Table 1. Patient characteristics and adverse events by treatment group

	Anti-TNF	JAKi
Mean age start of treatment (SD), yrs	50.8 (12.6)	57.6 (11.9)
Female, n (%)	3122 (58.8)	392 (79.5)
Disease duration, median (IQR)	7.0 (2.7-13.7)	9.9 (4.9-16.8)
First line biologic, n (%)	2614 (49.3)	117 (23.7)
Rheumatoid Arthritis	1385 (41.1)	339 (95.2)
Ankylsosing Spondylitis	1031 (30.6)	1 (0.3)
Psoriatic Arthritis	957 (28.4)	16 (4.5)
DAS28-ESR	4.3 (1.4)	4.7 (1.4)
Survival first year (IC 95%)	73.3 (71.9-74.6)	69.7 (66.0-73.0)
Charlson Index, mean (SD)	1.9 (1.3)	2.3 (1.6)
Reason to stop therapy (n)*:		
Lack of efficacy	1534 (53.2)	57 (58.8)
Adverse event	723 (25.1)	33 (34.0)
Adverse events (AE)*		
Serious infections	14.2 (12.4-16.2)	33.2 (19.3-57.3)
Herpes zoster	5.7 (4.6-7.1)	12.8 (5.3-30.7)
Tuberculosis	0.7 (0.4-1.3)	0.0 (0.0-0.0)
Malignancy/Neoplasia	10.2 (8.7-11.9)	15.3 (6.9-34.2)
Cardiac events	13.9 (12.2-16.0)	30.7 (17.4-54.0)
GI perforation	1.2 (0.8-1.9)	10.2 (3.8-27.3)
Vascular events	9.8 (8.3-11.5)	25.6 (13.8-47.5)

*Data show the incidence rate ratio per 1000 patient-years (PYs; 95% CI)

Conclusion: Serious infections and herpes zoster tend to be more frequent in patients on JAKi. However patients on JAKi were older, presented higher comorbidity and have a longer disease duration.

Disclosure of Interests: None declared

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OP0124 EFFECTS OF NINTEDANIB IN PATIENTS WITH PROGRESSIVE FIBROSING INTERSTITIAL LUNG DISEASE ASSOCIATED WITH RHEUMATOID ARTHRITIS (RA-ILD) IN THE INBUILD TRIAL

C. Kelly[1], E. Matteson[2], M. Aringer[3], G. R. Burmester[4], H. Mueller[5], L. Moros[6], K. Rohr[6], M. Kolb[7] on behalf of the INBUILD Trial Investigators.. [1]*Newcastle University, Institute of Cellular Medicine, Newcatle upon Tyne, United Kingdom*; [2]*Mayo Clinic College of Medicine and Science, Division of Rheumatology, Rochester, United States of America*; [3]*University Medical Center & Faculty of Medicine, TU Dresden, Rheumatology, Medicine III, Dresden, Germany*; [4]*Charité–University Medicine Berlin, Department of Rheumatology and Clinical Immunology, Berlin, Germany*; [5]*Boehringer Ingelheim Pharma GmbH & Co. KG, Biostatistics and Data Sciences, Biberach, Germany*; [6]*Boehringer Ingelheim International GmbH, TA Inflammation Med, Ingelheim am Rhein, Germany*; [7]*McMaster University and St. Joseph's Healthcare, Department of Medicine, Hamilton, Canada*

Background: In the INBUILD trial in subjects with progressive fibrosing ILDs other than idiopathic pulmonary fibrosis (IPF), nintedanib reduced the rate of decline in FVC (mL/year) over 52 weeks by 57% compared with placebo.

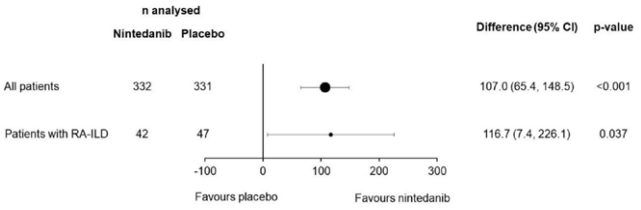
Objectives: To assess the rate of decline in FVC in subjects with RA-ILD in the INBUILD trial.

