Abstract P173 Table 1 Non-elective Hospitalizations in Patients Treated With Pirfenidone or Placebo over 12 Months

	All-Cause Hospitalizations		Respiratory-Related Hospitalizations		Non-Respiratory Hospitalizations	
Hospitalizations	**Pirfenidone (N = 623)**	**Placebo (N = 624)**	**Pirfenidone (N = 623)**	**Placebo (N = 624)**	**Pirfenidone (N = 623)**	**Placebo (N = 624)**
Events, n	140	147	57	86	83	61
Patients with ≥1 event						
n (%)	106 (17)	112 (18)	44 (7)	74 (12)	68 (11)	51 (8)
Odds ratio (95% CI)	0.94 (0.70, 1.26)		0.56 (0.38, 0.84)		1.38 (0.94, 2.02)	
P-value	0.662		0.004		0.099	
Died after hospitalisation, n (%)	18 (17)	37 (33)	12 (27)	34 (46)	7 (10)	9 (18)

describe the proportion of patients from the three Phase 3 pirfenidone IPF trials with at least one non-elective hospitalisation (all-cause, respiratory-related and non-respiratory-related) over 12 months.

Methods In three Phase 3 randomised, placebo-controlled studies of pirfenidone for IPF (CAPACITY I/II and ASCEND), patients were randomised to pirfenidone (2403 mg/day) or placebo. In the two CAPACITY studies, respiratory-related hospitalizations were a pre-specified endpoint. In ASCEND, hospitalizations were reported as adverse events (AEs), and retrospectively categorised as respiratory-related or non-respiratory by case review. The pooled rates of patients experiencing ≥1 non-elective hospitalizations (all-cause, respiratory-related and non-respiratory-related) for pirfenidone and placebo patients over 12 months are summarised. Rate of death post-hospitalisation was also reported.

Results A total of 1,247 patients (692 CAPACITY and 555 ASCEND) were included (Table). In pooled analyses, the proportion of patients experiencing ≥1 all-cause hospitalizations over 12 months was no different between pirfenidone and placebo-treated patients. The proportion of patients experiencing ≥1 respiratory-related hospitalizations was 12% in the placebo group vs 7% in the pirfenidone group (odds ratio 0.56; $P = 0.004$). Deaths after hospitalisation were numerically reduced in the pirfenidone group, most substantially for respiratory-related hospitalizations.

Conclusion Patients with IPF frequently require hospitalisation for a variety of reasons. Pirfenidone may reduce the risk of non-elective respiratory-related hospitalizations over 12 months.

P174 EFFECT OF CONTINUED TREATMENT WITH PIRFENIDONE FOLLOWING A ≥10% RELATIVE DECLINE IN PERCENT PREDICTED FORCED VITAL CAPACITY (%FVC) IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS (IPF)

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Background The variability in disease progression in patients with IPF complicates the assessment of treatment response. Previously a pooled analysis of three Phase 3 trials showed that patients who experienced a ≥10% *absolute* decline in %FVC during the first 6 months of treatment derived a clinical benefit with continued pirfenidone treatment in the subsequent 6 months [Nathan *et al*. *ATS* 2015]. To further explore the potential benefit of continued pirfenidone treatment in patients who initially experienced more modest declines, we assessed subsequent outcomes after a ≥ 10% *relative* decline in %FVC during the first 6 months of treatment.

Methods Source data included all patients randomised to receive pirfenidone 2403 mg/d or placebo in the ASCEND or CAPACITY trials (N = 1247). All patients with a ≥10% relative decline in%FVC were selected by the 6-month study visit. The proportion of patients in the pirfenidone and placebo groups who experienced any of the following during the subsequent 6-month interval were compared: (1) ≥10% relative decline in% FVC or death; (2) death; or (3) no further decline in %FVC.

Results Of the pooled patients that experienced an initial ≥10% relative decline in %FVC, 80 and 140 patients received pirfenidone and placebo, respectively. In the subsequent 6 months, 17 (21.3%) and 50 (35.7%) patients, respectively, experienced a ≥ 10% relative decline in %FVC or death. In addition, more patients in the pirfenidone group had no further decline in % FVC and fewer patients died compared with placebo during the subsequent 6-month interval (**Table 1**).

Conclusions In patients who experienced a ≥10% relative decline in %FVC during the first 6 months of treatment, continued treatment with pirfenidone appeared to lower the risk of % FVC decline or death during the subsequent 6 months, similar to previous results observed with a ≥10% absolute %FVC cut-off. Using relative change to calculate a ≥10% initial FVC decline identified more than twice as many patients compared to using absolute change. These findings suggest a potential benefit to continued treatment with pirfenidone despite an initial clinically meaningful decline in FVC ≥10% regardless of calculation method.

Abstract P174 Table 1 Outcomes during the 6-month period following an initial ≥10% relative decline in %FVC during the first 6 months of treatment

Initial ≥10% Relative%FVC Decline				
Outcome in subsequent 6 months, n (%)	**Pirfenidone (N = 80)**	**Placebo (N = 140)**	**Relative Difference,%**	***P*-value**
≥10% relative decline in FVC or death	17 (21.3)	50 (35.7)	–40.5	0.033
Death	5 (6.3)	16 (11.4)	–45.3	0.242
No further decline in FVC	41 (51.3)	50 (35.7)	43.5	0.033

FVC, forced vital capacity.