

## ONLINE SUPPLEMENTARY MATERIAL

**SUPPLEMENTARY TABLE S1.** Adverse events in the overall population by inclusion criteria for ILD progression.

	Group A		Group B		Group C	
	Nintedanib (n=160)	Placebo (n=172)	Nintedanib (n=110)	Placebo (n=97)	Nintedanib (n=62)	Placebo (n=61)
Any adverse event(s)	152 (95.0)	158 (91.9)	104 (94.5)	85 (87.6)	61 (98.4)	52 (85.2)
Most frequent adverse events*						
Diarrhoea	107 (66.9)	31 (18.0)	71 (64.5)	33 (34.0)	44 (71.0)	15 (24.6)
Nausea	50 (31.3)	10 (5.8)	33 (30.0)	15 (15.5)	13 (21.0)	6 (9.8)
Bronchitis	23 (14.4)	21 (12.2)	14 (12.7)	16 (16.5)	4 (6.5)	9 (14.8)
Cough	14 (8.8)	23 (13.4)	9 (8.2)	14 (14.4)	10 (16.1)	6 (9.8)
Vomiting	33 (20.6)	5 (2.9)	23 (20.9)	9 (9.3)	5 (8.1)	3 (4.9)
Decreased appetite	21 (13.1)	9 (5.2)	15 (13.6)	5 (5.2)	12 (19.4)	3 (4.9)
Weight decreased	21 (13.1)	6 (3.5)	10 (9.1)	2 (2.1)	10 (16.1)	3 (4.9)
ALT increased	28 (17.5)	7 (4.1)	12 (10.9)	2 (2.1)	3 (4.8)	3 (4.9)
Progression of ILD <sup>†</sup>	8 (5.0)	27 (15.7)	7 (6.4)	8 (8.2)	1 (1.6)	4 (6.6)
Serious adverse event(s) <sup>‡</sup>	54 (33.8)	70 (40.7)	36 (32.7)	27 (27.8)	17 (27.4)	13 (21.3)
Fatal adverse event	7 (4.4)	10 (5.8)	3 (2.7)	6 (6.2)	1 (1.6)	1 (1.6)

Adverse event(s) leading to permanent treatment discontinuation	33 (20.6)	22 (12.8)	26 (23.6)	8 (8.2)	6 (9.7)	4 (6.6)
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Data are n (%) of subjects with  $\geq 1$  such adverse event reported over 52 weeks (or until 28 days after last trial drug intake in subjects who discontinued trial drug before week 52). Group A: decline in FVC  $\geq 10\%$  predicted; Group B: decline in FVC  $\geq 5$ – $<10\%$  predicted with worsened respiratory symptoms and/or increased extent of fibrosis on HRCT; Group C: worsened respiratory symptoms and increased extent of fibrosis on HRCT only. \*Adverse events reported in  $>15\%$  of subjects in any group, coded based on preferred terms in the Medical Dictionary for Regulatory Activities (MedDRA). <sup>†</sup>Corresponded to MedDRA preferred term “interstitial lung disease”. <sup>‡</sup>Adverse events that resulted in death, were life-threatening, resulted in hospitalisation or prolongation of hospitalisation, resulted in persistent or clinically significant disability or incapacity, were a congenital anomaly or birth defect, or were deemed to be serious for any other reason. ALT, alanine aminotransferase; ILD, interstitial lung disease.