Safety, Tolerance, and Pharmacokinetics of Single Intravenous Doses of TP-271, a Novel Fluorocycline Antibiotic

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Introduction

TP-271 is a novel, fully-synthetic fluorocycline antibiotic being developed for the IV/oral treatment of serious bacterial infections, including respiratory infections caused by multidrug resistant pathogens. In in vitro assays, TP-271 had potent activity against key community respiratory Gram-positive and Gram-negative pathogens, including Streptococcus pneumoniae (MIC0.03 mg/L).

Methods (cont’d)

Methods

TP-271 was well tolerated at doses that resulted in high plasma exposures. These results support continued clinical development of TP-271.

Safety Results

Overall, 38.6% subjects reported 37 TEAEs during the study (38.7% of the placebo arm and 39.5% of the treatment arm reported TEAEs). – Except for 1 moderate TEA (abdominal discomfort) reported by 1 subject (1.8%), all TEAEs were mild in severity – No clinically significant changes in lab values, ECG parameters, or physical exam findings occurred – There were no deaths, serious or severe AEs, or discontinuations during the study – The most frequently reported AEs in the TP-271 groups were gastrointestinal; nausea was reported by 1 subject (0.2 mg/kg group) and by 4 subjects in the 5.0 mg/kg group; vomiting was reported by one subject in the 4.0 mg/kg group and 3 subjects in the 5.0 mg/kg group. No placebo subjects reported nausea or vomiting.

Conclusions

Following single IV doses of TP-271, plasma exposures increased as dose increased in a greater than dose-proportional manner – TP-271 was well tolerated at single doses that resulted in high plasma exposures – The results of this phase I SAD study support the continued clinical development of TP-271.

References


Disclosures

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