OP0140

Long-Term Outcome of Tocilizumab for Patients With Giant Cell Arteritis: Results From Part 2 of the GiACTA Trial

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for the GiACTA investigators

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DISCLOSURES

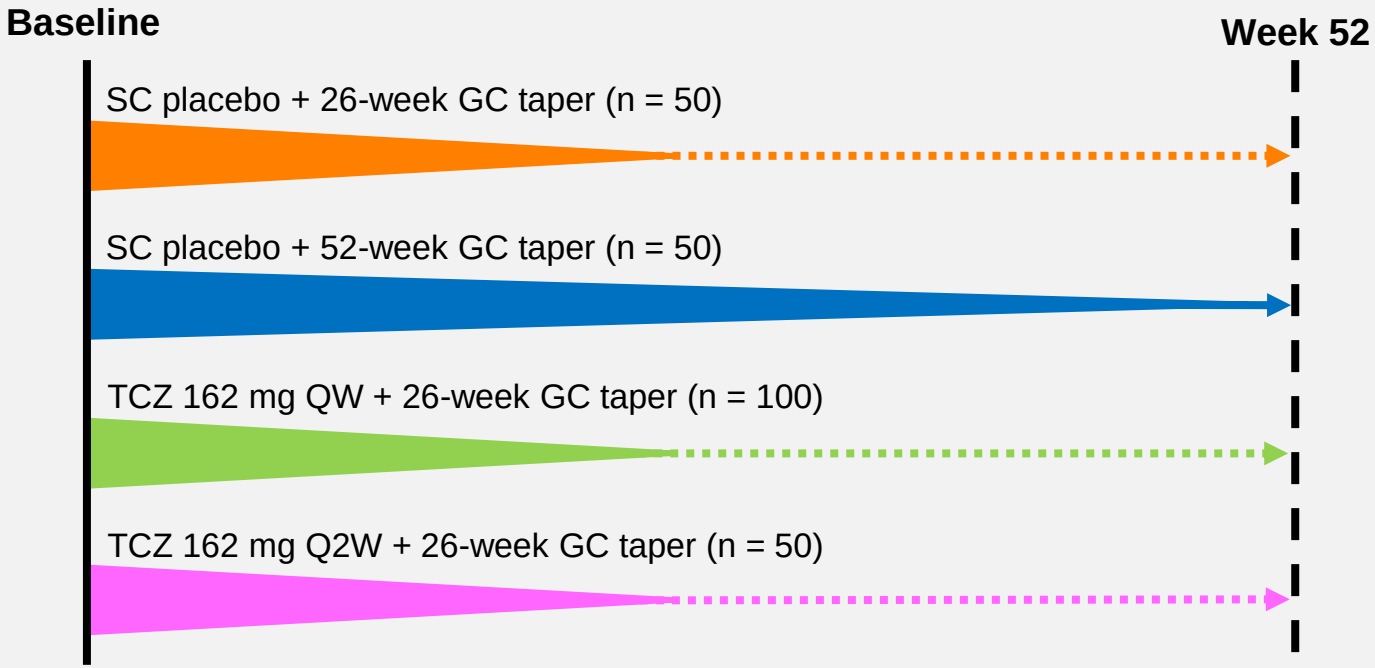
- JH Stone: research grants and consulting fees from Roche
- M Bao: employee of Genentech
- J Han: employee of Genentech
- M Aringer: consulting fees and speakers bureau for Roche and Chugai
- D Blockmans: nothing to disclose
- E Brouwer: nothing to disclose
- MC Cid: regional principal investigator in GiACTA trial, sponsored by Roche
- B Dasgupta: consulting fees from Roche, GSK, and Sanofi Aventis
- J Rech: nothing to disclose
- C Salvarani: nothing to disclose
- R Spiera: grants/research support from Roche/Genentech, GSK, BMS, Boehringer Ingelheim, Cytomri, Chemocentryx, and Corbus; consulting fees from Roche/Genentech, GSK, CSL Behring, and Sanofi
- SH Unizony: nothing to disclose

