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

Edward W. Hook III¹, David Oldach², Brian Jamieson², Kay Clark², Prabhavathi Fernandes²
¹Division of Infectious Diseases, Department of Medicine, University of Alabama at Birmingham, Birmingham, AL; ²Cempra Pharmaceuticals, Inc., Chapel Hill, NC

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.