

Omadacycline (PTK 0796) Publications/Posters/Oral Presentations

Publications				
Date	Journal	Citation	First Author	Title
Nov 2020	European J Drug Metabolism and Pharmacokinetics	Epub ahead of print. PMID: 33180250.	Hunt	The Effect of Verapamil, a P-gp Inhibitor, on the Pharmacokinetics, Safety, and Tolerability of Omadacycline in Healthy Adults: A Phase I, Open-Label, Single-Sequence Study
Nov 2020	Antimicrob. Agents and Chemother.	64(11):e01379-20	Kovacs	An Open-Label Study of the Impact of Hepatic Impairment on the Pharmacokinetics and Safety of Single Oral and Intravenous Doses of Omadacycline
Sept 2020	Antibiotics	9(9):E577	Lodise	Hospital Admission Patterns in Adult Patients with Community-Acquired Pneumonia Who Received Ceftriaxone and a Macrolide by Disease Severity across United States Hospitals
June 2020	Internal Med res Open J	5(2):1-6	Dubois	<i>In Vitro</i> and Intracellular Activities of Omadacycline against <i>Staphylococcus aureus</i> Isolates
May 2020	Diagnostic Micro. & Infect. Dis.	97(3):115054	Mendes	Omadacycline <i>In Vitro</i> Activity against a Molecularly Characterized Collection of Clinical Isolates with Known Acquired Tetracycline Resistance Mechanisms
May 2020	J Antimicrob. Chemother.	75(8):2160-2163	Pagano	<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
Apr 2020	Antimicrob. Agents and Chemother.	64(5):e01972-19	Dubois	<i>In Vitro</i> and Intracellular Activities of Omadacycline against <i>Legionella pneumophila</i>
Apr 2020	Antimicrob. Agents and Chemother.	64(6):e02265-19	VanScoy	Pharmacokinetic-Pharmacodynamic Characterization of Omadacycline Against <i>Haemophilus influenzae</i> Using a One-Compartment <i>In Vitro</i> Infection Model
Apr 2020	Antimicrob. Agents and Chemother.	64(7): e02263-19	Lakota	Population Pharmacokinetic Analyses for Omadacycline Using Phase 1 and 3 Data
Apr 2020	Antimicrob. Agents and Chemother.	64(5):e02488-19	Pfaller	Surveillance of Omadacycline Activity Tested Against Clinical Isolates from the United States and Europe: Report from the SENTRY Antimicrobial Surveillance Program, 2016-2018
Jan 2020	Antimicrob. Agents and Chemother.	64(2):e02058-19	Lepak	<i>In Vivo</i> Pharmacodynamic Evaluation of Omadacycline against <i>Staphylococcus aureus</i> in the Neutropenic Mouse Pneumonia Model

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Dec 2019	J. Global Antimicrobial Resistance	19: 56-63	Huband	Surveillance of Omadacycline Activity Tested against Clinical Isolates from the United States and Europe: Results from the SENTRY Antimicrobial Surveillance Programme, 2017
Oct 2019	Lancet Infect Dis.	19(10):1080-1090	O’Riordan	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
Oct 2019	Antimicrob. Agents and Chemother.	63:e00922-19	Darpo	A Randomized, Double-Blind, Placebo- and Positive-Controlled Crossover Study of the Effects of Omadacycline on QT/QTc Intervals in Healthy Subjects
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S1-5	Gallagher	Omacycline: A Modernized Tetracycline
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S6-15	Karlowsky	Microbiology and Preclinical Review of Omacycline
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S16-22	Rodvold	Pharmacokinetics and Pharmacodynamics of Oral and Intravenous Omacycline
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S23-32	Abrahamian	Omacycline for Acute Bacterial Skin and Skin Structure Infections
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S33-39	Ramirez	Early Clinical Response in Community-acquired Bacterial Pneumonia: From Clinical Endpoint to Clinical Practice
Aug 2019	Clin. Infect. Dis.	69(Supplement 1): S40-47	Opal	An Integrated Safety Summary of Omacycline, a Novel Aminomethylcycline Antibiotic
July 2019	American Health & Drug Benefits	12(4):168-176	Lodise	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
June 2019	Antimicrob. Agents and Chemother.	63:e00624-19	Lepak	<i>In Vivo</i> Pharmacodynamics of Omacycline against <i>Staphylococcus aureus</i> in the Neutropenic Murine Thigh Infection Model
May 2019	New England J of Medicine	380:2072-2074	Garrity-Ryan	Omacycline for Bacterial Infections. Reply.
May 2019	Diagnostic Micro. & Infect. Dis.	94(1):78-80	Fluit	Minimal Inhibitory Concentration of Omacycline and Doxycycline against Bacterial Isolates with Known Tetracycline Resistance Determinants

