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

DOI: 10.1136/annrheumdis-2021-eular.2645

OP0124

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

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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.

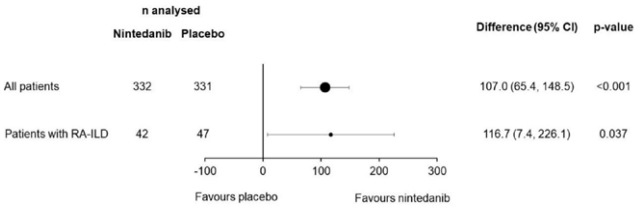
Objectives: To assess the rate of decline in FVC in subjects with RA-ILD in the INBUILD trial.

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.



Acknowledgements: The INBUILD trial was funded by Boehringer Ingelheim. Medical writing support was provided by Fleishman Hillard Fishburn, London, UK. The authors meet criteria for authorship as recommended by the International Committee of Medical Journal Editors (ICMJE).

Disclosure of Interests: Clive Kelly Speakers bureau: Boehringer Ingelheim, Consultant of: Boehringer Ingelheim, Eric Matteson Speakers bureau: Boehringer Ingelheim, Consultant of: Boehringer Ingelheim and Gilead Sciences, Grant/research support from: Sun Pharmaceuticals and Pfizer, Martin Aringer Speakers bureau: AbbVie, AstraZeneca, Bristol-Myers Squibb, Boehringer Ingelheim, Chugai, Gilead, GlaxoSmithKline, HEXAL, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi and UCB, Consultant of: AbbVie, AstraZeneca, Bristol-Myers Squibb, Boehringer Ingelheim, GlaxoSmithKline, Lilly, Merck Sharp & Dohme, Novartis, Pfizer, Roche, Sanofi and UCB, Gerd Rüdiger Burmester Speakers bureau: AbbVie, Bristol-Myers Squibb, Boehringer Ingelheim, Gilead, Lilly, Merck Sharp & Dohme, Pfizer, Roche and Sanofi, Consultant of: AbbVie, Bristol-Myers Squibb, Boehringer Ingelheim, Gilead, Lilly, Merck Sharp & Dohme, Pfizer, Roche and Sanofi, Heiko Mueller Employee of: Currently an employee of Boehringer Ingelheim, Lizette Moros Employee of: Currently an employee of Boehringer Ingelheim, Klaus Rohr Employee of: Currently an employee of Boehringer Ingelheim, Martin Kolb Consultant of: Algernon, Boehringer Ingelheim, Pieris Pharmaceuticals and Roche, Grant/research support from: Boehringer Ingelheim, Pieris Pharmaceuticals and Prometic

DOI: 10.1136/annrheumdis-2021-eular.969

OP0125

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

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Ann Rheum Dis: first published as 10.1136/annrheumdis-2021-eular.1236 on 19 May 2021. Downloaded from http://ard.bmj.com/ on December 11, 2021 at AMS/ANKUNIV*VETERINER P O Box 750. Protected by copyright.

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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

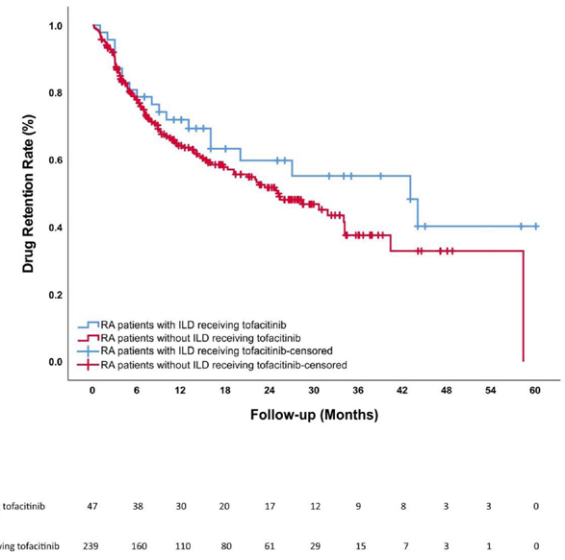

Figure 1. Tofacitinib retention rates in the RA patients with and without ILD

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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Disclosure of Interests: Umut Kalyoncu Speakers bureau: Pfizer, Abbvie, UCB, Amgen, Emre Bilgin: None declared, Abdulsamet Erden: None declared, Hasan Satış: None declared, abdurrahman tufan: None declared, Emre Tekgoz: None declared, Aşkın Ateş: None declared, Belkıs Nihan Coşkun: None declared, Burcu Yağız: None declared, Orhan Küçükşahin: None declared, Veli yazısız: None declared, Gezmiş Kimyon: None declared, Cemal Bes: None declared, Ali İhsan Ertenli: None declared, Sedat Kiraz: None declared
DOI: 10.1136/annrheumdis-2021-eular.1236

OP0126 INFECTIONS AND SERIOUS INFECTIONS IN THE FILGOTINIB RHEUMATOID ARTHRITIS PROGRAM

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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).

Ann Rheum Dis: first published as 10.1136/annrheumdis-2021-eular.1236 on 19 May 2021. Downloaded from http://ard.bmj.com/ on December 11, 2021 at AMS/ANKUNIV*VETERINER P O Box 750. Protected by copyright.