Background: OMC, a first-in-class aminomethylcycline antibiotic, is currently in phase 3 development for the treatment of community-acquired bacterial pneumonia (CAP). Tigecycline (TGC), a glycylcycline antibiotic, is approved for the treatment of CAP and has previously been studied in combination with other antibiotics. This study compared the PK of OMC and TGC dosed as intravenous (IV) saline in healthy subjects. This is the first study that has compared the PK of OMC and TGC dosed IV to healthy subjects.

Methods: A total of 96 healthy subjects received OMC (100 mg IV q12h x 2 doses) or TGC (100 mg IV q12h x 2 doses). Subjects were randomized to receive OMC or TGC, with 6 subjects receiving each drug dose. Subjects were monitored for 12 h after the start of the last dose. The PK parameters included area under the plasma concentration-time curve (AUC) and mean peak plasma concentration (Cmax).

Results: AUC (OMC) was significantly lower than Cmax (TGC) for both single and multiple dose administration. For both OMC and TGC, the AUC and Cmax values decreased with increasing time after the start of the last dose.

Conclusion: OMC and TGC are structurally different antibiotics with unique PK profiles. These findings were generally consistent with the known short half-lives of OMC and TGC in the plasma, with limited accumulation after multiple doses. OMC was well tolerated over the 4 days of dosing in this study; no serious adverse events were reported during this study treatment or the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events.

Results: There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events. There were no serious adverse events reported in either treatment group during the study. Two TGC subjects discontinued study treatment and the study due to adverse events.