European Respiratory Society
Annual Congress 2012

Abstract Number: 1735

Publication Number: P718

Abstract Group: 1.5. Diffuse Parenchymal Lung Disease

Keyword 1: Idiopathic pulmonary fibrosis **Keyword 2:** Interstitial lung disease **Keyword 3:** Treatments

Title: Safety and tolerability of pirfenidone (PFD) in patients with idiopathic pulmonary fibrosis (IPF) receiving commonly used concomitant medications

Prof. Carlo 12327 Albera carlo.albera@yahoo.it MD [1], Dr. Williamson 12328 Bradford bbradford@intermune.com MD [2], Prof. Ulrich 12329 Costabel Ulrich.Costabel@ruhrlandklinik.uk-essen.de MD [3], Dr. Talmadge 12330 King tking@medicine.ucsf.edu MD [4], Dr. Paul 12331 Noble paul.noble@duke.edu MD [5], Dr. Steven 12332 Sahn sahnsa@musc.edu MD [6], Prof. Dominique 12335 Valeyre dominique.valeyre@avc.ap-hop-paris.fr MD [7] and Prof. Roland 12336 du Bois dubois.rm@gmail.com MD [8]. [1] Department of Clinical and Biological Sciences, University of Turin, Italy ; [2] Clinical Research, InterMune, Inc., Brisbane, CA, United States ; [3] Pneumologie/Allergologie, Ruhrlandklinik, Essen, Germany ; [4] Department of Medicine, University of California San Francisco, United States ; [5] Department of Medicine, Duke University School of Medicine, Durham, NC, United States ; [6] Department of Medicine, Medical University of South Carolina, Charleston, SC, United States ; [7] Department of Medicine, Assistance Publique-Hôpitaux, Paris, France and [8] Department of Medicine, Imperial College, London, United Kingdom .

Body: Introduction: The CAPACITY Program (CAP) included two Phase 3 trials of PFD in 779 patients with IPF. Analyses were conducted to assess the safety of PFD in patients receiving commonly used concomitant medications. Objective: Examine the safety/tolerability of PFD in IPF patients receiving commonly used concomitant medications. Methods: Pooled data from the CAP trials were analyzed. Commonly used concomitant medications were defined as those used by ≥25% of patients in any treatment group between the first and last dose of study drug. The percentage of patients with selected treatment emergent adverse events (TEAEs) while on or within 28 d of cessation of commonly used concomitant medications was assessed. Patients in the PFD 2403 mg/d group were evaluated using a composite safety endpoint that included any Grade 3 or 4 TEAE, discontinuation of PFD, interruption/dose reduction of PFD, or any TE serious AE. Results: Commonly used concomitant medications and vaccines included: acetylsalicylic acid, azithromycin, influenza vaccine, multivitamins, omeprazole, paracetamol, salbutamol, and simvastatin. No evidence of a clinical pattern of TEAEs was observed with the use of PFD and these commonly used medications or vaccines. Patients receiving these agents were no more likely to meet the composite safety endpoint than those not receiving a commonly used concomitant agent. Conclusions: These data suggest that PFD is safe and generally well tolerated in patients with IPF when used with a spectrum of common medications. More long-term data will be collected in RECAP, an open-label extension trial evaluating PFD in patients with IPF.