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Date	Journal	Citation	First Author	Title
May 2019	Antimicrob. Agents and Chemother.	63:e02083-18	Overcash	Pharmacokinetics, Safety, and Clinical Outcomes of Omadacycline in Women with Cystitis: Results from a Phase 1 Study
Feb 2019	American Health & Drug Benefits	12(1):Supplement 1, S1-S12	LaPensee	Budget Impact of Omadacycline for the Treatment of Patients with Community-Acquired Bacterial Pneumonia in the United States from the Hospital Perspective
Feb 2019	American Health & Drug Benefits	12(1):Supplement 2, S13-S24	LaPensee	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
Feb 2019	New England J of Medicine	380:517-27	Stets	Omacycline for Community-Acquired Bacterial Pneumonia
Feb 2019	New England J of Medicine	380:528-38	O’Riordan	Omacycline for Acute Bacterial Skin and Skin-Structure Infections
Feb 2019	Antimicrob. Agents and Chemother.	63:e01907-18	Kohlhoff	<i>In Vitro</i> Activity of Omadacycline against <i>Chlamydia pneumoniae</i>
Feb 2019	Antimicrob. Agents and Chemother.	63:e01581-18	Moura	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
Dec 2018	American Health & Drug Benefits	11(9):449-459	LaPensee	Potential Cost-Savings with Once-Daily Aminomethylcycline Antibiotic versus Vancomycin in Hospitalized Patients with Acute Bacterial Skin and Skin Structure Infections
June 2018	Diagnostic Micro. & Infect. Dis.	91(2):179-183	Pfaller	Activity of Omadacycline Tested against Enterobacteriaceae Causing Urinary Tract Infections from a Global Surveillance Program (2014)
Apr 2018	Antimicrob. Agents and Chemother.	62:e02551-17	Goldstein	Omacycline: Comparative <i>In Vitro</i> Activity against Dog and Cat Bite Wound Isolates
Apr 2018	Antimicrob. Agents and Chemother.	62:e00047-18	Stapert	The <i>In Vitro</i> Activity of Omadacycline and Comparators Against Anaerobic Bacteria
Apr 2018	Antimicrob. Agents and Chemother.	62: e02327-17	Pfaller	Surveillance of Omadacycline Activity Tested against Clinical Isolates from the United States and Europe: Report from the SENTRY Antimicrobial Surveillance Program, 2016

