The primary objective of this study was to evaluate the relative bioavailability of a single 300 mg oral dose of omadacycline administered in various fed states compared with the fasted state.

Study Assessments
- Bioavailability was assessed after a single oral dose of omadacycline administered to the fasted state (Treatment A) and to the 4 randomized, evaluator-blind, phase 2 studies conducted at Paratek Pharmaceuticals, Inc. (Noel et al., 2012; Noel et al., 2012a).

- Pharmacokinetic data were collected through a series of tablet and salt formulations in the development of omadacycline.

- Compared with a fasted dose, omadacycline exposure (C_{max} and AUC) was reduced by 40% to 42% for a nondairy meal 2 hours before dosing.

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- The between-subject variability in systemic exposure to omadacycline was similar across all treatment groups.

- The safety and tolerability of omadacycline was comparable across all treatment groups.

- There were no clinically significant changes in clinical laboratory tests.

- No serious adverse events were observed when omadacycline 300 mg was administered in various fed states compared with the fasted state.

- The effect of food was more pronounced when a high-fat meal was consumed closer to dosing and when dairy was included in the meal 2 hours before dosing.

- For Treatment D the CV was 42.6–44.4% for these parameters.

- Compared with a fasted dose, omadacycline exposure (C_{max} and AUC) was reduced by 40% to 42% for a nondairy meal 2 hours before dosing.

- The CV for the test-to-reference ratios were 45.2% for AUC_{0-24}, 38.3% for C_{max}, and 29.4% for C_{last}.

- For the Tukey’s Studentized test was performed.

- The reduction in exposure was observed when oral omadacycline 300 mg was administered under fasting conditions.

- The results support the current recommendation that oral omadacycline tablets should be taken in a fasted state.