upper respiratory tract infections, 2 urinary tract infection, 1 *Herpes labialis*), while 3 patients manifested Herpes Zoster reactivation, 2 deep vein thrombosis (one with pulmonary embolism), 2 discontinued due to severe anemia and pancytopenia, and 2 developed self-limiting liver enzymes elevation.

Conclusion: In our real-world dataset, baricitinib is effective in reducing RA disease activity, after 12 weeks, being generally well-tolerated with few severe adverse events.

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AB0447

BIOLOGICAL THERAPY AND RADIOSYNOVIORTHESIS IN PATIENTS WITH RHEUMATOID ARTHRITIS AND PSORIATIC ARTHRITIS

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Background: The treatment of patients with rheumatoid arthritis (RA) has been spectacularly changed since the 1950's. Introduction of the steroid compounds and their local application, the chemical and radionuclide synovectomy, surgical synovectomy, use of non steroid drugs, the basic treatment and the spread of biological therapy are the most important steps. Introduction of the biological therapy has changed the quality of life for these patients.

Objectives: During biological therapy sometimes 1 or 2 joints could be affected by inflammation. In this cases always the question is how to solve the problem. Change of the biological or basic therapy, use surgical synovectomy or radiosynovectomy (RSO)?

Methods: In our rheumatological department 2100 patients with RA and PA were treated with biological therapy between 2002 and 2015. In 100 patients we applied RSO because of the inflammation of the knee joint during biological therapy. We made a long term follow-up in 72 patients. All participants provided written informed consent.

62 participants inflammatory knee joint disease was diagnosed on the basis of the American College of Rheumatology. 55 of 62 patients with rheumatoid arthritis were seropositive, 7 seronegative. Steinbrocker functional stadium II was observed in 52, stadium III in 10. 10 patients were psoriatic arthritis. Mean age of 13 male and 61 female patients was 51.4 years (range 24-79) years. In 38 patients the right knee, in 34 the left knee was treated by radiosynovectomy. Mean duration of disease was 7.3 years (range 0.5-25), of synovitis (6.3month (range 3-8) Mean number of punctions of the treated joint prior to radiosynovectomy was 4,2 per patient and of steroid administrations prior to radiosynovectomy 3,0. In 12 patients a systemic steroid therapy has been performed.

Results: During the study period, inflammation decreased. In the first two years excellent and good results were recorded in 82,2%. Two years after radiosynoviorthesis 83,3% of patients did not need another puncture. Before the knee inflammation patients were in complete remission which status has been achieved after RSO as well. DAS: 2,4+0,4.

Conclusion:

1. RSO is an effective method to treat the inflammation of the knees.
2. The RSO performed during biological therapy is as effective as in the case of patients without biological therapy.
3. In case of a successful RSO there is no need for biological or basic therapy neither for surgical synovectomy.

4. However an intraarticular injection has a low risk for infection it is recommended to avoid the biological therapy during the RSO.

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AB0448

SAFETY AND EFFICACY OF FILGOTINIB IN JAPANESE PATIENTS ENROLLED IN A GLOBAL PHASE 3 TRIAL OF PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE OR INTOLERANCE TO BIOLOGIC DMARDs

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Background: Filgotinib (FIL), an oral, selective inhibitor of Janus kinase 1 (JAK1), has demonstrated efficacy in a phase 3 study in bDMARD-IR patients with active rheumatoid arthritis (RA).

Objectives: We report results of Japanese patients enrolled in the FINCH2 study (ClinicalTrials.gov Identifier: NCT02873936) of FIL in patients with RA and an inadequate response or intolerance to ≥ 1 bDMARDs.

Methods: FINCH2 (ClinicalTrials.gov: NCT02873936) was a 24-week, randomized, placebo-controlled, phase 3 trial conducted globally at 114 sites, including at sites in Japan, from July 2016–June 2018. Male and female adults with moderately-to-severely active RA and inadequate response/intolerance to ≥ 1 prior bDMARDs were randomized 1:1:1 to oral doses of FIL 200 mg, FIL 100 mg, or placebo (PBO) once daily (QD) for 24 weeks; patients continued background therapy with conventional synthetic DMARDs.

Results: Primary and all key secondary endpoints were met for both global (N=448, Genovese, 2018) and Japanese patient populations (n=40; FIL 200 mg, n=12; FIL 100 mg, n=15; and PBO, n=13). ACR20 response rates, HAQ-DI LS mean changes from baseline, and the percentage of Japanese patients with DAS28(CRP) ≤ 3.2 at week 12 are shown in Table 1. In Japanese patients, treatment-emergent adverse event (AE) rates were similar for FIL 200 mg, FIL 100 mg, and PBO (75%, 60%, and 77%, respectively) and there were no serious AEs; there was 1 case of uncomplicated herpes zoster (FIL 200 mg); and no

venous thrombotic events, opportunistic infection/active TB, malignancy, GI perforation, or death.

Table 1. Efficacy measures in the Japanese subgroup at weeks 12 and 24.

	FIL 200 mg QD (n=12)	FIL 100 mg QD (n=15)	PBO QD (n=13)
ACR20 (%)	83% (p=0.015)	53% (p=0.28)	31%
Week 12			
ACR20 (%)	92% (p<0.001)	60% (p=0.024)	15%
Week 24			
HAQ-DI (LSM CFB)	-0.55 (95% CI: -0.81, -0.29)	-0.30 (CI: -0.53, -0.07)	0.09 (CI: -0.16, 0.35)
Week 12			
DAS28(CRP) ≤3.2 (%)	67% (p<0.001)	47% (p=0.007)	0%
Week 12			

LSM CFB, least square mean change from baseline. P-values are vs PBO.

Conclusion: In this phase 3 study in bDMARD-IR patients with active RA, treatment with FIL over a 24-week period was associated with significant improvements in signs and symptoms of RA, with a safety and efficacy profile in Japanese patients consistent with that in the global population. Thus, FIL may provide a novel treatment option for patients who continue to have active RA despite prior biologic therapy.

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AB0449 PAIN REDUCTION IN PATIENTS WITH RHEUMATOID ARTHRITIS RECEIVING TOFACITINIB MONOTHERAPY WITH OR WITHOUT PAIN MEDICATION: A POST HOC ANALYSIS OF POOLED DATA FROM PHASE 2, PHASE 3 AND PHASE 3B/4 STUDIES

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Background: Tofacitinib is an oral JAK inhibitor for the treatment of RA. Pain is the most common symptom reported by patients (pts) with RA,^{1,2} thus reduction of pain is an important treatment goal.

Objectives: To evaluate the effect of tofacitinib monotherapy ± pain medication on pain in pts with RA.

Methods: This pooled post hoc analysis included pts who received tofacitinib 5 mg BID monotherapy (ie without csDMARDs) in Phase (P)2 (NCT00550446), P3 (ORAL Solo; NCT00814307) and P3b/4 (ORAL