SOLITAIRE-IV: Results of a Phase 3 IV to Oral Trial in Adults with Community-Acquired Bacterial Pneumonia Comparing Solithromycin to Moxifloxacin

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1. The ITT (intent-to-treat) population consists of all randomized patients; the mITT (microbiologically evaluable) population consists of all randomized patients with a baseline pathogen identified; the CE (clinically evaluable) population consists of patients who met inclusion/exclusion criteria without significant protocol violations. The ME (microbiologically evaluable) population is the intersection of the ITT and CE populations. The modified-CE population was a post-hoc analysis which removed 5 patients without adequate IV study drug supply from the CE population.

2. Safer, more effective, and more convenient oral antibiotic therapy for patients with community-acquired bacterial pneumonia (CABP) is associated with serious infections requiring systemic antibiotic therapy, significant morbidity and mortality, despite advances in therapeutic options.

3. This Phase 3 trial evaluated the safety and efficacy of IV to oral solithromycin compared to IV to oral moxifloxacin in adults with CABP in the outpatient setting (SOLITAIRE-Oral trial).

4. Overall, a baseline pathogen was identified in 37.8% of patients (mITT population). The most common baseline pathogen was Streptococcus pneumoniae (75.1%), followed by Haemophilus influenzae (11.7%), S. aureus (11.3%), and L. pneumophila (11.0%). By-pathogen outcome at ECR and SFU are shown in Table 3. In the ME population, 100% of solithromycin recipients (10/10) with macrolide-resistant pneumococcus were considered successes.

5. ECR, early clinical response; SFU, short-term follow-up.


7. These elevations declined with continued dosing or soon after the end of therapy.

8. S. pneumoniae drug-resistant pneumococcus at SFU in the mITT population. IV to oral solithromycin is a promising potential monotherapy for empiric treatment of adults with CABP.