EUROPEAN RESPIRATORY SOCIETY
INTERNATIONAL CONGRESS 2023
MILAN Italy, 9-13 September

Therapeutic doses of efzofitimod significantly improve multiple pulmonary sarcoidosis efficacy measures

A. Chandrasekaran (Chennai, India), N. Kinnersley (Harpenden, United Kingdom), P. Ramesh (Chennai, India), V. Niranjan (Chennai, India), S. Shukla (San Diego, CA, United States), R. Baughman (Cincinnati, OH, United States)

Introduction: Efzofitimod was evaluated in an ascending dose study (3 cohorts - 1, 3, 5 mg/kg; 6 monthly doses) in patients with chronic pulmonary sarcoidosis (prednisone equivalent dose ≥10 mg/day). Patients were randomized 1:2 (placebo:efzofitimod). Dose dependent improvements in steroid burden, FVC and patient reported outcomes (PROs) were noted [1]. We pooled data to gain precision and investigate novel definitions of responder analyses.

Methods: The placebo (n=12) and 1 mg/kg arm (n=8) were subtherapeutic and pooled. The 3 (n=8) and 5 mg/kg arm (n=9) were considered therapeutic and pooled. The analysis population remained the same. We compared the time to relapse (log rank test) for steroid use; random coefficient regression model with baseline adjustment to test the difference in slope for FVC (i.e. rate of change); and proportion of patients with changes that are multiples of the minimal clinically important difference (MCID) for PROs (KSQ-L).

Results: In the subtherapeutic group 54.4% of patients relapsed compared to 7.7% in the therapeutic group (p=0.017). The rate of change for FVC was significantly improved for the therapeutic group (p=0.035) compared to the subtherapeutic group. In the therapeutic group 9 patients (52.9%) showed increase ≥12 for KSQ-L (3 times MCID) compared with 3 (15.0%) in the subtherapeutic group (p=0.032). Significant improvements were observed in several composite endpoints combining any taper in steroids without worsening in FVC or PROs.

Conclusions: These findings provide further evidence of efficacy for efzofitimod and initial proposals for responder endpoints in pulmonary sarcoidosis.

1. Culver DA et al. Chest. 2022 Nov 8;S0012-3692(22)04053-3