glucocorticoid induction regimen, or relapse severity) had a significant differential effect on the primary outcome. By 24 months after entry, 20 months after randomization, 11/85 (13%) patients in the RTX group had experienced a relapse compared to 32/85 (38%) patients in the AZA group. 19/85 (22%) patients in the RTX group and 31/85 (36%) patients in the AZA group experienced at least one severe adverse event (SAE). 25/85 (29%) and 42/85 (49%) patients in the RTX group developed hypogammaglobulinaemia (IgG <5g/l) and non-severe infections respectively, compared to 21/85 (25%) and 41/85 (48%) in the AZA group.

Figure 1. Relapse-free survival in RITAZAREM trial: rituximab versus azathioprine

Conclusion: In the RITAZAREM trial, following induction of remission with RTX, RTX was superior to AZA for preventing disease relapse in patients with AAV with a prior history of relapse. There were no new major safety signals for use of these medications in this population.

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OP0027

TIME TO FLARE AND GLUCOCORTICOID EXPOSURE IN PATIENTS WITH NEW-ONSET VERSUS RELAPSING GIANT CELL ARTERITIS TREATED WITH TOCILIZUMAB OR PLACEBO PLUS PREDNISONE TAPERING: 3-YEAR RESULTS FROM A RANDOMIZED CONTROLLED PHASE 3 TRIAL

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Background: In part 1 of the 52-week, double-blind GiACTA trial, tocilizumab (TCZ) every week (QW) or every other week (Q2W) + prednisone tapering reduced the risk for flare versus placebo (PBO) + 26-week prednisone tapering among patients with new-onset giant cell arteritis (GCA) at baseline. Among patients with relapsing GCA, TCZ QW but not Q2W + prednisone reduced the risk for flare versus both PBO groups, and there was separation in the time to flare between the TCZ QW and Q2W groups.¹

Objectives: To report time to first flare and potential cumulative glucocorticoid (GC) sparing over 3 years of the GiACTA trial (part 1 + 2-year open-label part 2) among patients with new-onset or relapsing GCA.

Methods: At the end of part 1, patients entered open-label part 2, in which GCA therapy (including initiation/termination of open-label TCZ and/or GCs) was given at the investigator's discretion according to disease status. Time to first GCA flare during the 3-year study period was assessed using Kaplan-Meier analysis for patients in the intention-to-treat population according to disease onset status at baseline (new-onset/relapsing) based on their originally assigned treatment groups: TCZ QW, TCZ Q2W, or pooled PBO (PBO+26-week and PBO+52-week prednisone taper).

Results: Among patients randomly assigned in part 1, 47 of 100 (47%) in the TCZ QW group, 26 of 49 (53%) in the TCZ Q2W group, and 46 of 101 (46%) in the pooled PBO group had new-onset GCA at baseline; the rest had relapsing GCA. Median time to first flare over 3 years was longer for patients assigned to TCZ treatment in part 1 than for patients assigned to PBO; Kaplan-Meier analysis showed a clear separation between the TCZ QW and the pooled PBO groups over 3 years for patients with new-onset and relapsing GCA (Figure 1A). Separation between the TCZ QW and TCZ Q2W groups was also observed over 3 years in patients with new-onset and relapsing GCA, although this was more evident in patients with relapsing GCA (Figure 1B). Higher proportions of patients in the TCZ QW group (new-onset, 49%; relapsing, 47%) than the pooled PBO group (new-onset, 28%; relapsing, 31%) and the TCZ Q2W group (new-onset, 27%; relapsing, 35%) remained flare-free during their entire treatment period. Cumulative prednisone dose over 3 years was lower for patients originally assigned to TCZ QW versus those originally assigned to PBO for patients with new-onset GCA and those with relapsing GCA at baseline (Figure 2).

Conclusion: In this 3-year analysis of GiACTA parts 1 and 2, time to first flare favored TCZ QW over TCZ Q2W in patients with new-onset and relapsing GCA. TCZ QW delayed time to first flare and resulted in lower cumulative GC exposure compared with PBO in patients with new-onset and relapsing GCA, supporting TCZ QW dosing in patients with GCA regardless of disease onset.

References:

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Figure 2. Cumulative Prednisone Dose Over 3 Years: TCZ QW Versus PBO groups

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OP0028

EFFICACY OF APREMILAST FOR THE PAIN OF ORAL ULCERS ASSOCIATED WITH ACTIVE BEHÇET'S SYNDROME: 12-WEEK RESULTS FROM THE RANDOMIZED, PHASE III RELIEF STUDY

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