Table 1. Efficacy endpoints at Week 12

Endpoint ^a	UPA 15mg QD (n=169)	PBO (n=169)
Primary endpoint		
ACR20, %	71.6***	31.4
Secondary endpoints		
Δ DAS28(CRP)	-2.56***	-0.95
Δ HAQ-DI	-0.62***	-0.18
Δ SF-36 PCS	8.93***	3.36 ^d
DAS28(CRP) ≤3.2, %	46.2***	13.6
DAS28(CRP) <2.6, %	29.6***	5.3
CDAI ≤10, %	35.5***	11.2
ACR50, % ^b	40.8***	8.3
ACR70, % ^b	21.3***	3.6
ACR20 at Week 1, % ^b	25.4***	5.9

***p<0.001 vs PBO

^aNRI for binary endpoints; ANCOVA with multiple imputation for DAS28(CRP) and HAQ-DI; mixed model repeated measures for other continuous endpoints^bUnranked secondary endpoint. ^cn=143. ^dn=149

the primary endpoint of ACR20 (71.6% vs 31.4%, p<0.001). UPA also demonstrated statistically significant improvements in all ranked secondary endpoints vs PBO at Week 12 (Table 1), including mean change in DAS28(CRP), HAQ-DI, and SF-36 PCS, and patients achieving DAS28(CRP) ≤3.2, DAS28(CRP) <2.6, and CDAI ≤10. Greater responses were also seen with UPA vs PBO for other key secondary endpoints including ACR50 and ACR70. Onset of UPA action was rapid with more patients on UPA achieving ACR20 by Week 1 (25.4% vs 5.9%, p<0.001). The frequency of AEs (61.5% vs 49.1%) and serious AEs (7.1% vs 3.0%) was higher with UPA vs PBO. The frequency of AEs of special interest was generally similar between UPA and PBO, with the exception of herpes zoster (1.8% vs 0.6%), hepatic disorders (9.5% vs 7.1%), neutropenia (3.0% vs 0%), and elevated creatine phosphokinase (1.8% vs 0.6%), which were higher with UPA. One case of breast cancer (on Day 1 of study) and one VTE (pulmonary embolism and deep vein thrombosis in a patient with history of deep vein thrombosis) were reported with UPA treatment.

Conclusion: Efficacy of UPA was demonstrated in this csDMARD-IR population from China, Brazil, and South Korea. The safety of UPA was comparable with the global Phase 3 program.

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SAT0161

THE ANALGESIC EFFECT OF TOFACITINIB MAY HAVE CLINICAL SIGNIFICANCE IN PATIENTS WITH RHEUMATOID ARTHRITIS. DATA FROM THE MOSCOW UNIFIED REGISTER OF ARTHRITIS (MUAR)

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Background: Some theoretical data suggest that the JAK-kinase blocker tofacitinib (TOFA) may have a direct analgesic effect.

Objectives: to evaluate the clinical significance of the analgesic effect in patients with rheumatoid arthritis (RA) in real clinical practice.

Methods: Hypothesis being tested: the analgesic effect of TOFA may be manifested by a decrease in the ratio of subjective to objective indicators of arthritis activity.

Data from RA patients receiving biologics (bDMARD) and/or TOFA and included in the MUAR register were analyzed. The tender joints count (TJC),

Table. Ratios of objective and subjective indicators during the treatment with tofacitinib and with tDMARDs therapy in general

Index	Unadjusted values		Identified confounders	Adjusted values (TOFA)	Significance of difference TOFA from average values
	TOFA	Average			
TJC / (SJC +1)	1,93 ± 2,40	2,40 ± 2,78	Age, year of inclusion in registry	1,95 ± 0,45	0,014
HAQ/ (SJC +1)	0,78 ± 0,60	0,89 ± 0,64	Age, year of inclusion in registry, duration of RA, duration of treatment	0,583 ± 0,114	0,039
RAPID3 / (SJC +1)	6,69 ± 4,96	8,13 ± 5,36	Age, year of inclusion in registry, duration of treatment	6,75 ± 0,80	0,001
TJC / (CRP +1)*	1,15 ± 1,83	1,17 ± 1,73	Morning stiffness duration at the RA onset	1,15 ± 0,18	0,263
HAQ/ (CRP +1)*	0,38 ± 0,36	0,40 ± 0,41	Gender, RA duration	0,342 ± 0,04	0,123
RAPID3/(CRP +1)*	3,26 ± 2,74	3,78 ± 3,71	BMI, duration of treatment	3,47 ± 0,43	0,527

* - when calculating the indices, episodes of treatment with tocilizumab (n = 113) were excluded, CRP - level of C-reactive protein, mg/l; TJC - tender joints count, SJC - swollen joints count, TOFA - tofacitinib, RA - rheumatoid arthritis, BMI - body mass index.

the HAQ-DI functional ability index, and the RAPID3 disease activity index were considered as subjective estimates. The swollen joints count (SJC) and the level of CRP were treated as objective indicators. The estimation of quotients from the division of subjective indicators into objective ones in all combinations is made.

Taking into account the observational nature of the study, we searched for confounders for each of these ratios. Comparison of the calculated indices during the treatment with various targeted DMARDs (tDMARDs) was made with an adjustment for the detected confounders.

Results: the analysis included 944 treatment episodes in 832 patients, including 93 episodes of TOFA treatment. The average age was 55.3 ± 12.4 years, women - 698 (83.9%), seropositive for RF - 672 (80.8%). The analysis of the adjusted values showed that the ratios of the TJC, HAQ-DI and RAPID3 to the SJC during the treatment with TOFA was significantly lower than with tDMARDs on average. There were no significant differences in the ratios of objective indicators to the CRP level (Table).

Conclusion: the severity of subjective feelings and functional disorders in RA patients receiving TOFA may be less with the same level of objective signs of arthritis compared with bDMARDs.

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SLE, Sjögren's and APS - treatment

SAT0162

WITHDRAWAL OF LOW-DOSE STEROIDS IN SYSTEMIC LUPUS ERYTHEMATOSUS IN REMISSION: PREDICTORS OF FLARES AND DIFFERENCE IN OUTCOMES IN SEROLOGICALLY ACTIVE CLINICALLY QUIESCENT PATIENTS

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Background: According to the recent recommendations for Systemic Lupus Erythematosus (SLE), a progressive tapering until withdrawal of glucocorticoids (GC) is considered one of the main goals of SLE management (1). However, which patient may be a candidate for safe GC withdrawal has not been determined yet and a proportion of patients are kept on long-term low-dose prednisone despite clinical remission.

Objectives: to evaluate the rate of low-dose GC withdrawal in SLE patients in remission and to identify predictors of flares.

Methods: Eligible patients were SLE patients according to the ACR criteria (2) who were in prolonged clinical remission defined by a cSLEDAI=0 for at least 2 years and on a stable SLE treatment (immunosuppressive drugs and/