

**Omadacycline (PTK 0796) Publications/Posters/Oral Presentations**

<b>Publications</b>				
<b>Date</b>	<b>Journal</b>	<b>Citation</b>	<b>First Author</b>	<b>Title</b>
Sept 2020	Antibiotics	9(9):E577	Lodise	<b>Hospital Admission Patterns in Adult Patients with Community-Acquired Pneumonia Who Received Ceftriaxone and a Macrolide by Disease Severity across United States Hospitals</b>
Aug 2020	Antimicrob. Agents and Chemother.	64(11):e01379-20	Kovacs	<b>An Open-Label Study of the Impact of Hepatic Impairment on the Pharmacokinetics and Safety of Single Oral and Intravenous Doses of Omadacycline</b>
June 2020	Internal Med res Open J	5(2):1-6	Dubois	<b><i>In Vitro</i> and Intracellular Activities of Omadacycline against <i>Staphylococcus aureus</i> Isolates</b>
May 2020	Diagnostic Micro. & Infect. Dis.	97(3):115054	Mendes	<b>Omadacycline <i>In Vitro</i> Activity against a Molecularly Characterized Collection of Clinical Isolates with Known Acquired Tetracycline Resistance Mechanisms</b>
May 2020	J Antimicrob. Chemother.	75(8):2160-2163	Pagano	<b><i>In Vitro</i> Activity of Omadacycline and Levofloxacin against <i>Escherichia coli</i>, <i>Klebsiella pneumoniae</i> and <i>Staphylococcus saprophyticus</i> in Human Urine Supplemented with Calcium and Magnesium</b>
Apr 2020	Antimicrob. Agents and Chemother.	64(5):e01972-19	Dubois	<b><i>In Vitro</i> and Intracellular Activities of Omadacycline against <i>Legionella pneumophila</i></b>
Apr 2020	Antimicrob. Agents and Chemother.	64(6):e02265-19	VanScoy	<b>Pharmacokinetic-Pharmacodynamic Characterization of Omadacycline Against <i>Haemophilus influenzae</i> Using a One-Compartment <i>In Vitro</i> Infection Model</b>
Apr 2020	Antimicrob. Agents and Chemother.	64(7): e02263-19	Lakota	<b>Population Pharmacokinetic Analyses for Omadacycline Using Phase 1 and 3 Data</b>
Apr 2020	Antimicrob. Agents and Chemother.	64(5):e02488-19	Pfaller	<b>Surveillance of Omadacycline Activity Tested Against Clinical Isolates from the United States and Europe: Report from the SENTRY Antimicrobial Surveillance Program, 2016-2018</b>
Jan 2020	Antimicrob. Agents and Chemother.	64(2):e02058-19	Lepak	<b><i>In Vivo</i> Pharmacodynamic Evaluation of Omadacycline against <i>Staphylococcus aureus</i> in the Neutropenic Mouse Pneumonia Model</b>
Dec 2019	J. Global Antimicrobial Resistance	19: 56-63	Huband	<b>Surveillance of Omadacycline Activity Tested against Clinical Isolates from the United States and Europe: Results from the SENTRY Antimicrobial Surveillance Programme, 2017</b>

