

**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)
Ankylosing 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)
<b>Adverse events (AE)*</b>		
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

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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.

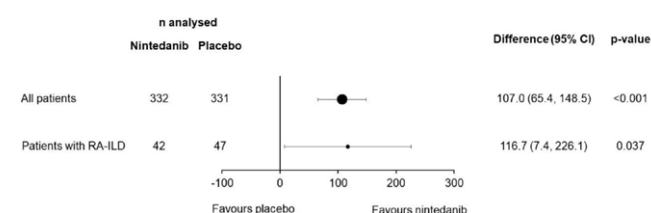
**Methods:** Subjects in the INBUILD trial had a chronic fibrosing ILD other than IPF, reticular abnormality with traction bronchiectasis (with or without honeycombing) of >10% extent on high-resolution computed tomography (HRCT), forced vital capacity (FVC)  $\geq$ 45% predicted, diffusing capacity of the lungs for carbon monoxide  $\geq$ 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 ( $\leq$ 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

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