Patients treated with baricitinib and tofacitinib were comparable for age, disease duration, PDN dose and previous number of csDMARDs and bDMARDs; 30 patients (47.6%) were treated with JAKi in monotherapy. At baseline, the median daily PDN dose was 5 (7.25) mg; after 4, 12 and 24 weeks the median daily dose significant decreased to 5 (6.25) mg, 2.5 (5) mg and 0 (5) mg, respectively ($p<0.0001$). The percentage of patients treated with GC decreased from 81.5% to 63.5% at week 4, and to 48.4% at week 12 and 24. After 4, 12 and 24 weeks we detected a significant reduction of DAS28 ($p<0.00001$ compared to baseline). A similar percentage of patients who withdrew PDN compared to those who were still on PDN achieved remission after 12 and 24 months. Similarly, the reduction in DAS28 was comparable between the two groups at week 4 [4.8 (4.2) in those who withdrew vs 4.1 (1) in those who did not] at week 12 [4.8(1.6) for both] and at week 24 [3.7 (1.4) in those who withdrew vs 2.3 (0.7) in those who did not].

Table 1. Demographic, clinic and clinimetric characteristics of the 64 patients

	Baricitinib= 41	Tofacitinib=23	P value
Female:male	33:8	17:6	P=ns
Age, median (IQR), years	58 (15)	66 (14.5)	P=ns
Disease duration, median (IQR), months	144 (144)	150 (120)	P=ns
N° of previous csDMARDs	3 (3)	3 (1)	P= ns
N° of previous bDMARDs	2 (3)	1 (3)	P= ns
DAS28 _{CRP} at baseline	4.7 (1.6)	4.8 (2)	P=ns
PDN dose at baseline, median (IQR), mg	5 (7.5)	5 (5)	P=ns
PDN dose at 4 weeks, median (IQR), mg	5 (7.5)	5 (5)	P=ns
PDN dose at 12 weeks, median (IQR), mg	2 (5)	2.5 (4.7)	P=ns
PDN dose at 24 weeks, median (IQR), mg	0 (5)	2.5 (0)	P=ns

IQR: interquartile range; DAS28_{CRP}: Disease Activity Score 28 using C-Reactive Protein, csDMARDs: conventional synthetic Disease Modifying anti-rheumatics drugs, bDMARDs: biotechnological Disease Modifying anti-rheumatics drugs PDN= prednisone

Conclusion: The rapid reduction of disease activity determined by JAK inhibitors allows a fast tapering of PDN, as suggested by the last EULAR recommendations for the management of RA.

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FRI0122

EFFICACY AND PATIENT-REPORTED OUTCOME MEASURES FROM A TWO-PART MULTICENTER, PLACEBO-CONTROLLED, RANDOMIZED WITHDRAWAL TRIAL OF REPOSITORY CORTICOTROPIN INJECTION FOR PERSISTENTLY ACTIVE RHEUMATOID ARTHRITIS

R. Fleischmann¹, D. Furst², G. Wan³, M. Panaccio³, J. Liu³, J. Zhu³, R. Brasington⁴, ¹University of Texas Southwestern Medical Center, Metroplex Clinical Research Center, Dallas, United States of America; ²David Geffen School of Medicine, Los Angeles, United States of America; ³Mallinckrodt Pharmaceuticals, Bedminster, United States of America; ⁴Washington University School of Medicine, St Louis, United States of America

Background: Repository corticotropin injection (RCI) is a naturally sourced complex mixture of adrenocorticotrophic hormone analogs and other pituitary peptides approved for short-term adjunctive treatment of rheumatoid arthritis (RA).

Objectives: This two-part, international, multicenter, placebo (PBO)-controlled study assessed the efficacy of RCI in persistently active RA patients (pts) using clinical and patient-reported outcome measures (PROMs) (ClinicalTrials.gov NCT02919761).

Methods: Adults ≥18 years with persistently active RA (DAS28-ESR >3.2) despite disease-modifying anti-rheumatic drug and glucocorticoid use received open-label RCI (80U) subcutaneously 2x/week (BIW) for 12 weeks (Part 1). Pts with DAS28-ESR <3.2 at Week (W) 12 entered the double-blind maintenance phase (Part 2) and were randomized to 80U RCI or PBO BIW through W24. Efficacy endpoints included the proportion of pts who achieved DAS28-ESR <3.2 at W12 (primary) and maintained it through W24 (secondary). Mean changes from baseline (BL) were assessed for select PROMs (exploratory): Patient Global Assessment of Pain (PGAP); Patient Global Assessment of Disease Activity (PGADA); Health Assessment Questionnaire Disability Index (HAQ-DI); Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F) scale; and Work Productivity and Activity Impairment (WPAI) questionnaire. Analyses used the modified intent-to-treat population (mITT-P; pts who received ≥1 dose of study drug and contributed any efficacy data).