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Oct 2019	Lancet Infect Dis.	19(10):1080-1090	O’Riordan	<b>Once-daily Oral Omadacycline versus Twice-daily Oral Linezolid for Acute Bacterial Skin and Skin Structure Infections (OASIS-2): A Phase 3, Double-blind, Multicentre, Randomised, Controlled, Non-inferiority Trial</b>
Oct 2019	Antimicrob. Agents and Chemother.	63:e00922-19	Darpo	<b>A Randomized, Double-Blind, Placebo- and Positive-Controlled Crossover Study of the Effects of Omadacycline on QT/QTc Intervals in Healthy Subjects</b>
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S1-5	Gallagher	<b>Omacycline: A Modernized Tetracycline</b>
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S6-15	Karlowsky	<b>Microbiology and Preclinical Review of Omadacycline</b>
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S16-22	Rodvold	<b>Pharmacokinetics and Pharmacodynamics of Oral and Intravenous Omadacycline</b>
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S23-32	Abrahamian	<b>Omacycline for Acute Bacterial Skin and Skin Structure Infections</b>
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S33-39	Ramirez	<b>Early Clinical Response in Community-acquired Bacterial Pneumonia: From Clinical Endpoint to Clinical Practice</b>
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S40-47	Opal	<b>An Integrated Safety Summary of Omadacycline, a Novel Aminomethylcycline Antibiotic</b>
July 2019	American Health & Drug Benefits	12(4):168-176	Lodise	<b>Cost-Saving Opportunities with an Oral and Intravenous Once-Daily Aminomethylcycline Antibiotic for Hospitalized Patients with Community-Acquired Bacterial Pneumonia: Findings from Decision-Analytic Models</b>
June 2019	Antimicrob. Agents and Chemother.	63:e00624-19	Lepak	<b><i>In Vivo</i> Pharmacodynamics of Omadacycline against <i>Staphylococcus aureus</i> in the Neutropenic Murine Thigh Infection Model</b>
May 2019	New England J of Medicine	380:2072-2074	Garrity-Ryan	<b>Omacycline for Bacterial Infections. Reply.</b>
May 2019	Diagnostic Micro. & Infect. Dis.	94(1):78-80	Fluit	<b>Minimal Inhibitory Concentration of Omadacycline and Doxycycline against Bacterial Isolates with Known Tetracycline Resistance Determinants</b>
May 2019	Antimicrob. Agents and Chemother.	63:e02083-18	Overcash	<b>Pharmacokinetics, Safety, and Clinical Outcomes of Omadacycline in Women with Cystitis: Results from a Phase 1 Study</b>
Feb 2019	American Health & Drug Benefits	12(1):Supplement 1, S1-S12	LaPensee	<b>Budget Impact of Omadacycline for the Treatment of Patients with Community-Acquired Bacterial Pneumonia in the United States from the Hospital Perspective</b>

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<b>Date</b>	<b>Journal</b>	<b>Citation</b>	<b>First Author</b>	<b>Title</b>
Feb 2019	American Health & Drug Benefits	12(1):Supplement 2, S13-S24	LaPensee	<b>Budget Impact Model of Omadacycline on Replacing a Proportion of Existing Treatment Options Among Patients Who Present to the Emergency Department with Acute Bacterial Skin and Skin Structure Infections</b>
Feb 2019	New England J of Medicine	380:517-27	Stets	<b>Omacycline for Community-Acquired Bacterial Pneumonia</b>
Feb 2019	New England J of Medicine	380:528-38	O'Riordan	<b>Omacycline for Acute Bacterial Skin and Skin-Structure Infections</b>
Feb 2019	Antimicrob. Agents and Chemother.	63:e01907-18	Kohlhoff	<b><i>In Vitro</i> Activity of Omacycline against <i>Chlamydia pneumoniae</i></b>
Feb 2019	Antimicrob. Agents and Chemother.	63:e01581-18	Moura	<b>Omacycline Gut Microbiome Exposure does not Induce <i>Clostridium difficile</i> Proliferation or Toxin Production in a Model that Simulates the Proximal, Medial and Distal Human Colon</b>
Dec 2018	American Health & Drug Benefits	11(9):449-459	LaPensee	<b>Potential Cost-Savings with Once-Daily Aminomethylcycline Antibiotic versus Vancomycin in Hospitalized Patients with Acute Bacterial Skin and Skin Structure Infections</b>
June 2018	Diagnostic Micro. & Infect. Dis.	91(2):179-183	Pfaller	<b>Activity of Omacycline Tested against Enterobacteriaceae Causing Urinary Tract Infections from a Global Surveillance Program (2014)</b>
Apr 2018	Antimicrob. Agents and Chemother.	62:e02551-17	Goldstein	<b>Omacycline: Comparative <i>In Vitro</i> Activity against Dog and Cat Bite Wound Isolates</b>
Apr 2018	Antimicrob. Agents and Chemother.	62:e00047-18	Stapert	<b>The <i>In Vitro</i> Activity of Omacycline and Comparators Against Anaerobic Bacteria</b>
Apr 2018	Antimicrob. Agents and Chemother.	62: e02327-17	Pfaller	<b>Surveillance of Omacycline Activity Tested against Clinical Isolates from the United States and Europe: Report from the SENTRY Antimicrobial Surveillance Program, 2016</b>
Feb 2018	Antimicrob. Agents and Chemother.	62: e01487-17	Bundrant	<b>Safety and Pharmacokinetics of the Aminomethylcycline Antibiotic Omacycline Administered to Healthy Subjects in Oral Multiple Dose Regimens</b>
Feb 2018	Antimicrob. Agents and Chemother.	62: e02057-17	Berg	<b>Pharmacokinetics and Safety of Omacycline in Subjects with Impaired Renal Function</b>