Methods: Subjects in the INBUILD trial had a chronic fibrosing ILD other than IPF, reticular abnormality with traction bronchiectasis (with or without honeycombing) of >10% extent on high-resolution computed tomography (HRCT), forced vital capacity (FVC) ≥45% predicted, diffusing capacity of the lungs for carbon monoxide ≥30%–<80% predicted, and met criteria for progression of ILD within the 24 months before screening, despite management deemed appropriate in clinical practice. Patients taking stable doses of approved medications to treat RA or connective tissue disease could participate, except that the protocol excluded those taking azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, rituximab, cyclophosphamide, or oral glucocorticoids >20 mg/day. We analysed the rate of decline in FVC (mL/year) over 52 weeks and adverse events in subjects with RA-ILD.

Results: Of 663 subjects who received trial medication, 89 had RA-ILD (42 nintedanib, 47 placebo), of whom 60.7% were male, 64.0% were current or former smokers, 86.5% had a usual interstitial pneumonia (UIP)-like pattern on HRCT; 93.3% had received confirmation of their RA diagnosis from a rheumatologist. At baseline, 21.3% of subjects were taking biologic disease-modifying anti-rheumatic drugs (DMARDs), 53.9% were taking non-biologic DMARDs and 73.0% were taking glucocorticoids (≤20 mg/day prednisone or equivalent). At baseline, mean (SD) age was 66.9 (9.6) years, time since RA diagnosis was 9.9 (9.4) years, time since ILD diagnosis was 3.6 (3.2) years, FVC was 71.5 (16.2) % predicted and C-reactive protein was 13.7 (22.5) mg/L. The adjusted mean (SE) rate of decline in FVC over 52 weeks was -82.6 (41.3) mL/year in the nintedanib group versus -199.3 (36.2) mL/year in the placebo group (difference 116.7 mL/year [95% CI 7.4, 226.1]; nominal p=0.037), consistent with findings in the overall trial population (Figure). As in the overall trial population, the most common adverse event in subjects with RA-ILD was diarrhoea (reported in 54.8% of the nintedanib group and 25.5% of the placebo group). Adverse events led to permanent discontinuation of trial drug in 19.0% of subjects in the nintedanib group and 12.8% of subjects in the placebo group.

Conclusion: In the INBUILD trial, nintedanib slowed the rate of decline in FVC in patients with progressive fibrosing RA-ILD, with adverse events that were manageable for most patients. The efficacy and safety of nintedanib in subjects with RA-ILD were consistent with those observed in the overall trial population.

Figure. Rate of decline in FVC (mL/year) over 52 weeks with nintedanib versus placebo in all subjects and in subjects with RA-ILD in the INBUILD trial.



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OP0125 TOFACITINIB IN RHEUMATOID ARTHRITIS-ASSOCIATED INTERSTITIAL LUNG DISEASE: EFFICACY AND SAFETY ANALYSIS FROM TREASURE REAL-LIFE DATA

U. Kalyoncu[1], E. Bilgin[1], A. Erden[2], H. Satış[3], A. Tufan[3], E. Tekgoz[4], A. Ateş[5], B. N. Coşkun[6], B. Yağız[6], O. Küçükşahin[7], V. Yazısız[8], G. Kimyon[9], C. Bes[10], A. İ. Ertenli[1], S. Kiraz[1]. [1]*Hacettepe University, Internal Medicine, Rheumatology, Ankara, Turkey*; [2]*Ankara City Hospital, Internal Medicine, Rheumatology, Ankara, Turkey*; [3]*Gazi University, Internal Medicine, Rheumatology, Ankara, Turkey*; [4]*University of Health Sciences Turkey, Gulhane Faculty of Medicine, Internal Medicine, Rheumatology, Ankara, Turkey*; [5]*Ankara University, Internal Medicine, Rheumatology, Ankara, Turkey*; [6]*Uludağ University, Internal Medicine, Rheumatology, Bursa, Turkey*; [7]*Yıldırım Beyazıt University, Internal Medicine, Rheumatology, Ankara, Turkey*; [8]*Akdeniz University, Internal Medicine, Rheumatology, Antalya, Turkey*; [9]*Mustafa Kemal University,*

