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Title: Phase 2 trial of FG-3019, anti-CTGF monoclonal antibody, in idiopathic pulmonary fibrosis (IPF): Preliminary safety and efficacy results

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Body: Introduction: Connective tissue growth factor (CTGF) is implicated in the pathogenesis of IPF and is a potential novel therapeutic target. Objectives: To evaluate the safety, tolerability, and efficacy of FG-3019 in subjects with IPF. Methods: Phase 2 prospective, open label study of FG-3019 (15 mg/kg IV every 3 weeks for 45 weeks) in subjects with well-defined IPF (duration ≤5 years, evidence of disease progression during the preceding year, FVC 45–85% predicted, DLCO ≥ 30% predicted, and 10–50% parenchymal fibrosis by HRCT). Treatment response was assessed by changes in extent of parenchymal disease (HRCT and FVC). Results: 54 subjects (males 83%, mean age 67 years, median FVC % predicted 63.2%) were enrolled. Quantified HRCT scores of whole lung fibrosis (QLF) and all abnormal interstitial lung disease (QILD) at week 24 showed decreases from baseline greater than analytical variability (±2%) in 6 (24%) and 8 (32%) of 25 subjects, respectively. Changes in both QLF and QILD score were significantly correlated with changes in FVC % predicted (for QILD, r=-0.55, p=0.004). Mean decreases in FVC % predicted were less than in historical controls. Safety findings to date include 13 SAEs (none drug-related), 1 acute exacerbation, 9 respiratory-related hospitalizations, and 3 deaths (all related to IPF). Conclusions: FG-3019, a novel anti-fibrotic agent, is well tolerated by subjects with IPF. No drug-related SAEs have been reported to date. Promising results of measurement of quantified lung fibrosis scores and FVC warrant pursuing the clinical trial with a higher dose of FG-3019 to further assess safety and efficacy in subjects with IPF.