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Title: The long-term safety of pirfenidone (PFD) in patients with idiopathic pulmonary fibrosis (IPF)

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Body: Introduction: PFD is an oral molecule that is approved in Europe and Japan for the treatment of IPF. Long-term safety is being assessed in two open-label (OL) studies in patients with IPF. Objective: Further examine the long-term safety of PFD in patients with IPF. Methods: All patients receiving PFD 2403 mg/d in the CAPACITY studies or one of two ongoing OL studies of PFD in patients with IPF (Studies 002 and 012) were included in the analysis. Study 002 is a compassionate use study in the U.S.; Study 012 is an OL extension study evaluating PFD in patients who completed CAPACITY. Results: A total of 789 patients were included in the analysis. The median duration of exposure to PFD was 2.6 years (range, 1 week–7.7 years); the median daily dose was 2257 mg (range 25–3600). The cumulative total exposure was 2,052 person exposure years (PEY). Consistent with previous studies, almost all patients (99.7%) reported at least one treatment emergent adverse event (AE). Gastrointestinal and skin-related events were the most commonly reported AE's; these were generally mild to moderate and rarely led to treatment discontinuation. AST/ALT elevations (>3 x ULN) occurred in 21/789 (2.7%) patients; the adjusted incidence of AST/ALT elevations was 1.7 per 100 PEY. Conclusions: Analysis of safety data from IPF patients receiving PFD for up to 7.7 years demonstrates that long-term treatment with PFD is safe and generally well tolerated.