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Internal Medicine, Rheumatology, Hatay, Turkey; [10]*University of Health Sciences Basaksehir Can and Sakura State Hospital, Internal Medicine, Rheumatology, İstanbul, Turkey*

Background: Beyond the joints, rheumatoid arthritis (RA) may affect lungs. Especially the involvement of the paranchyme, RA-associated interstitial lung disease (RA-ILD), is a major cause of mortality and morbidity. Tofacitinib, an oral JAK 1/3 inhibitor, has been used increasingly in the management of rheumatoid arthritis (RA) in recent years. Recently, a couple of animal and human studies reported promising results (1).

Objectives: To assess the real-life efficacy and safety of tofacitinib in patients with RA-ILD in TReasure registry.

Methods: This is a multicenter, observational study included RA patients with ILD diagnosis based on the HRCT images of the lungs, and were followed in 8 different centers participated in the TReasure database. Demographic data and patients' characteristics regarding RA and RA-ILD at the visit in which tofacitinib was initiated and for the last follow-up visit under tofacitinib were recorded. Using the present study cohort, the RA patients with ILD receiving tofacitinib were compared with those without ILD receiving tofacitinib (controls) in terms of the general and disease-related characteristics and data of concomitant DMARD use. To evaluate retention rates of tofacitinib and reasons for discontinuation, data of the patients with RA-ILD in this study cohort were compared with the data of RA patients without ILD who were followed in Hacettepe University (major contributor of the TReasure registry). This research was funded by Pfizer.

Results: A total of 47 RA patients with RA-ILD and a control group of 387 patients without ILD were included. The RA patients with ILD receiving tofacitinib were mostly male, older, and had higher baseline disease activity as compared with those without ILD (Table). The ILD pattern was known in 44 (93.6%) of 47 RA-ILD: 16 (36.3%) had UIP, 24 (54.5%) had NSIP, and 4 (9.1%) had airway disease. While 15 (31.9%) of the patients was asymptomatic, most common initial symptom was shortness of breath (in 14 (29.7%) patients). 18 patients had pre- and post-treatment FVC% and FEV1% values (with a median of 12 (9-19) months). Mean FEV1%; 82.1 vs. 82.8 (pre and post-treatment, respectively, p=0.079), mean FVC%; 79.8 vs. 82.8 (pre and post-treatment, respectively, p=0.014). To evaluate retention rates and reasons for discontinuation, 47 RA-ILD and 239 RA patients without ILD were analyzed. Retention rates were similar (p=0.21, log-rank) (Figure). Most common cause of tofacitinib discontinuation in RA-ILD group was infections (5 (25%) patients). Follow-up durations under tofacitinib were 15 (7-32) and 11 (4-24) months in ILD + and – groups, respectively. The rate of drug discontinuation due to infection in the RA patients with and without ILD was 6.3 per 100 patient-years and 2.4 per 100 patient-years, respectively.

