Pharmacokinetic-Pharmacodynamic Target Attainment Analysis Supporting Solithromin (CEM-101) Phase 2 Dose Selection

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Abstract

• Using a previously derived population PK model which was developed using plasma and ELF data from 91 healthy volunteers enrolled in Phase 1, the PK parameters for M. pneumoniae were re-estimated with a Monte Carlo simulation. The dataset was divided into two groups: PK data were used to determine the probability of PK-PD TA for each CEM-101 dose regimen for the treatment of patients with community-acquired bacterial pneumonia (CAP).

Materials and Methods

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Results

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Conclusions

• Solithromin (CEM-101) is a broad spectrum macrolide antibiotic, a subspecies of the macrolide family, with activity against atypical and typical bacterial respiratory pathogens.

Cautions: Due to the high probability of PK-PD TA within the dose range of CEM-101, it is critical to avoid the use of higher dose regimens than 400 mg Q24h. This will be used to support dose decisions for a Phase 2 study in patients with CAP.

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