

Online data supplement

Nintedanib in patients with idiopathic pulmonary fibrosis and preserved lung volume

Martin Kolb, Luca Richeldi, Jürgen Behr, Toby M Maher, Wenbo Tang, Susanne Stowasser, Christoph Hallmann, Roland M du Bois

Supplementary table

Table S1. Summary of adverse events by subgroup (n [%])

	FVC >90% predicted		FVC ≤90% predicted	
	Nintedanib	Placebo	Nintedanib	Placebo
	(n=166)	(n=108)	(n=472)	(n=315)
Any adverse event(s)	156 (94.0)	100 (92.6)	453 (96.0)	278 (88.3)
Most frequent adverse event(s)*				
Diarrhoea	103 (62.0)	17 (15.7)	295 (62.5)	61 (19.4)
Nausea	44 (26.5)	8 (7.4)	112 (23.7)	20 (6.3)
Nasopharyngitis	21 (12.7)	20 (18.5)	66 (14.0)	48 (15.2)
Cough	19 (11.4)	18 (16.7)	66 (14.0)	39 (12.4)
Vomiting	25 (15.1)	2 (1.9)	49 (10.4)	9 (2.9)
Decreased appetite	15 (9.0)	4 (3.7)	53 (11.2)	20 (6.3)
Bronchitis	12 (7.2)	11 (10.2)	55 (11.7)	34 (10.8)
Progression of IPF [†]	4 (2.4)	6 (5.6)	59 (12.5)	55 (17.5)
Weight decreased	14 (8.4)	2 (1.9)	48 (10.2)	13 (4.1)
Upper respiratory tract infection	10 (6.0)	10 (9.3)	48 (10.2)	32 (10.2)
Dyspnoea	6 (3.6)	12 (11.1)	43 (9.1)	36 (11.4)
Arthralgia	1 (0.6)	11 (10.2)	13 (2.8)	10 (3.2)
Severe adverse event(s)	37 (22.3)	18 (16.7)	137 (29.0)	81 (25.7)
Serious adverse event(s)	38 (22.9)	28 (25.9)	156 (33.1)	99 (31.4)
Fatal adverse event(s)	4 (2.4)	2 (1.9)	33 (7.0)	29 (9.2)
Adverse event(s) leading to	36 (21.7)	8 (7.4)	87 (18.4)	46 (14.6)

treatment discontinuation‡

Diarrhoea	7 (4.2)	0 (0.0)	21 (4.4)	1 (0.3)
Progression of IPF†	2 (1.2)	2 (1.9)	11 (2.3)	19 (6.0)
Nausea	5 (3.0)	0 (0.0)	8 (1.7)	0 (0.0)
Decreased appetite	4 (2.4)	1 (0.9)	5 (1.1)	0 (0.0)

*Adverse events reported in >10% of patients in any treatment group; †Corresponds to Medical Dictionary for Regulatory Activities (MedDRA) term 'IPF', which included disease worsening and acute exacerbations of IPF; ‡Adverse events leading to treatment discontinuation in >2% of patients in any treatment group.

Supplementary Figures

Figure S1. Mean (SE) change from baseline in forced vital capacity (FVC) over time by subgroup.

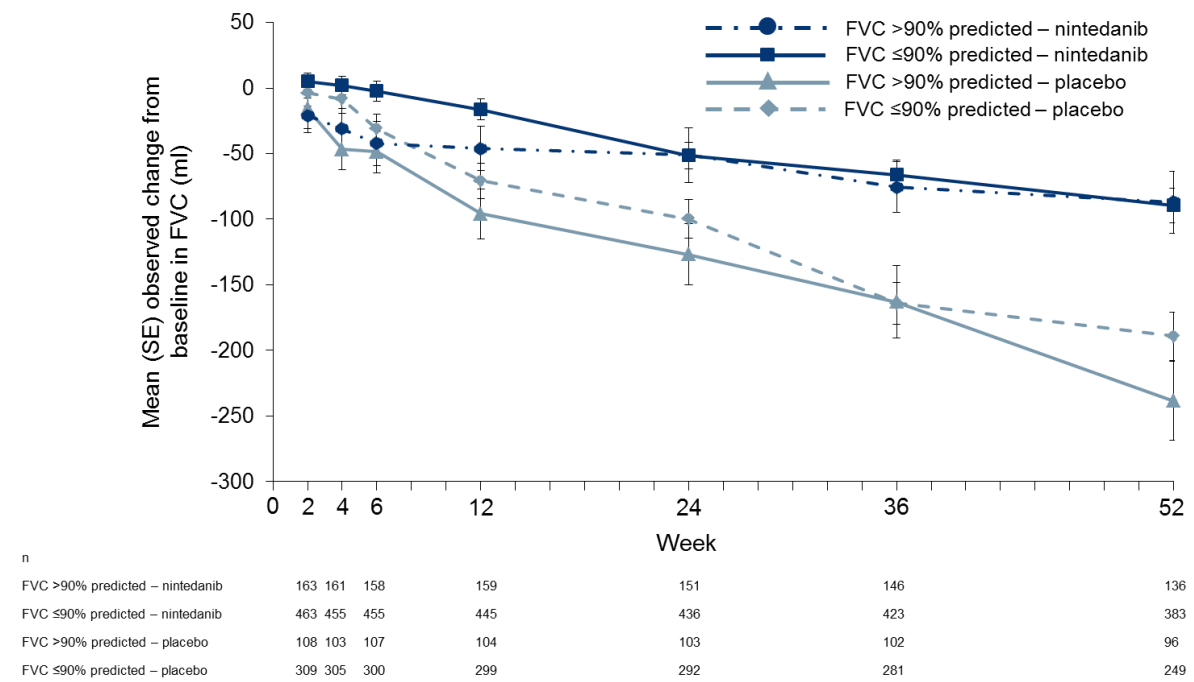


Figure S2. Adjusted mean (SE) change from baseline in St George's Respiratory Questionnaire (SGRQ) total score over 52 weeks by subgroup.