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Feb 2018	Antimicrob. Agents and Chemother.	62: e01487-17	Bundrant	Safety and Pharmacokinetics of the Aminomethylcycline Antibiotic Omadacycline Administered to Healthy Subjects in Oral Multiple Dose Regimens
Feb 2018	Antimicrob. Agents and Chemother.	62: e02057-17	Berg	Pharmacokinetics and Safety of Omadacycline in Subjects with Impaired Renal Function
Feb 2018	Diagnostic Micro. & Infect. Dis.	90(2):143-147	Pfaller	Activity of Omadacycline Tested against <i>Streptococcus pneumoniae</i> from a Global Surveillance Program (2014)
Sept 2017	Antimicrob. Agents and Chemother.	61: e01135-17	Gotfried	Comparison of Omadacycline and Tigecycline Pharmacokinetics in the Plasma, Epithelial Lining Fluid, and Alveolar Cells in Healthy Adult Subjects
May 2017	Antimicrob. Agents and Chemother.	61: e02434-16	Steenbergen	<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>
May 2017	Antimicrob. Agents and Chemother.	61: e02368-16	Lepak	<i>In Vivo</i> Pharmacodynamic Evaluation of Omadacycline (PTK 0796) against <i>Streptococcus pneumoniae</i> in the Murine Pneumonia Model
May 2017	Antimicrob. Agents and Chemother.	61: e00018-17	Pfaller	Surveillance of Omadacycline Activity against Clinical Isolates from a Global Collection (North America, Europe, Latin America, Asia-Western Pacific), 2010-2011
May 2017	Xenobiotica	47:8, 682-696	Flarakos	Clinical Disposition, Metabolism and <i>In Vitro</i> Drug–drug Interaction Properties of Omadacycline
Mar 2017	Antimicrob. Agents and Chemother.	61: e02411-16	Pfaller	Activity of Omadacycline and Comparator Agents When Tested against <i>Staphylococcus aureus</i> from a Surveillance Program Conducted in North America and Europe
Mar 2017	J. Clin. Pharmacol.	57(3): 321-327	Tzanis	Effect of Food on the Bioavailability of Omadacycline in Healthy Subjects
Jan 2017	Antimicrob. Agents and Chemother.	61: e01784-16	Lin	Pharmacokinetics, Distribution, Metabolism, and Excretion of Omadacycline Following a Single Intravenous or Oral Dose of ¹⁴C-omadacycline in Rats
Dec 2016	Bioorg. Med. Chem.	24(2016): 6409-6419	Tanaka	Discovery, Pharmacology, and Clinical Profile of Omadacycline, A Novel Aminomethylcycline Antibiotic

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Dec 2016	Antimicrob. Agents and Chemother.	60(12): 7431-7435	Sun	A Randomized, Open-label Study of the Pharmacokinetics and Safety of Oral and Intravenous Administration of Omadacycline to Healthy Subjects
Dec 2016	Antimicrob. Agents and Chemother.	60(12): 7502-7504	Waites	<i>In Vitro</i> Activities of Omadacycline (PTK 0796) and Other Antimicrobial Agents Against Human Mycoplasmas and Ureaplasmas
Oct 2016	Future Microbiol.	11(11): 1421-1434	Villano	Omacycline: Development of a Novel Aminomethylcycline Antibiotic for Treating Drug-Resistant Bacterial Infections
Sept 2016	Antibiotics	5: 32	Heidrich	The Novel Aminomethylcycline Omadacycline Has High Specificity for the Primary Tetracycline-Binding Site on the Bacterial Ribosome
Sept 2016	Antimicrob. Agents and Chemother.	60(9): 5247-5253	Tanaka	<i>In Vitro</i> and <i>In Vivo</i> Assessment of Cardiovascular Effects with Omadacycline
Nov 2015	Antimicrob. Agents and Chemother.	59(11): 7044-7053	Honeyman	Structure-Activity Relationship of the Aminomethylcyclines and the Discovery of Omadacycline
Mar 2014	Antimicrob. Agents and Chemother.	58(3): 1279–1283	Draper	Mechanism of Action of the Novel Aminomethylcycline Antibiotic Omadacycline
Feb 2014	Antimicrob. Agents and Chemother.	58(2): 1127-1135	Macone	<i>In Vitro</i> and <i>In Vivo</i> Antibacterial Activities of Omadacycline, a Novel Aminomethylcycline
Nov 2012	Antimicrob. Agents and Chemother.	56(11): 5650-5654	Noel	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

