Background: Tocilizumab (TCZ) monotherapy has been studied in the short-term (AMBITION) and long-term (LTE) setting. TCZ has demonstrated safety and efficacy in randomised clinical trials. The long-term exposure to TCZ was studied in the LTE setting in patients with rheumatoid arthritis (RA). 243 patients remained on monotherapy until withdrawal or data cut. We aimed to assess efficacy and safety in this population.

Methods: Patients randomised to TCZ 8 mg/kg monotherapy in AMBITION (n = 286) who entered the LTE (n = 243) were included. During the LTE, MTX/other allowable disease-modifying anti-rheumatic drugs (DMARDs) could be added to TCZ 8 mg/kg monotherapy. Assessments were performed at baseline, weeks 12, 24, and every 24 weeks thereafter. Safety assessments were performed up to 240 weeks. Efficacy and safety were assessed up to 240 weeks. The trial was approved by institutional ethics committees and all participants provided informed consent.

Results: Of the 243 patients, 139 (57.2%) remained on monotherapy in the LTE study until withdrawal or data cut, and 104 (42.8%) added DMARDs. The median duration of monotherapy was 240 weeks (range 24-756 weeks). In this post hoc exploratory analysis, efficacy and safety were evaluated in patients from AMBITION who added DMARDs. The majority of patients added methotrexate (82 of 104, 78.8%). TCZ was generally well tolerated. AEs (including treatment-emergent AEs) were also assessed up to 240 weeks. The most common AEs were infections (22 of 139, 15.8%) and musculoskeletal and connective tissue disorders (21 of 139, 15.1%). The median time to addition of the first DMARD was 26 weeks (183 days; range 0-256 weeks).

Conclusion: Over 240 weeks, patients who were MTX naive or MTX free for 6 months prior to study start, TCZ 8 mg/kg monotherapy resulted in statistically greater ACR20/50/70 responses at 24 weeks compared with MTX. TCZ monotherapy was generally well tolerated. The safety profile of TCZ monotherapy was consistent with that reported in previous studies.

**REFERENCES**