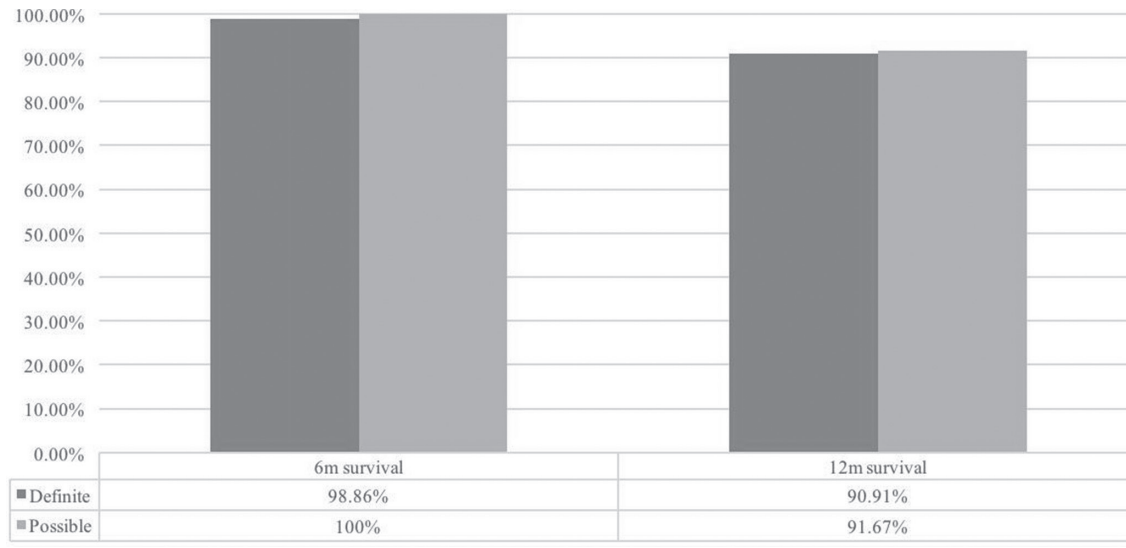

	6m survival	12m survival
Definite	98.86%	90.91%
Possible	100%	91.67%

Abstract P167 Figure 1 Pirfenidone therapy and survival rates in definite UIP, and Possible UIP

Results 116 patients out of 170 were started on antifibrotic therapy. The average duration of therapy was 256 days. There was a trend towards higher treatment failure in possible (n = 3 of 12 25%) versus definite UIP patterns (n = 6 of 55 11%), this was not statistically significant. Overall mortality rates were similar between possible and definite UIP patterns at 6- and 12-months (Figure 1). 5 patients with UIP and pleural plaques were started on therapy.

Conclusions Mortality at 12 months was similar in possible UIP and UIP groups; there was a trend towards higher levels of treatment failure in patients with possible UIP. A different disease process may exist in some patients with possible UIP which is non-responsive to antifibrotic treatment. Numbers are relatively small and further observation is warranted.

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P168 SAFETY AND TOLERABILITY OF NINTEDANIB IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS (IPF): ONE-YEAR DATA FROM POST-MARKETING SURVEILLANCE IN THE UNITED STATES

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Introduction In the two replicate, 52-week, placebo-controlled INPULSIS® trials, nintedanib 150 mg twice daily significantly reduced the annual rate of decline in forced vital capacity compared with placebo and had a side-effect profile that was manageable for most patients. After the US approval of nintedanib for the treatment of IPF in October 2014, post-marketing surveillance was initiated to obtain additional information on the safety and tolerability of nintedanib in the real-world clinical setting.

Methods Data were collected from the drug safety database from the time of drug launch (15 October 2014) to 23 October 2015. Data on adverse events in patients treated with nintedanib were collected both via proactive patient communications, as part of a patient support programme, and by the spontaneous reporting system. Adverse events were coded according to preferred terms in the Medical Dictionary for Regulatory Activities. Serious adverse events were defined according to International Conference on Harmonisation criteria as adverse events that were fatal or life threatening, required or prolonged hospitalisation, were associated with a congenital anomaly, or resulted in a disability.

Results In the period from drug launch to 23 October 2015, 6,758 patients were treated with nintedanib, with duration of exposure 6 to 390 days (median 113 days). This analysis will present 1-year adverse event data collected both via proactive patient communications, as part of a patient support programme, and by the spontaneous reporting system. Previously reported data collected from drug launch up to 31 May 2015, from 3,838 patients, were consistent with the safety profile described in the product label. In this dataset and as observed in the Phase III trials, the most frequently reported adverse events with nintedanib were gastrointestinal in nature and non-serious in severity.

Conclusion Data from post-marketing surveillance in the US are consistent with the safety profile of nintedanib as described in the label. Treatment with nintedanib in the real-world clinical setting appears to have an acceptable safety and tolerability profile, with no new safety concerns identified.

P169 LONG-TERM SAFETY OF PIRFENIDONE IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS: POOLED ANALYSIS OF 4 CLINICAL TRIALS

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