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Feb 2018	Diagnostic Micro. & Infect. Dis.	90(2):143-147	Pfaller	<b>Activity of Omadacycline Tested against <i>Streptococcus pneumoniae</i> from a Global Surveillance Program (2014)</b>
Sept 2017	Antimicrob. Agents and Chemother.	61: e01135-17	Gotfried	<b>Comparison of Omadacycline and Tigecycline Pharmacokinetics in the Plasma, Epithelial Lining Fluid, and Alveolar Cells in Healthy Adult Subjects</b>
May 2017	Antimicrob. Agents and Chemother.	61: e02434-16	Steenbergen	<b><i>In Vitro</i> and <i>In Vivo</i> Activity of Omadacycline Against Two Biothreat Pathogens: <i>Bacillus anthracis</i> and <i>Yersinia pestis</i></b>
May 2017	Antimicrob. Agents and Chemother.	61: e02368-16	Lepak	<b><i>In Vivo</i> Pharmacodynamic Evaluation of Omadacycline (PTK 0796) against <i>Streptococcus pneumoniae</i> in the Murine Pneumonia Model</b>
May 2017	Antimicrob. Agents and Chemother.	61: e00018-17	Pfaller	<b>Surveillance of Omadacycline Activity against Clinical Isolates from a Global Collection (North America, Europe, Latin America, Asia-Western Pacific), 2010-2011</b>
May 2017	Xenobiotica	47:8, 682-696	Flarakos	<b>Clinical Disposition, Metabolism and <i>In Vitro</i> Drug–drug Interaction Properties of Omadacycline</b>
Mar 2017	Antimicrob. Agents and Chemother.	61: e02411-16	Pfaller	<b>Activity of Omadacycline and Comparator Agents When Tested against <i>Staphylococcus aureus</i> from a Surveillance Program Conducted in North America and Europe</b>
Mar 2017	J. Clin. Pharmacol.	57(3): 321-327	Tzanis	<b>Effect of Food on the Bioavailability of Omadacycline in Healthy Subjects</b>
Jan 2017	Antimicrob. Agents and Chemother.	61: e01784-16	Lin	<b>Pharmacokinetics, Distribution, Metabolism, and Excretion of Omadacycline Following a Single Intravenous or Oral Dose of <sup>14</sup>C-omadacycline in Rats</b>
Dec 2016	Bioorg. Med. Chem.	24(2016): 6409-6419	Tanaka	<b>Discovery, Pharmacology, and Clinical Profile of Omadacycline, A Novel Aminomethylcycline Antibiotic</b>
Dec 2016	Antimicrob. Agents and Chemother.	60(12): 7431-7435	Sun	<b>A Randomized, Open-label Study of the Pharmacokinetics and Safety of Oral and Intravenous Administration of Omadacycline to Healthy Subjects</b>
Dec 2016	Antimicrob. Agents and Chemother.	60(12): 7502-7504	Waites	<b><i>In Vitro</i> Activities of Omadacycline (PTK 0796) and Other Antimicrobial Agents Against Human Mycoplasmas and Ureaplasmas</b>

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Oct 2016	Future Microbiol.	11(11): 1421-1434	Villano	<b>Omadacycline: Development of a Novel Aminomethylcycline Antibiotic for Treating Drug-Resistant Bacterial Infections</b>
Sept 2016	Antibiotics	5: 32	Heidrich	<b>The Novel Aminomethylcycline Omadacycline Has High Specificity for the Primary Tetracycline-Binding Site on the Bacterial Ribosome</b>
Sept 2016	Antimicrob. Agents and Chemother.	60(9): 5247-5253	Tanaka	<b><i>In Vitro</i> and <i>In Vivo</i> Assessment of Cardiovascular Effects with Omadacycline</b>
Nov 2015	Antimicrob. Agents and Chemother.	59(11): 7044-7053	Honeyman	<b>Structure-Activity Relationship of the Aminomethylcyclines and the Discovery of Omadacycline</b>
Mar 2014	Antimicrob. Agents and Chemother.	58(3): 1279–1283	Draper	<b>Mechanism of Action of the Novel Aminomethylcycline Antibiotic Omadacycline</b>
Feb 2014	Antimicrob. Agents and Chemother.	58(2): 1127-1135	Macone	<b><i>In Vitro</i> and <i>In Vivo</i> Antibacterial Activities of Omadacycline, a Novel Aminomethylcycline</b>
Nov 2012	Antimicrob. Agents and Chemother.	56(11): 5650-5654	Noel	<b>A Randomized, Evaluator-Blind, Phase 2 Study Comparing the Safety and Efficacy of Omadacycline to Those of Linezolid for Treatment of Complicated Skin and Skin Structure Infections</b>