GiACTA Part 2: Objectives

- To evaluate long-term safety of TCZ-treated GCA patients
- To explore maintenance of efficacy after TCZ discontinuation

GiACTA Part 1: Randomized

Part 1
52 Weeks Double-Blind*[1,2]

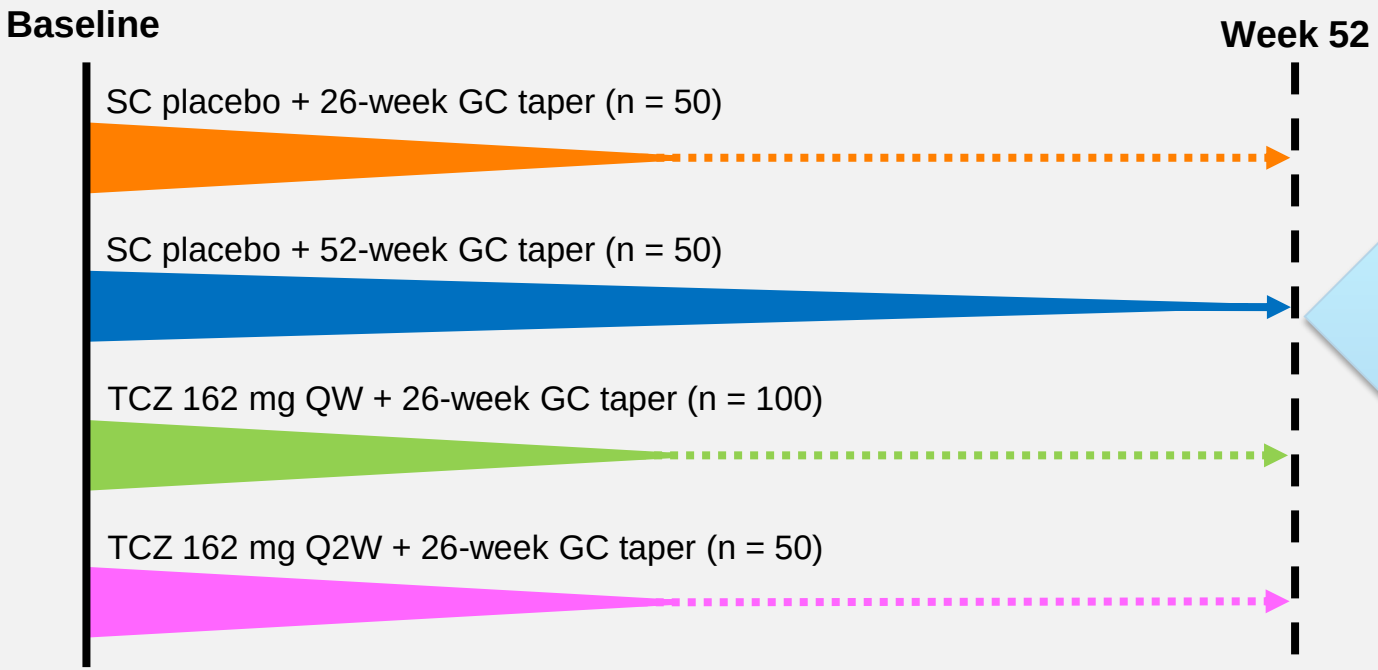


GC, glucocorticoid; QW, every week; Q2W, every 2 weeks; SC, subcutaneous; TCZ, tocilizumab.
*Prednisone ≤30 vs >30 mg per day.

1. Stone JH et al. *N Engl J Med*. 2017;377:317-328.
2. Collinson N et al. *Int J Rheumatol*. 2015;2015:58984.

GiACTA Part 2: Not Randomized

Part 1
52 Weeks Double-Blind*[1,2]



Different categories at end of part 1:

- **In remission, no treatment**
- **In remission, on treatment**
- **Recently active, on treatment**

*Prednisone ≤30 vs >30 mg per day.

