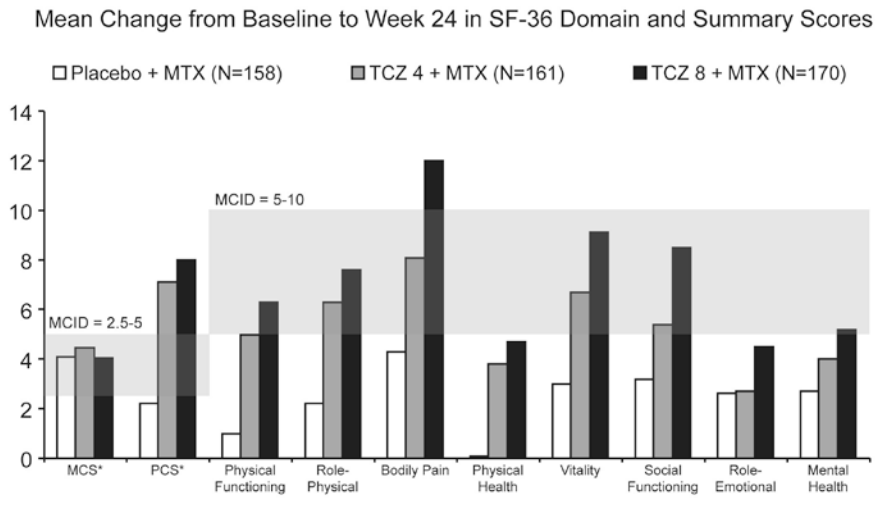

*Adjusted Mean Change
Shaded areas indicate mean clinically important difference (MCID) ranges.