FVC decline $\geq 10\%$ pred in INPULSIS had higher mortality in INPULSIS-ON than patients with FVC decline $< 10\%$ pred.

Conclusion Independent of FVC decline in the first year, most patients had FVC decline $< 10\%$ pred with continued nintedanib for a second year. FVC decline $\geq 10\%$ pred over 1 year did not predict subsequent FVC decline, but was associated with higher mortality.

Please refer to page A261 for declarations of interest in relation to abstract M29.

Abstract M29 Table 1

Absolute decline in FVC from baseline to week 52 of INPULSIS in patients treated with nintedanib (first year of treatment)	Outcome in the first year of INPULSIS-ON (second year of treatment)*	n (%)
$< 10\%$ predicted (n=383)	Absolute decline in FVC $< 10\%$ predicted [†]	301 (78.6)
	Absolute decline in FVC $\geq 10\%$ predicted	64 (16.7)
	Death	18 (4.7)
$\geq 10\%$ predicted (n=47)	Absolute decline in FVC $< 10\%$ predicted [†]	31 (66.0)
	Absolute decline in FVC $\geq 10\%$ predicted	8 (17.0)
	Death	8 (17.0)

*Patients who discontinued INPULSIS-ON without having an absolute decline in FVC $\geq 10\%$ predicted or having died were counted in the category "absolute decline in FVC $< 10\%$ predicted". [†]Includes patients with an increase, no decline, or an absolute decline in FVC $> 0\%$ but $< 10\%$ predicted in the first year of INPULSIS-ON.

M30

EFFECT OF DOSE REDUCTIONS AND/OR INTERRUPTIONS ON THE EFFICACY OF NINTEDANIB IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS (IPF): SUBGROUP ANALYSIS OF THE INPULSIS TRIALS

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Introduction and Aim The efficacy and safety of nintedanib in patients with IPF were assessed in two replicate Phase III placebo-controlled INPULSIS trials. In both trials, nintedanib reduced disease progression by reducing decline in FVC. The recommended dose of nintedanib was 150 mg bid, but dose reductions to 100 mg bid and treatment interruptions were allowed for the management of adverse events. Following dose reduction, the dose could be re-escalated to 150 mg bid. We assessed whether dose reductions and/or treatment interruptions influenced the effect of nintedanib on reducing FVC decline.

Methods We assessed change from baseline in FVC (mL) at week 52 in subgroups of patients by their last dose (150 mg bid or 100 mg bid) and whether they had experienced a dose reduction and/or treatment interruption using pooled data from both INPULSIS trials. Patients who prematurely

discontinued trial medication but had an FVC value at week 52 were included in the analysis. Analyses were descriptive and based on observed cases.

Results A total of 864 patients were included in the analysis (519 treated with nintedanib, 345 with placebo). Most (75%) patients did not have a dose reduction or treatment interruption. Mean (SD) changes from baseline in FVC at week 52 in subgroups by dose are shown in the Table. In patients who took nintedanib 150 mg bid as their last dose, absolute mean changes from baseline in FVC at week 52 were -118 mL and -90 mL in patients who did and did not have any prior dose reduction and/or treatment interruption, respectively. In patients who took nintedanib 100 mg bid as their last dose, mean change from baseline in FVC at week 52 was -74 mL. These changes were consistent with the decline in FVC observed in the whole nintedanib group (-89 mL).

Conclusion Pooled data from the INPULSIS trials show that decline in FVC was similar in patients treated with nintedanib irrespective of whether they had dose reductions and/or treatment interruptions. These Results suggest that the dosing regimen used in the INPULSIS trials was effective at reducing disease progression in patients with IPF.

Please refer to page A261 for declarations of interest in relation to abstract M30.

Abstract M30 Table 1 Change from baseline in FVC (mL) at week 52 by dose subgroups in INPULSIS

	Nintedanib		Placebo	
	N	Mean (SD)	N	Mean (SD)
All patients	519	-89 (264)	345	-203 (293)
Patients who did not have a dose reduction or treatment interruption	340	-90 (265)	309	-200 (292)
Patients who took 150 mg bid as last dose and had ≥ 1 dose reduction and/or treatment interruption	56	-118 (251)	31	-203 (273)
Patients who took 100 mg bid as last dose after ≥ 1 dose reduction and/or treatment interruption	123	-74 (269)	5	-391 (422)

M31

SAFETY OF COMBINED PIRFENIDONE AND NINTEDANIB IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS

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Background Safety data on combined pirfenidone and nintedanib use are limited.

Methods A single-arm, open-label study (NCT02598193) assessed safety and tolerability of 24 weeks' pirfenidone (1602–2403 mg/day) and nintedanib (200–300 mg/day) in patients with idiopathic pulmonary fibrosis (IPF) with forced vital capacity (FVC) $\geq 50\%$ and diffusing capacity of the lung for carbon monoxide (DLco) $\geq 30\%$. Before initiating nintedanib, patients had received pirfenidone for ≥ 16 weeks and tolerated a stable dose