# Oral solithromycin has a favorable profile versus oral moxifloxacin for treatment of adult community-acquired bacterial pneumonia (CABP) in elderly patients and those with COPD or asthma

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**Authors**: D.W. Oldach[1], C.M. Barrera[2], C. Luna[3], P. Szabo[4], I. Mitha[5], C.M. Tanaseanu[6], A Doreski[7], K. Clark[1], B. Jamieson[1], A. Das[8], K. Keedy[1], P. Fernandes[1]

1) Cempra Pharmaceuticals, Inc. - Chapel Hill, NC/US; 2) A & L Clinical Research - Miami, FL/US; 3) University of Buenos Aires-Buenos Aires, Argentina; 4) University Teaching Hospitals -Nyiregyhaza/HU; 5) World Wide Clinical Trials - Benoni/ZA; 6) St. Pantelimon Emergency Clinical Hospital - Bucharest/RO; 7) Centro Medico Dra. De Salvo - Buenos Aires/AR; 8) InClin, Inc. -San Francisco, CA/US

**Rationale & Methods**: Advanced age and underlying lung disease are risk factors for CABP morbidity. We evaluated a 4$^{th}$ generation macrolide antibiotic, Solithromycin (S), vs Moxifloxacin (M) in a global, P3, DB-RCT for CABP of PORT II-IV severity. Outcomes included clinical improvement at 72 hours (early clinical response or ECR) and success at short term follow up visit (SFU), 5-10 days after last dose of study drug.

**Results**: 860 CABP patients from 16 countries were randomized 1:1 to receive oral S or M. Mean age was 58.5 years (S) versus 56.7 years (M). 50.7% of S patients had PORT III/IV CABP (11.3%, PORT IV) vs. 48.6% of M patients (8.8% PORT IV). S was non-inferior to M in ECR and SFU success rates (%) in the ITT population (78.2 vs 77.9 and 84.5 vs 86.6, respectively). Among patients ≥ age 75, ECR and SFU success rates (%) (83.9 vs 69.8 and 85.5 vs 84.1, respectively) favored S. Among patients with history of COPD or asthma, ECR (71.0 vs 67.2) and SFU (91.9 vs 85.9) success rates (%) also favored S. S demonstrated comparable safety to M in the occurrence of adverse events (AEs) (36.6% vs 35.6%), study drug related AEs (10.1% vs 12.5%), Serious Adverse Events (6.6% vs 6.3%) (none attributed to study drug) and deaths (1.4% vs 1.4%). Two episodes of *C. difficile* diarrhea were detected, both among M recipients.

**Conclusions**: Oral S was non-inferior to oral M for treatment of CABP. Strikingly, S demonstrated greatest efficacy relative to M in the elderly and among patients with history of COPD or asthma. A global P3 CABP trial evaluating IV-to-Oral solithromycin versus moxifloxacin is ongoing.

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