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 hypogammaglobulinemia (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 OR RELAPSING GIANT CELL ARTERITIS TREATED WITH TOCILIZUMAB OR PLACEBO PLUS PRENIDONE TAPERING: 3-YEAR RESULTS FROM A RANDOMIZED CONTROLLED PHASE 3 TRIAL**


**1**Massachusetts General Hospital Rheumatology Unit, Harvard Medical School, Boston, United States of America; **2**Roche Products Ltd, Welwyn Garden City, United Kingdom; **3**University Medical Center and Faculty of Medicine, TU Dresden, Dresden, Germany; **4**Department of General Internal Medicine, University Hospitals Gasthuisberg, Leuven, Belgium; **5**Department of Rheumatology and Clinical Immunology, University of Groningen, Groningen, Netherlands; **6**Department of Autoimmune Diseases, Hospital Clinic, University of Barcelona, Institut d’Investigacions Biomèdiques August Pi i Sunyer, Barcelona, Spain; **7**Southend University Hospital, NHS Foundation Trust, Westcliff-on-Sea, United Kingdom; **8**Friedrich-Alexander-University Erlangen-Nürnberg, Department of Internal Medicine 3–Rheumatology and Immunology, Universitätsklinikum Erlangen, Erlangen, Germany; **9**Division of Rheumatology, Arcispedale Santa Maria Nuova–IRCCS, Reggio Emilia, Italy; **10**Hospital for Special Surgery, Cornell, United States of America; **11**Genentech, South San Francisco, United States of America

**Background:** In part 1 of the 52-week, double-blind GIACTA trial, tocilizumab (TCZ) every week (QW) or every other week (Q2W) plus prednisone 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.

**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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**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**

Background: Oral ulcers (OU) associated with Behçet's syndrome are often painful, may interfere with the ability to eat and can negatively affect quality of life. Apremilast (APR), an oral phosphodiesterase 4 inhibitor, demonstrated efficacy in the treatment of OU associated with Behçet's syndrome in a phase III, multicenter, randomized, double-blind, placebo (PBO)-controlled study (RELIEF; BCT-002).

Objectives: To describe the efficacy of APR treatment in improving OU pain associated with Behçet's syndrome in RELIEF.

Methods: Patients were randomized (1:1) to APR 30 mg twice daily (APR 30 BID) or PBO twice daily for a 12-week PBO-controlled phase, followed by a 52-week active treatment extension. Eligible patients were ≥18 years of age and had active Behçet's syndrome with ≥3 OU at randomization or ≥2 OU at screening and randomization and without active major organ involvement. Clinical improvement in OU was evaluated by the area under the curve for the number of OU through Week 12 (AUCWk0-12; primary efficacy endpoint) and by assessments of OU number and OU pain (VAS). The proportion of patients achieving the minimal clinically important difference (MCID) and higher rates of improvement, defined as ≥10-mm, ≥30-mm (3-fold MCID), ≥50-mm (5-fold MCID) improvements in OU pain VAS scores, respectively, were analyzed through Week 12. An ANCOVA model was used to analyze the primary endpoint and assessments of OU number and OU pain (VAS). The proportion of patients achieving improvement in OU pain VAS scores at Week 12 were summarized descriptively.

Results: A total of 207 patients were randomized and received ≥1 dose of study medication (APR: n=104; PBO: n=103). At baseline, the mean (SD) number of OU was 4.2 (3.7) in the APR 30 BID group and 3.9 (2.7) in the PBO group, and the mean (SD) OU pain VAS scores were 61.2 (27.6) and 60.8 (26.9), respectively. At Week 12, significantly greater improvements were observed with APR 30 BID vs. PBO in AUCWk0-12 (least-squares [LS] mean [SE]: 129.5 [15.9] vs. 222.1 [15.9]; P<0.0001), number of OU (LS mean [SE]: 1.1 [0.2] vs. 2.0 [0.3]; P=0.0003) and OU pain VAS scores (LS mean [SE] change from baseline: −40.7 [3.3] vs. −15.9 [3.3]; P<0.0001). The proportion of patients who achieved the MCID of ≥10-mm improvement in OU pain VAS scores at Week 12 was greater with APR 30 BID vs. PBO; this pattern was also observed for the higher 3- and 5-fold improvements in MCID (Figure 1). Greater proportions of APR 30 BID vs. PBO patients achieved ≥10-mm and ≥30-mm improvements in OU pain VAS scores over 12 weeks. Notably, greater achievement of ≥50-mm improvement in OU pain VAS scores was observed with APR 30 BID vs. PBO as early as Week 1 and maintained up to Week 12 (Figure 2).

Conclusion: For patients with active Behçet's syndrome, APR 30 BID provided significantly greater improvements vs. PBO in OU number and OU pain at Week 12, including the greater proportion of patients achieving MCID and 3- and 5-fold MCID of OU pain in the APR 30 BID group vs. the PBO group. These results indicate a clinically meaningful treatment effect of APR 30 BID on the OU associated with Behçet's syndrome.

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