<b>Posters and Oral Presentations</b>				
<b>Date</b>	<b>Conference</b>	<b>Presentation / Abstract Number</b>	<b>First Author</b>	<b>Title</b>
Oct 21-25, 2020	IDWeek	1202	Serio	<b>Subinhibitory Concentrations of Omadacycline Inhibit <i>Staphylococcus aureus</i> Hemolytic Activity <i>In Vitro</i></b>
Oct 21-25, 2020	IDWeek	1253	Huband	<b><i>In Vitro</i> Activity of Omadacycline against 7000 Bacterial Pathogens from the United States Stratified by Infection Type (2019)</b>
Oct 21-25, 2020	IDWeek	1267	Stone	<b>Comparative Activity of Omadacycline Against Extended-Spectrum Beta-lactamase Positive and Negative <i>Escherichia coli</i> and <i>Klebsiella pneumoniae</i> Strains Recovered from Urine Specimens</b>
Oct 21-25, 2020	IDWeek	1290	Morrisette	<b>Real-World Experience with Omadacycline for Nontuberculous Mycobacterial and MDR/XDR Gram-Negative Infections: A Multicenter Evaluation</b>
Oct 21-25, 2020	IDWeek	1492	Rodriguez	<b>Targeted Substitution of Omadacycline in Place of Standard of Care for CABP Treatment is Associated with a Risk Reduction of <i>Clostridioides difficile</i> Infection and Financial Cost Savings in the Acute Care Setting</b>
Oct 21-25, 2020	IDWeek	1687	Overcash	<b>Omacycline in Female Adults with Acute Pyelonephritis: Results from a Randomized, Double-Blinded, Adaptive Phase 2 Study</b>
Oct 21-25, 2020	IDWeek	1688	Overcash	<b>Omacycline in Female Adults with Cystitis: Results from a Randomized, Double-Blinded, Adaptive Phase 2 Study</b>
Oct 18-21, 2020	CHEST	A307-A308	Surani	<b>Treatment of <i>Legionella pneumophila</i> using Omadacycline versus Moxifloxacin: Subanalysis Results from a Phase 3 Randomized Double-Blind Multicenter Study (OPTIC)</b>
Jul 8, 2020	MHSRS	MHSRS-20-00985	Besece	<b>Treatment of Wound Infection using Omadacycline versus Linezolid: Pooled Results from Phase 3 Randomized, Double-blind, Multicenter Studies (OASIS-1 and -2)</b>
Jul 8, 2020	MHSRS	MHSRS-20-00527	Huband	<b>Activity of Omadacycline and Comparator Agents against Bacterial Isolates from Skin, Respiratory, and Wound Infections from United States and European Medical Centers (2014 – 2019)</b>
May 5, 2020	ECCMID	5313	Rodriguez	<b>Predicted Risk and Observed Occurrence of <i>Clostridioides difficile</i> Infection in Patients with Community-Acquired Bacterial Pneumonia Treated with Omadacycline or Moxifloxacin</b>
May 5, 2020	ECCMID	2481	Lapensee	<b>Self-Reported Health Status in Ambulatory Acute Bacterial Skin and Skin Structure Infection Patients Who Inject Drugs, Who Received Oral Therapy with Omadacycline or Linezolid</b>
May 5, 2020	ECCMID	1764	Lapensee	<b>Epidemiology of <i>Clostridioides Difficile</i> Infections Among Hospitalised Community-Acquired Pneumonia Patients Who Received Empiric Treatment with Ceftriaxone Plus a Macrolide</b>
May 5, 2020	ECCMID	949	Huband	<b>Activity of Omadacycline and Comparator Agents Against Bacterial Pathogens from the United States by Infection Type (2019)</b>
Oct 2-6, 2019	IDWEEK	110	Sakoulas	<b>Clinical Outcomes of Patients with Secondary Bacteremia in the Omadacycline Phase 3 Acute Bacterial Skin and Skin Structure Infections and Community-Acquired Bacterial Pneumonia Studies</b>