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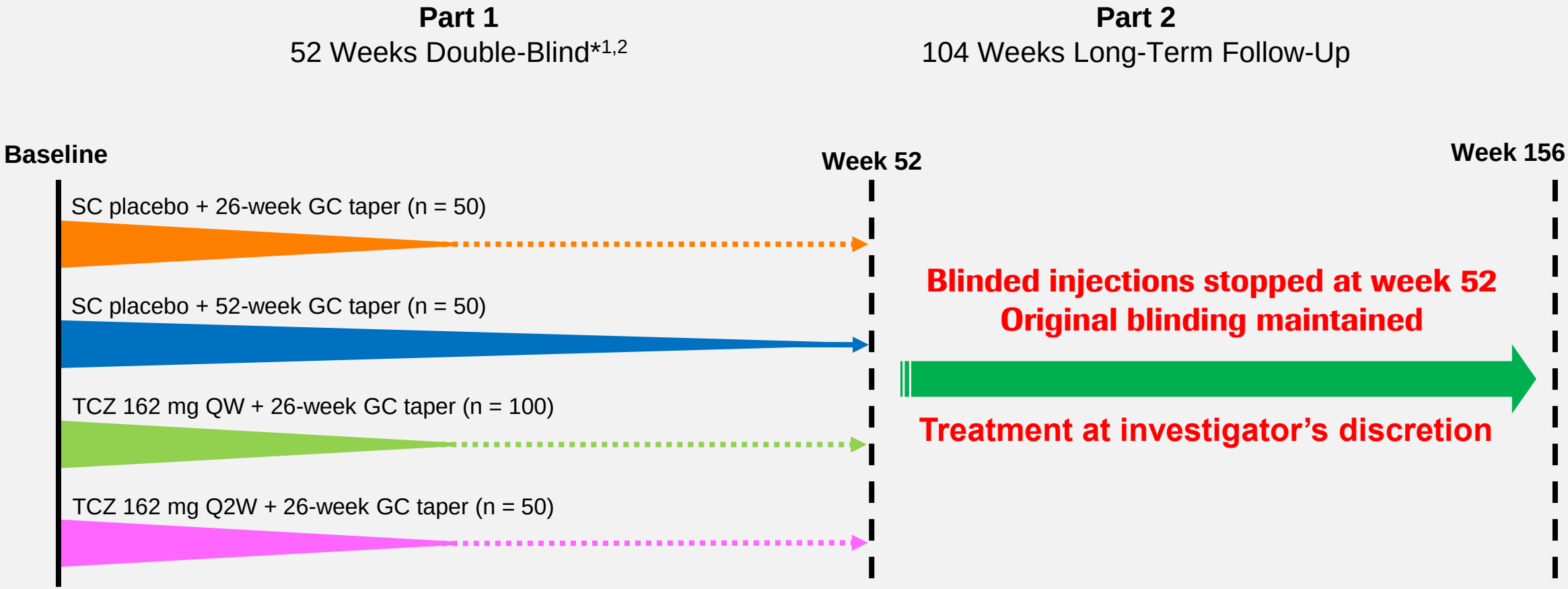
GiACTA Part 2: Not Randomized



