

LONG-TERM EFFICACY OF TOCILIZUMAB UP TO 3.5 YEARS IN PATIENTS WITH RHEUMATOID ARTHRITIS: AN INTERIM ANALYSIS OF LONG-TERM EXTENSION STUDIES

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Short-term efficacy and safety of tocilizumab (TCZ), an IL-6 receptor inhibitor, have been shown in phase 3 trials in rheumatoid arthritis (RA) patients (pts). This analysis presents up to 3.5 y of long-term efficacy data from ongoing extension studies.

Methodology

Data were pooled for pts who had ≥ 1 dose of TCZ in randomized, double-blind, controlled, phase 3 trials and open-label, long-term extensions (GROWTH95/96) through Feb 6, 2009. Pt populations included DMARD inadequate responders (DMARD-IR: OPTION, TOWARD, LITHE), anti-TNF-IR (RADIATE) and pts never exposed to or who never failed MTX (monotherapy, AMBITION). Clinical outcomes were assessed every 12 wk from initial TCZ exposure. Data were analyzed to 180 wk, after which pt numbers were too low to draw conclusions.

Results

3986 pts were analyzed: DMARD-IR, n=2904; anti TNF-IR, n=464; monotherapy, n=618. Numbers of pts with assessments decreased over time due to different times at which pts received rescue, entered extensions or withdrew. By the cutoff date, ~ 4% and ~14% withdrew due to insufficient response and safety reasons, respectively. Results are presented for the largest pt subgroup: in DMARD-IR pts, TCZ efficacy was shown by continuously increasing absolute numbers of pts who achieved ACR50 up to wk 96 and ACR70, LDAS and DAS28 remission up to wk 72 (Table). At later visits, proportions of pts achieving clinical response were at least maintained if not further increased with continued TCZ therapy to wk 180 (Table). Similar trends were observed for anti TNF-IR and monotherapy. At wk 96, percentages of DMARD-IR/anti TNF-IR /monotherapy pts with ≥1 SJC were 46/34/55, respectively, and with ≥1 TJC were 37/23/35, respectively. Safety analysis will be presented separately.

Conclusion

Efficacy during long-term treatment with TCZ increased as evidenced by absolute numbers and proportions of pts achieving clinical response or low disease activity/remission. These data support TCZ as an effective, long-term treatment option in RA. LONG-TERM EFFICACY OF TOCILIZUMAB UP TO 3.5 YEARS IN PATIENTS WITH RHEUMATOID ARTHRITIS: AN INTERIM ANALYSIS OF LONG-TERM EXTENSION STUDIES

Table. ACR50/70 Responses, LDAS, and DAS28 Remission in DMARD-IR Patients Treated With TCZ

Week	0	24	48	72	96	120	144	168	180
No. pts with valid assessment for ACR50/70	2904	2693	2429	2284	2173	1822	1257	602	363
ACR50, % (n)	—	35 (929)	45 (1085)	51 (1156)	53 (1157)	58 (1050)	59 (738)	64 (387)	67 (242)
ACR70, % (n)	—	16 (423)	24 (580)	30 (687)	31 (683)	36 (650)	38 (478)	46 (275)	46 (168)
No. pts with valid assessment for maintenance of ACR70	—	—	2350	2358	2220	1977	1436	779	480
ACR70 maintained for 24 consecutive wks, % (n)	—	—	8 (192)	14 (326)	16 (360)	19 (383)	21 (306)	22 (169)	22 (103)
No. pts with valid assessment for DAS28	2889	2658	2385	2231	2104	1754	1211	571	344
LDAS, % (n)	2 (50)	43 (1137)	54 (1293)	62 (1380)	65 (1356)	69 (1212)	70 (848)	73 (414)	74 (256)
DAS28 remission, % (n)	1 (22)	27 (722)	40 (954)	47 (1050)	50 (1046)	54 (940)	56 (681)	58 (330)	62 (214)

Baseline (week 0) was the first active dose of TCZ: for patients randomly assigned to receive TCZ in the core studies, the first active dose was at the core study baseline; for patients randomly assigned to receive placebo, the first active dose of TCZ was at either the initiation of rescue therapy or the first dose received in the open-label or extension studies.