

Characterization of *Mycoplasma pneumoniae* Infection and Outcomes in the SOLITAIRE-Oral, Global Phase 3 Clinical Trial for Solithromycin

Conference: ID Week 2015

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Background: Solithromycin is a 4th generation macrolide antibiotic with potent activity against typical and atypical pathogens that cause community acquired bacterial pneumonia (CABP), including 'macrolide-resistant' pneumococci and *Mycoplasma pneumoniae* (Mpn). In SOLITAIRE-Oral, a global Phase 3 clinical trial, a 5-day course of oral solithromycin was demonstrated to be non-inferior to a 7-day course of oral moxifloxacin for treatment of community acquired bacterial pneumonia (CABP) among adult patients with PORT II-IV disease.

Methods: Patients with acute onset of radiographically confirmed CABP with consistent signs and symptoms were eligible. Mycoplasma transport media was inoculated with oropharyngeal swabs obtained at baseline and immediately frozen. Mpn was detected by culture and/or quantitative PCR. Acute and convalescent serum samples were assayed for diagnostic Mpn-IgG response (≥ 4 -fold rise to a titer $\geq 1:160$). Treatment efficacy was assessed on Day 4 (Early Clinical Response) and in follow-up (5-10 days following end of therapy).

Results: 860 patients with CABP were enrolled from sites in 16 countries, and a microbiological diagnosis (all pathogens) was established in 53.6% of patients. Mpn infection was diagnosed in 9.2% of all enrolled patients. Mpn was detected throughout the year, at overall rates by region ranging from 5.9% in South Africa to 10.9% in Europe. The mean age of Mpn patients was 52.9 (range 18-87), versus 57.6 (18-93) for non-Mpn patients. The mean baseline PSI score for Mpn patients was 68.9 (range 52-102) versus 71.4 (48-112). 44.3% of patients with Mpn had other CABP pathogen(s) identified. Mpn isolates (N=26) were highly susceptible to solithromycin (MIC₉₀ ≤ 0.000032 $\mu\text{g/mL}$) in comparison with moxifloxacin (MIC₉₀ 0.125 $\mu\text{g/mL}$). 83.8% of patients treated with solithromycin had an early clinical response versus 78.6% of those treated with moxifloxacin. Clinical success rates at the test of cure visit 5-10 days after treatment were comparable (89.2% vs. 90.5%).

Conclusion: Mpn is a significant, global etiologic agent of CABP, causing moderate to severe disease in adults of all ages. Mpn pneumonia was effectively treated by solithromycin.