Results: In the mITT-P (N=259), 62.9% ($p<0.0001$) achieved DAS28-ESR <3.2 at W12 (mean BL DAS28-ESR=6.3). In Part 2 (RCI, n=77; PBO, n=76), more RCI-treated pts maintained DAS28-ESR <3.2 at W24 (62.3%, $p=0.035$) vs. PBO (43.4%). Clinically significant improvements in PROMs from BL were observed through W12 and sustained to W24 (Table 1), with mean changes exceeding the reported minimal clinically important difference thresholds (MCIDs) for each.

Conclusion: RCI for persistently active RA resulted in clinically significant improvements in efficacy endpoints and PROMs for up to 6 months in pts who continued and discontinued RCI after 3 months of initial therapy.

References:

Table 1. PROMs From the 12-week Double-blind Withdrawal Phase, mITT-P

PROM (Score range) [MCID]	Baseline, Mean (SD)		Mean Change From Baseline (SD)							
	RCI	PBO	Week 12		Week 16		Week 20		Week 24	
	RCI	PBO	RCI	PBO	RCI	PBO	RCI	PBO	RCI	PBO
PGAP (0-100) [10]	65.7 (18.7)	62.8 (21.0)	-46.8 (23.4)	-45.8 (23.2)	-43.6 (26.1)	-41.2 (25.7)	-45.9 (23.7)	-42.8 (24.7)	-43.8 (23.9)	-40.7 (25.2)
PGADA (0-100) [10]	68.0 (16.6)	61.4 (20.0)	-48.1 (20.9)	-41.9 (24.5)	-44.5 (25.3)	-39.5 (26.5)	-48.5* (21.5)	-39.9 (27.7)	-45.9 (24.6)	-39.3 (28.2)
FACIT-F (0-52) [4]	22.7 (7.7)	22.6 (9.0)	-10.1 (8.1)	-10.2 (8.9)	-8.7 (8.2)	-8.6 (9.1)	-10.1 (7.8)	-10.5 (9.7)	-9.4 (7.9)	-10.5 (9.2)
WPAI (% due to RA) [N/A]										
Work time missed	19.9 (20.8)	31.9 (33.5)	-13.6 (25.4)	-20.7 (31.8)	-7.44 (35.3)	-15.7 (28.7)	-5.7 (26.5)	-14.2 (34.6)	-13.8 (24.9)	-9.2 (32.0)
Impairment while working	46.8 (25.8)	55.3 (30.7)	-34.7 (25.5)	-33.1 (24.3)	-31.3 (25.3)	-31.7 (32.7)	-27.2 (25.2)	-47.3 (28.7)	-30.0 (25.8)	-40.0 (28.3)
Overall work impairment	54.7 (28.9)	61.9 (33.4)	-36.9 (26.9)	-30.4 (26.9)	-33.4 (31.5)	-35.1 (40.2)	-23.6 (26.5)	-43.8 (34.3)	-32.7 (30.1)	-32.4 (28.8)
Activity impairment	64.9 (22.8)	61.1 (24.1)	-39.9 (24.3)	-37.2 (28.6)	-34.5 (25.8)	-30.0 (30.0)	-38.3 (23.8)	-37.7 (24.9)	-36.0 (24.9)	-37.9 (27.1)
HAQ-DI (0-3) [0.22]	1.7 (0.5)	1.7 (0.6)	-1.0 (0.6)	-1.0 (0.6)	-0.9 (0.5)	-0.9 (0.7)	-1.0 (0.6)	-1.0 (0.6)	-0.9 (0.6)	-1.0 (0.6)

* $p<0.05$ vs. PBO by 2-sample t test.

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SAFETY PROFILE OF BARICITINIB FOR THE TREATMENT OF RHEUMATOID ARTHRITIS UP TO 8.4 YEARS: AN UPDATED INTEGRATED SAFETY ANALYSIS

M. C. Genovese¹, J. S. Smolen², T. Takeuchi³, G. R. Burmester⁴, W. Deberdt⁵, D. Schlichting⁵, H. Song⁶, D. Mo⁵, C. Walls⁵, K. Winthrop⁷, ¹Stanford University, Division of Immunology and Rheumatology, Palo Alto, CA, United States of America; ²Medical University of Vienna, Division of Rheumatology, Department of Medicine, Vienna, Austria; ³Keio University School of Medicine, Division of Rheumatology, Department of Internal Medicine, Tokyo, Japan; ⁴Charité-University Medicine Berlin, Free University and Humboldt University Berlin, Department of Rheumatology and Clinical Immunology, Berlin, Germany; ⁵Eli Lilly and Company, Indianapolis, IN, United States of America; ⁶Syneos Health, Morrisville, NC, United States of America; ⁷Oregon Health Sciences University, Portland, OR, United States of America

Background: Baricitinib (bari) is an oral selective inhibitor of Janus kinase (JAK) 1 and 2, approved for the treatment of moderately to severely active rheumatoid arthritis (RA) in adults.