Table 1. Characteristics of the RA patients with and without ILD under tofacitinib

Variables	RA-ILD(+) n=47	RA-ILD(-) n=387	p
Male sex	20 (42.6)	69 (17.8)	<0.001
Age, years	64 (57-69)	56 (46-64)	<0.001
Disease duration for RA, months	128 (78-212)	110 (64-183)	0.171
Smoking status			
Never smoker	26 (55.3)	211 (56.4)	0.259
Current&Ex-smoker	19 (44.7)	163 (43.6)	
RF (+)	36 (78.3)	249 (68.8)	0.187
Anti-CCP (+)	30 (65.2)	196 (61.6)	0.640
RF positive or CCP (+)	41 (87.2)	242 (76.3)	0.094
Presence of comorbidity	33 (70.2)	203 (52.5)	0.021
DAS-28 before tofacitinib	5.4 (4.6-6.22)	4.36 (3.22-5.58)	<0.001
ESR before tofacitinib, mm/h	38 (19-73)	29 (17-45)	0.029
CRP before tofacitinib	6.75 (1.63-24)	9.95 (4.18-25.1)	0.065
Follow-up duration under tofacitinib	15 (7-32)	7 (3-12)	<0.001

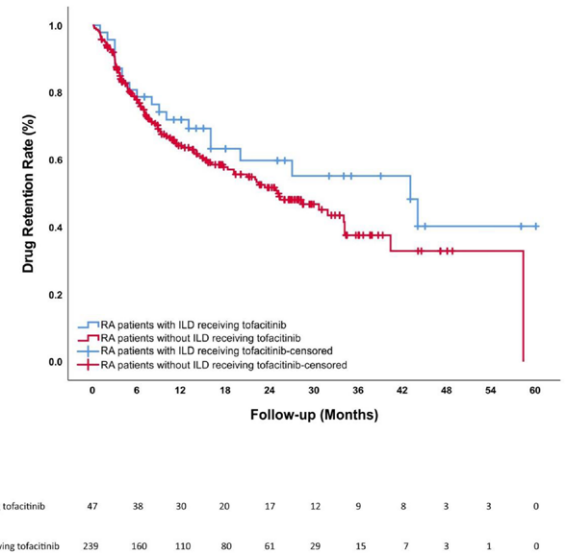


Figure 1. Tofacitinib retention rates in the RA patients with and without ILD

Conclusion: In majority of patients, pulmonary functions remained stable during follow-up. Tofacitinib seems as a promising option for RA-ILD. High rate of discontinuation due infections was observed in RA-ILD patients under tofacitinib; however, it should be kept in mind that RA-ILD patients were older than RA patients without ILD.

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OP0126

INFECTIONS AND SERIOUS INFECTIONS IN THE FILGOTINIB RHEUMATOID ARTHRITIS PROGRAM

J. Galloway[1], M. H. Buch[2], K. Yamaoka[3], C. Leatherwood[4], A. Pechonkina[5], I. Tiamiyu[4], D. Jiang[6], L. Ye[6], R. Besuyen[7], D. Aletaha[8], K. Winthrop[9]. [1]*King's College London, Centre for Rheumatic Diseases, School of Immunology and Microbial Sciences, London, United Kingdom*; [2]*University of Manchester, Division of Musculoskeletal & Dermatological Sciences, Manchester, United Kingdom*; [3]*Kitasato University School of Medicine, Department of Rheumatology and Infectious Diseases, Kanagawa, Japan*; [4]*Gilead Sciences, Inc., Clinical Research, Foster City, United States of America*; [5]*Gilead Sciences, Inc., Inflammation and Respiratory Therapeutic Area, Foster City, United States of America*; [6]*Gilead Sciences, Inc., Biostatistics, Foster City, United States of America*; [7]*Galapagos BV, Clinical Development, Leiden, Netherlands*; [8]*Medical University of Vienna, Division of Rheumatology, Department of Medicine 3, Vienna, Austria*; [9]*Oregon Health and Science University, Division of Infectious Diseases, Portland, United States of America*

Background: The Janus kinase (JAK)-1 preferential inhibitor filgotinib (FIL) improved rheumatoid arthritis (RA) signs and symptoms in 3 phase (P)3 trials.[1–3] Like other RA therapies, JAK inhibition is associated with increased infection rates.[4]

Objectives: To assess long-term safety across the FIL program regarding infections, including serious infections (SI).

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