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**Title:** Analysis of lung function and survival in RECAP: An open-label extension study of pirfenidone (PFD) in patients with idiopathic pulmonary fibrosis (IPF)

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**Body:** Introduction: RECAP is an open-label extension study evaluating long-term treatment with PFD in IPF patients who completed one of the CAPACITY (CAP) trials. Objective: Further examine the effect of PFD on lung function and survival in patients with IPF. Methods: PFD 2403 mg/d was administered orally in 3 equally divided doses. Forced vital capacity (FVC) was measured at baseline and Wks 12, 36, and 60. To facilitate comparison with CAP outcomes, analyses were based on patients newly-treated with PFD in RECAP who had baseline FVC and DLco values that met CAP entry criteria. Results: A total of 178 patients were newly-treated with PFD in RECAP and had baseline values that met CAP entry criteria. The mean change from baseline to Wk 60 in %FVC in this group was -5.8%; mean change over the corresponding period in CAP was -7.0% in the PFD group (N=345) and -9.4% in the placebo group (N=347). The percentage of patients with an FVC decline  $\geq 10\%$  was 16.6% in RECAP, compared with 16.8% and 24.8%, respectively, in the PFD and placebo groups in CAP. Overall survival in newly-treated patients in RECAP was similar to that of PFD patients in CAP (Figure 1). Conclusions: FVC and survival outcomes in IPF patients newly treated with PFD in RECAP were similar to those in PFD-treated patients in CAP. These data provide further evidence to support the use of PFD in patients with IPF.