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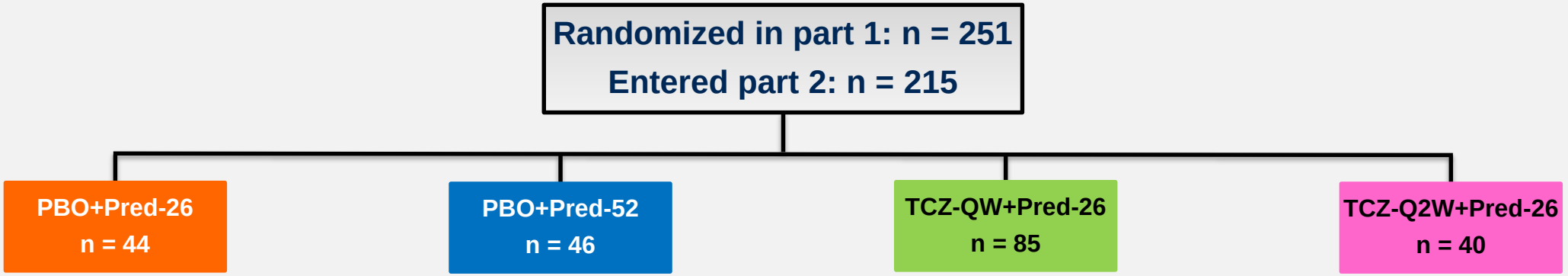
Patient Disposition by Disease Status in Part 2



197 (92%) completed part 2

PBO, placebo; Pred-26, prednisone taper or 26 weeks; Pred-52, prednisone taper for 52 weeks.

What Happened When Weekly TCZ Was Stopped?

- 81 patients were in clinical remission at the start of Part 2
- 59 received no treatment at the start of Part 2
- 25/59 (42%) completed Part 2 in clinical remission and receiving no treatment

Context: What Happened When Prednisone Was Stopped?

- **Part 1**
  - PBO+Pred-26 arm: 32% of patients did not experience flare during the first year
    - Most patients who experienced flare did so even before they stopped prednisone treatment
  - PBO+Pred-52 arm: 51% of patients did not experience flare during the first year
    - Most patients who experienced flare did so even before they stopped prednisone treatment

Original Assignment to TCZ Corresponded With Maintenance of Treatment-Free Remission

In Clinical Remission at Week 52	PBO+Pred-26 n = 33	PBO+Pred-52 n = 34	TCZ QW+Pred-26 n = 81	TCZ Q2W +Pred-26 n = 36
Maintained clinical remission in part 2[a]	18	20	38	13
Treatment-free	7/18 (39%)	10/20 (50%)	25/38 (66%)	8/13 (62%)
	17/38 (45%)		**33/51 (65%)**	

[a]Regardless of treatment; included patients in part 2 for >1.75 years.

What Treatments Had Patients Received Before Flares in Part 2?

In CR at Week 52	PBO+Pred-26 n = 33	PBO+Pred-52 n = 34	TCZ-QW+Pred-26 n = 81	TCZ-Q2W +Pred-26 n = 36	Total (%)
Experienced ≥1 flare regardless of treatment[a]	13	13	41	22	89
Treatment received before first flare (patients who experienced flare)					
Treatment-free	2 (15%)	4 (31%)	24 (59%)	17 (77%)	47 (53%)
GC only	10	6	14	4	33 (37%)
TCZ only	0	1	0	0	1 (1%)
GC + TCZ	1	2	3	1	8 (9%)