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Oct 2-6, 2019	IDWEEK	665	Huband	<b><i>In Vitro</i> Activity of Omadacycline against Recent (2018) Bacterial Pathogens from the United States and Europe Obtained from Skin and Skin Structure, Respiratory, and Urinary Tract Infections</b>
Oct 2-6, 2019	IDWEEK	700	Pai	<b>Safety and Efficacy of Omadacycline in Patients with Diabetes in Phase 3 Clinical Studies</b>
Oct 2-6, 2019	IDWEEK	733	Bhavnani	<b>Pharmacokinetic-Pharmacodynamic (PK-PD) Analyses for Alanine Aminotransferase (ALT) Using Phase 3 Data from Omadacycline (OMC)-Treated Patients</b>
Oct 2-6, 2019	IDWEEK	734	Friedrich	<b>Modeling the Pharmacokinetics and Pharmacodynamics of Intravenous and Oral Omadacycline with and without a Loading Dose</b>
Oct 2-6, 2019	IDWEEK	1561	Lakota	<b>Omacycline Pharmacokinetics: Influence of Mortality Risk Score Among Patients with Community-Acquired Bacterial Pneumonia</b>
Sept 3-6, 2019	ASM-ESCMID	T-21	Bhavnani	<b>Pharmacokinetic-Pharmacodynamic (PK-PD) Analyses for Cardiac Endpoints Using Clinical Study Data from Omadacycline (OMC)-Treated Patients</b>
Sept 3-6, 2019	ASM-ESCMID	T-36	Curran	<b>Bayesian Adaptive Dose-Response Studies in Complicated and Uncomplicated Urinary Tract Infection</b>
Sept 3-6, 2019	ASM-ESCMID	W-62	Mendes	<b>Omacycline is Not a Substrate for Clinically Relevant <math>\beta</math>-Lactamase Enzymes</b>
June 20-24, 2019	ASM Microbe	FRIDAY-CIV-155	Armstrong	<b>Analysis of Pooled Microbiological Data from Two Phase 3 Studies of Omadacycline Treatment for Acute Bacterial Skin and Skin Structure Infections</b>
June 20-24, 2019	ASM Microbe	FRIDAY-AAR-540	Huband	<b><i>In Vitro</i> Activity of Omadacycline and Comparators against Gram-Positive and -Negative Isolates Collected from Patients in United States Medical Centers (2018): SENTRY Surveillance Program Results</b>
June 20-24, 2019	ASM Microbe	SATURDAY-AAR-608	Thwaites	<b>Investigating the Interaction between Omadacycline and Other Antibacterial Agents against Gram-Positive and Gram-Negative Bacteria</b>
May 14-17, 2019	SAEM	88	Pollack	<b>Omacycline Treatment of Acute Bacterial Skin and Skin Structure Infections in Intravenous Drug Users</b>
Apr 13-16, 2019	ECCMID	O0304	Cornely	<b>Safety and Efficacy of Omadacycline for Treatment of Community-acquired Bacterial Pneumonia and Acute Bacterial Skin and Skin Structure Infections in Patients with Mild to Moderate Renal Insufficiency</b>
Apr 13-16, 2019	ECCMID	O0306	Pai	<b>Safety and Efficacy of Omadacycline for Treatment of Acute Bacterial Skin and Skin Structure Infections by Patient Body Mass Index</b>
Apr 13-16, 2019	ECCMID	P1876	Huband	<b><i>In Vitro</i> Activity of Omadacycline and Comparators against Gram-Positive and -Negative Clinical Isolates Collected in 2018 from Patients in European Medical Centres: SENTRY Surveillance Program Results</b>

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Apr 13-16, 2019	ECCMID	P1918	Pai	<b>Safety and Efficacy of Omadacycline by Body Mass Index in Patients with Community-acquired Bacterial Pneumonia</b>
Apr 13-16, 2019	ECCMID	P1943	Lakota	<b>Omadacycline Pharmacokinetics: Impact of Comorbidities</b>
Apr 13-16, 2019	ECCMID	P1944	Bhavnani	<b>Assessment of Pharmacokinetics-Pharmacodynamics to Support Omadacycline Dosing Regimens for the Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI)</b>
Apr 13-16, 2019	ECCMID	P2011	Tzanis	<b>Omadacycline Hepatic Safety: Integrated Analysis of Randomized Controlled Phase III Trials</b>
Apr 13-16, 2019	ECCMID	P2288	LaPensee	<b>Incidence of Emergency Department Visits and Hospitalizations after Outpatient Treatment with an Oral Antibiotic among Patients with Acute Bacterial Skin and Skin Structure Infections</b>