Omadacycline, an Aminolycycline Antibiotic, Has No Effect on QTc/QT Intervals in Healthy Subjects

Stephen Villano, MD; S. Ken Tanaka, PhD
Paratek Pharmaceuticals, King of Prussia, Pennsylvania, USA

ABSTRACT

Background: Omadacycline (OMC), a first-in-class aminolycycline, is in Phase 3 for the treatment of community-acquired pneumonia and skin and skin structure infections. Its effects on QT interval (QTc) prolongation, a marker of cardiac electrophysiology, were evaluated in a single-dose, open-label study.

Methods: Healthy volunteers were randomized to receive 100 mg (N=63) or 300 mg (N=62) omadacycline, or placebo (N=61), in random order, after an overnight fast. Safety and tolerability were evaluated through typical methods and pharmacokinetics were assessed using a 2-compartment model. QTc was measured at 14 timepoints over 24 hours.

Results: No subject had an increase from baseline in QTcF >30 msec at any timepoint. The incidence of treatment-emergent AEs was 18% with 100 mg and 25% with 300 mg, versus 11% for placebo. The incidence of treatment-emergent AEs was similar for both doses of omadacycline and placebo. The mean (standard deviation) change in QTcF for omadacycline was -0.3 (1.8) msec at 2 hours post-dose for the 300 mg group and -0.5 (2.1) msec at 2 hours post-dose for the 100 mg group, with estimated limits of the 90% confidence interval of -10.4 and 9.0, respectively.

Conclusions: Omadacycline 100 mg and 300 mg IV did not increase QTcF.

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NOMENCLATURE

• O = omadacycline
• M = moxifloxacin
• P = placebo

SYNOPSIS

• Omadacycline 100 mg and 300 mg IV did not increase QTcF.
• The incidence of treatment-emergent AEs was similar for both doses of omadacycline and placebo.

RESULTS

• No subject had an increase from baseline in QTcF >30 msec at any timepoint.
• The incidence of treatment-emergent AEs was 18% with 100 mg and 25% with 300 mg, versus 11% for placebo.
• The incidence of treatment-emergent AEs was similar for both doses of omadacycline and placebo.
• The mean (standard deviation) change in QTcF for omadacycline was -0.3 (1.8) msec at 2 hours post-dose for the 300 mg group and -0.5 (2.1) msec at 2 hours post-dose for the 100 mg group, with estimated limits of the 90% confidence interval of -10.4 and 9.0, respectively.

CONCLUSIONS

• Omadacycline 100 mg and 300 mg IV did not increase QTcF.
• The incidence of treatment-emergent AEs was similar for both doses of omadacycline and placebo.

REFERENCE