

A Phase II Study to Evaluate the Efficacy and Safety of Single-Dose Oral Solithromycin (CEM-101) for Treatment of Patients with Uncomplicated Urogenital Gonorrhea

Oral Presentation

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Objectives: Emerging resistance to available therapies, including oral and IM cephalosporins and azithromycin, has resulted in an urgent medical need for new therapies for uncomplicated urogenital gonorrhea. Solithromycin, a new 4th generation macrolide with 3 ribosomal binding sites, has greater *in vitro* potency against gonococci than azithromycin and is active against most azithromycin- and cephalosporin-resistant strains. A phase II study to evaluate the efficacy and safety of single-dose oral solithromycin for treatment of patients with uncomplicated urogenital gonorrhea was conducted.

Methods: Patients with suspected *Neisseria gonorrhoeae* infection were enrolled. Consenting eligible patients received a single oral dose of 1200 mg solithromycin. All patients were cultured for *N. gonorrhoeae* at the urethra/cervix, rectum, and pharynx at enrollment and Day 7. All patients also underwent *N. gonorrhoeae* and *Chlamydia trachomatis* nucleic acid amplification testing (NAAT; Gen-Probe Aptima Combo2) at baseline and Day 7 from each site. The primary outcome was bacterial eradication as measured by conversion from positive *N. gonorrhoeae* baseline urethral or cervical culture to negative at Day 7. Secondary outcomes included eradication of rectal or pharyngeal gonorrhea and the eradication of *N. gonorrhoeae* and *C. trachomatis* nucleic acid. Persistent NAAT positivity at Day 7 is anticipated for some patients, despite cure as assessed by culture.

Results: Twenty-eight patients were enrolled (14 M, 14 F); mean age 26.5 years, 96% Black, and 4% Hispanic. Gonococcal eradication rates in 22 evaluable patients (13 M, 9 F) were 100% (22/22) for urethral/cervical infections. Eradication rates were also 100% for rectal (2/2) and pharyngeal (5/5) infections. Susceptibility data from 25 isolates show the median MIC (range) for solithromycin was 0.06 µg/mL (0.015–0.125) and for azithromycin was 0.125 µg/mL (0.06–0.5). Eradication rates of *N. gonorrhoeae* nucleic acid were 86% urethral/cervical (19/22), 100% rectal (8/8), and 63% pharyngeal (5/8). 36% (8/22) were *C. trachomatis* NAAT-positive at baseline with an eradication rate of 88% (7/8) on Day 7. Solithromycin was generally well-tolerated, with mild gastrointestinal AEs common (86%; 24/28). The most common AE was mild diarrhoea (61%; 17/28) followed by mild nausea (32%; 9/28).

Conclusions: Based on these results, a single 1200 mg dose of solithromycin appears to be well tolerated and effective in eradicating *N. gonorrhoeae*.