Abstract 6013

The STEP-IPF Trial: Sildenafil Trial of Exercise Performance in Idiopathic Pulmonary Fibrosis

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Abstract Body

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Rationale: Pulmonary hypertension (PH) is common in patients with advanced idiopathic pulmonary fibrosis (IPF). Sildenafil is known to improve exercise performance in patients with pulmonary arterial hypertension. We hypothesized that sildenafil would improve exercise performance, dyspnea, and quality of life in patients with advanced IPF.

Methods: This was a two-period study lasting a total of 24 weeks. The first study period was a 12-week randomized, double-blinded, placebo-controlled trial of sildenafil 20mg three times daily (TID) vs. placebo in a population with DLco < 35% predicted. The second study period was a 12-week open-label extension of sildenafil 20mg TID used to estimate additional safety and longer-term effects. The primary endpoint is based on changes in the 6 minute walk test distance from enrollment to 12 weeks.

Results: Between September 2007 and March 2009, a total of 180 subjects were enrolled at 14 sites. Among surviving subjects, 95% completed period one and 93% completed period two. Baseline characteristics are described in the table.

Conclusions: STEP-IPF is a randomized, placebo-controlled trial designed to assess the safety and efficacy of sildenafil in advanced IPF patients. Preliminary data demonstrate successful enrollment of the target population and high rates of patient retention. Final study results will be presented.

Demographics and Baseline Characteristics

Mean age (years) 69

Male (%) 83

Caucasian (%) 91

Mean % predicted FVC 57

Mean % predicted DLco 26

Mean A-a gradient (mm Hg) 29

Mean 6-minute walk distance (m) 265

NYHA Class II (%) 89

NYHA Class III / IV (%) 9

Mean Brain Natriuretic Peptide (pg/mL) 73

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