

# First Year Antimicrobial Surveillance Results for CEM-101, a Novel Fluoroketolide with Potent Activity Against Pathogens Associated with Community-acquired Bacterial Pneumonia (CABP).

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## Background:

CEM-101 is a new fluoroketolide with an unusually wide spectrum against pathogens associated with CABP. CEM-101 has a potency generally equal to or 2-fold greater than telithromycin (TEL) or MLS<sub>B</sub> agents. We report results from a global study of CEM-101 potency and resistance (R) rates for 2008.

## Methods:

2901 CABP isolates of *S. pneumoniae* (SPN; 1738), *H. influenzae* (HI; 976) and *S. aureus* (SA; 187) were susceptibility (S) tested by CLSI broth microdilution methods with categorical interpretations (M07-A8, M100-S19) and QC against CEM-101 and >25 comparators. The geographic samples included 1362 strains from the United States (USA), 1273 from Europe (EU) and 266 from Latin America (LA).

## Results:

Organism population characteristics were: SPN penicillin-R ( $\geq 2$   $\mu\text{g/ml}$ ) ranged from 15.9 (LA) to 23.0% (USA), HI  $\beta$ -lactamase production at 14.7 (EU) to 25.4% (USA), and MRSA rates at 40.9 (LA) to 55.0% (USA). Other SPN-R rates were (USA/EU/LA in %); erythromycin (40.0/36.3/20.0), levofloxacin (LEV; 0.6/1.8/0.7), amoxicillin/clavulanate (17.8/8.2/12.4) and ceftriaxone (CFT; 9.7/8.3/4.8). CEM-101 was very potent versus SPN (MIC<sub>50</sub>, 0.016  $\mu\text{g/ml}$ ), 2-fold more potent than TEL and against SA (MIC<sub>50</sub>, 0.06  $\mu\text{g/ml}$ ). At the USA-FDA breakpoints for TEL, CEM-101 showed broader coverage for SPN (100.0 vs. 99.8%), HI (99.1 vs. 98.7%) and SA (70.1 vs. 69.5%). These ketolide-S rates were greater than LEV, CRO and all marketed ML<sub>SB</sub> agents.

## Conclusions:

CEM-101 showed wide coverage of CABP pathogens in a three continent sample. The potency and spectrum of activity make CEM-101 a promising candidate for further study as a therapeutic agent for CABP.

Pathogen (no. tested)	MIC ( $\mu\text{g/ml}$ )		Cum. % inhibited at CEM-101 MIC							
	50%	90%	$\leq 0.03$	0.06	0.12	0.25	0.5	1	2	
HI (976)	1	2	0.1	0.1	0.2	0.9	10.1	73.3	96.8	
SPN (1738)	0.016	0.25	80.3	87.3	89.6	97.4	99.8	100.0	-	
SA (187)	0.06	>4	20.3	63.1	69.5	69.5	70.1	70.1	71.1	