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Title: All-case post-marketing surveillance (PMS) of pirfenidone in Japan: Clinical characteristics, efficacy and safety profile in >1300 patients with idiopathic pulmonary fibrosis (IPF)

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Body: Background: In 2008, a novel anti-fibrotic agent, pirfenidone (PFD, Pirespa®) was approved for the treatment of IPF in Japan. Aims and objectives: After the approval in 2008, the PMS was conducted under government requirement to access the clinical characteristics, efficacy and safety profile of PFD in Japanese clinical setting. Methods: All patients (pts) who initiated PFD therapy from Dec 2008 to Oct 2009 in Japan were enrolled. All adverse drug reactions (ADR) were collected. The efficacy was evaluated on the changes in vital capacity (VC) from baseline. All cases who were enrolled were analyzed up to 1 year from the first dose. Results: The data on 1256 cases were locked by Oct 2012; 1247 cases were evaluable for safety. Mean age of pts was 69.4 yrs; 28.1% were 75 yr or older. At baseline (using Japanese severity grade of IPF), 40.7% of pts were diagnosed as grade IV {(PaO_2 at rest <60 Torr) or (PaO_2 at rest <70 Torr and 6MWT SpO_2 <90%)}. 60.6% of pts continued PFD therapy for 6 months or longer. Incidences of decreased appetite, photosensitivity reaction and nausea were 29.0%, 15.0% and 8.3%, respectively. Among pts treated with PFD for 6 months or longer, the mean change in VC was -0.07 L (median interval of measure: 278 days). The data will be updated at the congress. Conclusions: Our data from the largest PMS of PFD to date showed that PFD was tolerable and kept the decline in VC to a minimum. Although most

ADRs were manageable, the control of gastrointestinal symptoms was thought to be of importance in order that therapy could be continued and maximal benefit from PFD could be gained.