References:

[1] Tanaka Y et al. *Mod Rheumatol*. 2018;28:583-91[2] Tanaka Y et al. *Mod Rheumatol*. 2018;28:20-9

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SAT0157

NINTEDANIB DOSE ADJUSTMENTS AND ADVERSE EVENTS IN PATIENTS WITH PROGRESSIVE AUTOIMMUNE DISEASE-RELATED INTERSTITIAL LUNG DISEASES IN THE INBUILD TRIAL

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Background: In the INBUILD trial in patients with progressive fibrosing ILDs, the adverse event (AE) profile of nintedanib was characterised predominantly by gastrointestinal AEs. Dose adjustments were used to manage AEs.

Objectives: Assess AEs and dose adjustments in patients with autoimmune disease-related ILDs in the INBUILD trial.

Methods: Patients with progressive fibrosing ILDs other than idiopathic pulmonary fibrosis were randomised to nintedanib 150mg bid or placebo. Dose reductions to 100mg bid and treatment interruptions were permitted to manage AEs. AEs over 52 weeks of treatment (or 28 days after last trial drug intake for patients who discontinued drug before week 52) were assessed in patients who received ≥1 dose of trial drug.

Results: Of 663 patients in the INBUILD trial, 170 (82 nintedanib, 88 placebo) had autoimmune disease-related ILDs (89 RA-ILD, 39 SSC-ILD, 19 MCTD-ILD, 23 other autoimmune ILDs). In the nintedanib and placebo groups of patients with autoimmune disease-related ILDs, respectively, over 52 weeks, the proportions of patients with ≥1 dose reduction were 28.0% and 3.4%, with ≥1 treatment interruption were 31.7% and 10.2%, and with ≥1 dose reduction and/or treatment interruption were 40.2% and 12.5% (Table). Dose intensity (amount of drug administered divided by amount that would have been received had 150mg bid been administered over 52 weeks or until permanent treatment discontinuation) was >90% in 80.5% of patients in the nintedanib group and 95.5% in the placebo group. AEs led to permanent treatment discontinuation in 17.1% and 10.2% of patients treated with nintedanib and placebo, respectively. Diarrhoea was the most common AE, reported in 63.4% and 27.3% of patients in the nintedanib and placebo groups, respectively. Diarrhoea AEs led to dose reduction, treatment interruption and permanent treatment discontinuation in 7.3%, 9.8% and 4.9% of patients in the nintedanib group, compared with 0%, 1.1% and 1.1% of patients in the placebo group, respectively. Of the nintedanib-treated patients who experienced ≥1 diarrhoea AE, 80.8% experienced 1 or 2 events and 76.9% experienced events that were mild at worst (Common Terminology Criteria for Adverse Events [CTCAE] grade 1).

Conclusion: In the INBUILD trial, management of AEs via dose adjustments enabled most patients with autoimmune disease-related ILDs to remain on treatment for 52 weeks. Diarrhoea was the AE that most commonly led to dose adjustment.

Table

	Nintedanib (n=82)	Placebo (n=88)
Patients with ≥1 dose reduction or treatment interruption	33 (40.2)	11 (12.5)
Patients with ≥1 dose reduction	23 (28.0)	3 (3.4)
Total number of dose reductions	25	3
Patients with ≥1 dose re-escalation after dose reduction	5 (6.1)	2 (2.3)
Patients with ≥1 treatment interruption	26 (31.7)	9 (10.2)
Total number of treatment interruptions	32	11
Total duration of treatment interruptions, days, mean (SD)	20.1 (15.1)	19.3 (20.7)

Data are n (%) of patients unless otherwise indicated.

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SAT0158

EFFICACY AND SAFETY OF FILGOTINIB IN METHOTREXATE-NAÏVE PATIENTS WITH RHEUMATOID ARTHRITIS: FINCH 3 52-WEEK RESULTS

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Background: Filgotinib (FIL) is a potent, selective JAK 1 inhibitor. FINCH 3 assessed FIL efficacy and safety in methotrexate (MTX)-naïve patients (pts) with rheumatoid arthritis (RA); week (W)24 primary outcome results were previously presented.¹

Objectives: To report FINCH 3 (NCT02886728) results through W52.

Methods: This global, phase 3, double-blind, active-controlled study randomised MTX-naïve pts with moderately to severely active RA 2:1:1:2 to oral FIL 200mg once daily + MTX ≤20mg weekly, FIL 100mg + MTX, FIL 200mg monotherapy (mono) + placebo (PBO), or PBO + MTX up to W52. Comparisons at W52 were not adjusted for multiplicity. Safety was assessed from adverse events and laboratory abnormalities.

Results: Of 1249 treated pts, 975 received study drug through W52. FIL efficacy was sustained up to W52. Treatment with FIL + MTX or FIL mono increased proportions of pts achieving ACR20/50/70 and clinical disease remission by DAS28(CRP) <2.6 (FIL 200mg + MTX, 53%; FIL mono, 46%), CDAI, SDAI, and Boolean criteria; improved HAQ-DI; and halted radiographic progression vs MTX alone (Table 1 and Figure). Safety was consistent with W24 data (Table 2).

Table 1. Efficacy outcomes at week 52

	FIL 200mg + MTX (n = 416)	FIL 100mg + MTX (n = 207)	FIL 200mg (n = 210)	MTX (n = 416)
ACR20, %	75.0***	73.4**	74.8***	61.8
ACR50, %	62.3***	59.4**	61.4***	48.3
ACR70, %	47.8***	40.1*	45.2***	29.8
mTSS ^a	0.21***	0.27*	0.23*	0.74
HAQ-DI ^b	-1.00***	-0.97	-0.95*	-0.88

^aLeast-squares mean change from baseline.^bMean change from baseline.

*, p < 0.05; **, p < 0.01; ***, p < 0.001 vs MTX alone; not adjusted for multiplicity.

FIL, filgotinib; mTSS, van der Heijde modified total Sharp score; MTX, methotrexate.