**Abstract**

**Background:** Omadacycline (formerly PTK 0796) is a semisynthetic derivative of minocycline and is currently under development for the treatment of bacterial infections, including community-acquired pneumonia (CAP) and urinary tract infections. The Investigational New Drug (IND) application for omadacycline has been submitted to the US Food and Drug Administration (FDA) for Phase 3 development.

**Objectives:** To evaluate the clinical and microbiological activity of omadacycline against community-acquired respiratory infections (CARI) and urinary tract infections (UTI) due to microorganisms isolated from China.

**Methods:** Omadacycline has been tested in more than 100 clinical trials, including Phase 3 trials in patients hospitalized in China (11 studies), Hong Kong, and Taiwan. In these studies, omadacycline was evaluated in the treatment of CAP and UTIs due to a variety of Gram-positive and Gram-negative pathogens.

**Results:** Omadacycline was very potent against most gram-positive and gram-negative pathogens isolated from Greater China, and retained activity against methicillin-resistant isolates (MRSA; n=299; MIC\textsubscript{50}/90, 0.12/0.5 mg/L), and had similar activity among geographic regions.

**Conclusions:** Omadacycline showed potent activity against gram-positive and gram-negative pathogens isolated from Greater China, and retained activity against methicillin-resistant isolates. The clinical development of omadacycline in the geographic region is ongoing.

**Materials and Methods**

**Organic collection**

Organic collection was performed from consecutive patients hospitalized in China (11 studies), Hong Kong, and Taiwan. Organisms were isolated from sputum, blood, and urine.

**Quality control and results interpretation**

Quality control and results interpretation were performed in accordance with CLSI (Clinical and Laboratory Standards Institute) guidelines for antimicrobial susceptibility tests for bacteria that grow aerobically; approved standard—tenth edition (CLSI M6-A10, 2013).

**Results**

- Omadacycline was very potent against the following bacteria from all geographic regions: Escherichia coli (MIC\textsubscript{50}/90, 2/4 mg/L), β-haemolytic streptococci (BHS; highest MIC, 1 mg/L), viridans group streptococci (94) 0.25 mg/L, and Enterococcus faecium (MIC\textsubscript{50}/90, 0.12/0.25 mg/L and 93.5% of isolates were inhibited at these ECVs (Table 3)).

- Omadacycline showed potent activity against most gram-positive and gram-negative pathogens isolated from Greater China, and retained activity against methicillin-resistant isolates (MRSA; n=299; MIC\textsubscript{50}/90, 0.12/0.5 mg/L), and had similar activity among geographic regions.

**Conclusions**

- Omadacycline showed potent activity against gram-positive and gram-negative pathogens isolated from Greater China.

- There were no detectable changes in susceptibility profiles between China, Hong Kong, and Taiwan.

- The results indicate the potential for clinical development of omadacycline in the geographic regions tested.

**Acknowledgments**

This study was supported by JMI Laboratories (Shanghai, China).

**References**


Clinical and Laboratory Standards Institute (2013). *M7-A9*. Methods for determination of minimal inhibitory concentrations (MICs) forINFUTEC OGM® ECOV (ECF or EC) for organism groups against omadacycline

<table>
<thead>
<tr>
<th>Organism/organism group</th>
<th>MIC\textsubscript{90} (mg/L)</th>
<th>MIC\textsubscript{50} (mg/L)</th>
<th>ECV IC\textsubscript{min} (mg/L)</th>
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**Table 1** Antimicrobial activity of omadacycline tested against the main organisms and organism groups of isolates from all countries combined.

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<th>ECV IC\textsubscript{min} (mg/L)</th>
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**Table 2** Antimicrobial activity of omadacycline tested for geographic region.