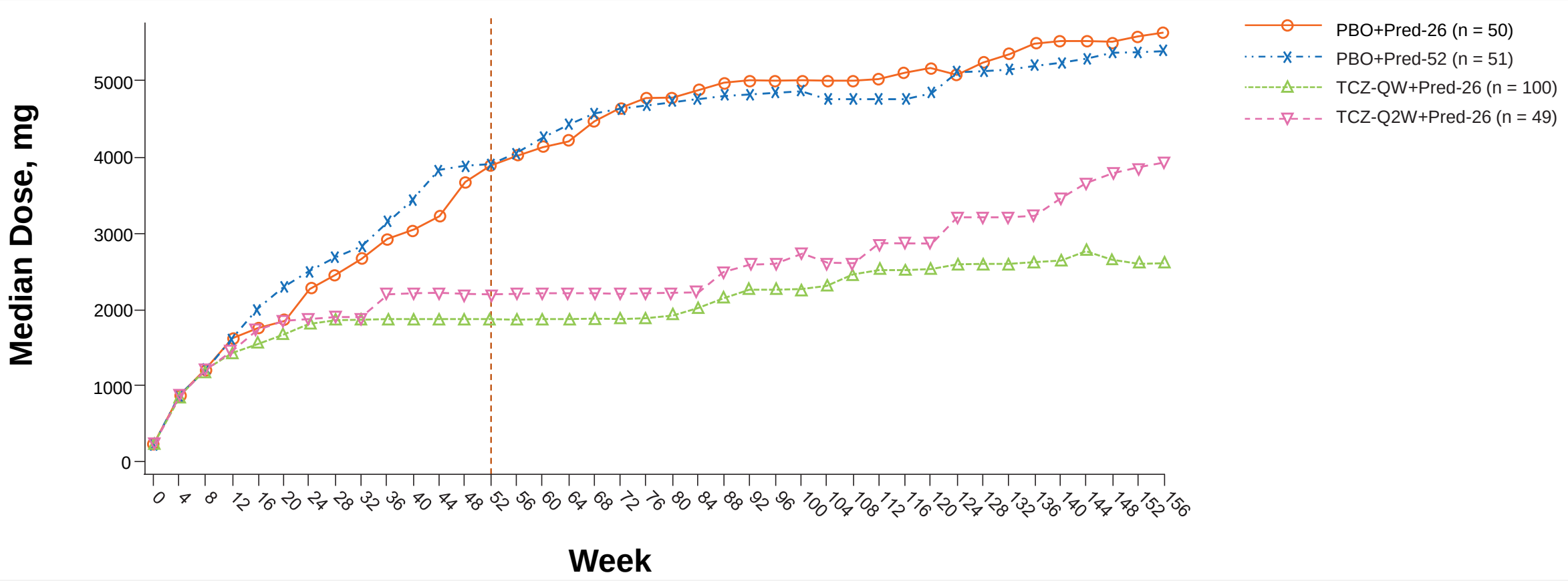
Among the total of 89 patients who experienced flare in part 2, only 9 (10%) were receiving TCZ

CR, clinical remission; GC, glucocorticoid.
Data are shown as number of patients (%).
[a]Includes patients who were in part 2 for >1.75 years.

Cumulative GC Dose Over 3 Years

Median Cumulative GC Dose, mg

PBO+Pred-26	PBO+Pred-52	TCZ-QW+Pred-26	TCZ-Q2W+Pred-26
5248	5323	2647	3782



TCZ-Based Therapy Restored Clinical Remission After Flares

In CR at Week 52	PBO+Pred-26 n = 33	PBO+Pred-52 n = 34	TCZ-QW+Pred-26 n = 81	TCZ-Q2W +Pred-26 n = 36
Treatment for flare				
TCZ only, n Median time to remission	2 70 days	0	11 15.0 days	4 7.5 days
TCZ + GC, n Median time to remission	8 8.0 days	7 8.0 days	13 8.5 days	9 18.0 days
GC only, n Median time to remission	4 53.5 days	5 74.0 days	15 37.5 days	6 69.5 days

n = number of patients who entered part 2, were in CR at week 52, and started TCZ treatment at least 4 weeks after their last treatment.

Safety Over 3 Years: No New Safety Signals

	Part 1 + Part 2	
	Never on TCZ	Ever on TCZ
Total PY	193.8	492.7
Rates per 100 PY		
AEs	636.3	538.3
SAEs	23.2	25.4
Infection	121.8	120.2
Serious infection	4.6	3.5
Malignancy	2.1	1.8
GI perforation	0	0.2

AE, adverse event; GI, gastrointestinal; PY, patient-years; SAE, serious adverse event.

Conclusions

- 42% of patients in clinical remission and on no treatment after 1 year of weekly tocilizumab treatment maintained their treatment-free remission for another 2 years
- Cumulative glucocorticoid exposure over 3 years was lower in patients originally assigned to tocilizumab
- Restarting tocilizumab restored clinical remission
- No new safety signals were observed in GCA patients treated with tocilizumab

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