adverse effects (1 deranged LFTs, 3 infection, 1 rash, 1 headache, 2 flares of IBD, 1 dizziness, 1 malignancy). Despite the refractory nature of their RA, 14 patients responded sufficiently to remain on Tofacitinib for an average of 24.5 months to date. 1 Patient who failed 3 bDMARDs achieved remission (DAS28 1.82) with 4 confirmed as having moderate disease activity (Mean DAS 3.58, SD 0.42). Of the 39 patients to receive Baricitinib, three had primary non-response, whilst the others remain on therapy. Response is to be determined in 16, 4 have achieved remission (Mean DAS 2.2, SD 0.32) and 14 MDA (Mean DAS 4.04, SD 0.44). 5 patients received both JAKis sequentially, switching from Tofacitinib to Baricitinib, 2 due to adverse events (both flares of IBD) and 3 due to non-response. Of these 5, 1 patient to date has shown a good response at 3 months, 2 have shown no response, with results pending for others. **Conclusion:** Our experience of patients treated with JAKi for RA indicates improvement in disease activity. Benefit was observed in a severely refractory subgroup that had previously failed multiple biologic therapies.

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THU0170

A MULTICENTER STUDY ASSESSING THE EFFICACY AND SAFETY OF REPOSITORY CORTICOTROPIN INJECTION IN PATIENTS WITH RHEUMATOID ARTHRITIS: INTERIM DATA FROM THE OPEN-LABEL TREATMENT PERIOD

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Background: Rheumatoid arthritis (RA) is an autoimmune disorder associated with chronic inflammation and is treated with disease-modifying anti-rheumatic drugs (DMARDs) for active disease. Both American College of Rheumatology (ACR) and EULAR recommend that short-term administration of corticosteroids (CSs) may be beneficial for its anti-inflammatory effects. Repository corticotropin injection (RCI) is a complex mixture containing purified porcine pituitary adrenocorticotrophic hormone (ACTH)-analogue and an agonist for all 5 melanocortin receptors (MCRs). Activation of MCRs by ACTH has been shown to have direct and indirect anti-inflammatory and immunomodulatory effects. RCI is approved in the United States as adjunctive therapy for short-term administration in RA.

Objectives: To present interim data after 100% enrollment from the initial 12-week open-label phase of a multicenter, 2-part study evaluating the efficacy, safety, and appropriate duration of RCI therapy in patients with persistently active RA despite receiving 1 or 2 DMARDs and/or CSs.

Methods: In the open-label period (Part 1, Weeks 0–12), all enrolled patients received RCI 1 mL (80 U SC) twice weekly for 12 weeks. Patients who achieved low disease activity (LDA; DAS28-ESR score <3.2) at Week 12 continued in the double-blind, randomized maintenance phase of the trial (Part 2) for an additional 12 weeks. The primary endpoint was the proportion of patients who achieved LDA at Week 12. Secondary endpoints included assessment of the safety and tolerability of RCI. Disease activity was also assessed by the proportion of patients who achieved ACR 20%, 50%, and 70% (ACR20, 50, 70) responses and patient reported outcomes at Week 12. Bone turnover markers were assessed as an exploratory endpoint.

Results: 259 patients had enrolled, 235 had completed and 24 had discontinued the 12-week open-label period of the study; 88.9% were female and mean age was 51 years. RCI treatment resulted in 62.5% of patients achieving LDA at Week 12; results for this interim analysis are presented in the **Table**. Bone turnover markers were stable from baseline

to Week 12, indicating no effect of RCI on bone metabolism. 98 (37.8%) patients reported adverse events (AEs) with 3 (1.2%) patients reporting serious AEs (ie, non-cardiac chest pain, pneumonia, and craniocerebral injury). The most common AEs were urinary tract infection (n=10), headache (n=9), and pharyngitis (n=7).

Abstract THU0170 – Table 1.

Table. Results for Patients Who Completed the Open-label Period (mITT; N=259)

Endpoints	Baseline	Week 4	Week 8	Week 12
LDA (DAS28-ESR <3.2; Primary Endpoint)	-	6.6%	14.3%**	62.5%**
ACR20	-	48.6%**	69.9%**	79.5%**
ACR50	-	12.0%**	35.9%**	62.2%**
ACR70	-	4.6%	8.5%	31.7%**
DAS28-ESR score, mean	6.3	4.9*	4.4*	3.6*
Tender joint count, mean	14.6	7.7*	5.7*	3.9*
Swollen joint count, mean	10.9	5.6*	4.0*	2.8*
Patient global assessment of disease activity (20% improvement)	-	56.0%**	71.8%**	80.3%**
FACIT-F, mean	22.9	17.5*	16.0*	13.9*
HAQ-DI, mean	1.7	1.2*	1.0*	0.8*

FACIT-F, Functional Assessment of Chronic Illness Therapy – Fatigue Scale; HAQ-DI, Health Assessment Questionnaire – Disability Index; LDA, low disease activity.
 The modified intent to treat (mITT) population includes all subjects who received RCI with any post-treatment efficacy assessments.

*p < 0.001 vs baseline. **p < 0.0001 vs baseline.

Conclusion: In the 12-week open label period of this study, RCI appeared to be generally safe and effective in patients with persistently active RA who were nonresponsive to DMARDs and CSs. This was demonstrated by improvement in multiple measures of disease activity. Further results will be evaluated in Part 2 of the study.

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THU0171

TOFACITINIB, AN ORAL JANUS KINASE INHIBITOR, IN THE TREATMENT OF RHEUMATOID ARTHRITIS – THE RESULTS OF RUSSIAN NATIONAL REGISTER OF PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH TOFACITINIB

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Background: Tofacitinib (TF) is an oral Janus Kinase inhibitor for the treatment of rheumatoid arthritis (RA).

Objectives: To evaluate the one-year effectiveness of tofacitinib as first-line therapy in RA conventional synthetic (cs) DMARDs non-responders.

Methods: Data from 415 patients from Russian national register of patients with RA treated with TF were analyzed. 119 RA patients, who had complete clinical and laboratory data from 4 consecutive visits after baseline with an interval of 3 months between the visits and who used the TF as first-line therapy after failure of cs DMARDs, were included. Treatment with any biologics ever was an exclusion criteria.