Posters and Oral Presentations				
Date	Conference	Presentation / Abstract Number	First Author	Title
Oct 26-29, 2020	ACEP	601	Giordano	Efficacy of Omadacycline in the Treatment of Acute Bacterial Skin and Skin Structure Infections in Patients with Cellulitis or Abscesses
Oct 21-25, 2020	IDWeek	1202	Serio	Subinhibitory Concentrations of Omadacycline Inhibit <i>Staphylococcus aureus</i> Hemolytic Activity <i>In Vitro</i>
Oct 21-25, 2020	IDWeek	1253	Huband	<i>In Vitro</i> Activity of Omadacycline against 7000 Bacterial Pathogens from the United States Stratified by Infection Type (2019)
Oct 21-25, 2020	IDWeek	1267	Stone	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
Oct 21-25, 2020	IDWeek	1290	Morrisette	Real-World Experience with Omadacycline for Nontuberculous Mycobacterial and MDR/XDR Gram-Negative Infections: A Multicenter Evaluation
Oct 21-25, 2020	IDWeek	1492	Rodriguez	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
Oct 21-25, 2020	IDWeek	1687	Overcash	Omacycline in Female Adults with Acute Pyelonephritis: Results from a Randomized, Double-Blinded, Adaptive Phase 2 Study
Oct 21-25, 2020	IDWeek	1688	Overcash	Omacycline in Female Adults with Cystitis: Results from a Randomized, Double-Blinded, Adaptive Phase 2 Study
Oct 18-21, 2020	CHEST	A307-A308	Surani	Treatment of <i>Legionella pneumophila</i> using Omadacycline versus Moxifloxacin: Subanalysis Results from a Phase 3 Randomized Double-Blind Multicenter Study (OPTIC)
Jul 8, 2020	MHSRS	MHSRS-20-00985	Besece	Treatment of Wound Infection using Omadacycline versus Linezolid: Pooled Results from Phase 3 Randomized, Double-blind, Multicenter Studies (OASIS-1 and -2)
Jul 8, 2020	MHSRS	MHSRS-20-00527	Huband	Activity of Omadacycline and Comparator Agents against Bacterial Isolates from Skin, Respiratory, and Wound Infections from United States and European Medical Centers (2014 – 2019)
May 5, 2020	ECCMID	5313	Rodriguez	Predicted Risk and Observed Occurrence of <i>Clostridioides difficile</i> Infection in Patients with Community-Acquired Bacterial Pneumonia Treated with Omadacycline or Moxifloxacin
May 5, 2020	ECCMID	2481	Lapensee	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
May 5, 2020	ECCMID	1764	Lapensee	Epidemiology of <i>Clostridioides Difficile</i> Infections Among Hospitalised Community-Acquired Pneumonia Patients Who Received Empiric Treatment with Ceftriaxone Plus a Macrolide

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May 5, 2020	ECCMID	949	Huband	Activity of Omadacycline and Comparator Agents Against Bacterial Pathogens from the United States by Infection Type (2019)
Oct 2-6, 2019	IDWEEK	110	Sakoulas	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
Oct 2-6, 2019	IDWEEK	665	Huband	<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
Oct 2-6, 2019	IDWEEK	700	Pai	Safety and Efficacy of Omadacycline in Patients with Diabetes in Phase 3 Clinical Studies
Oct 2-6, 2019	IDWEEK	733	Bhavnani	Pharmacokinetic-Pharmacodynamic (PK-PD) Analyses for Alanine Aminotransferase (ALT) Using Phase 3 Data from Omadacycline (OMC)-Treated Patients
Oct 2-6, 2019	IDWEEK	734	Friedrich	Modeling the Pharmacokinetics and Pharmacodynamics of Intravenous and Oral Omadacycline with and without a Loading Dose
Oct 2-6, 2019	IDWEEK	1561	Lakota	Omacycline Pharmacokinetics: Influence of Mortality Risk Score Among Patients with Community-Acquired Bacterial Pneumonia
Sept 3-6, 2019	ASM-ESCMID	T-21	Bhavnani	Pharmacokinetic-Pharmacodynamic (PK-PD) Analyses for Cardiac Endpoints Using Clinical Study Data from Omadacycline (OMC)-Treated Patients
Sept 3-6, 2019	ASM-ESCMID	T-36	Curran	Bayesian Adaptive Dose-Response Studies in Complicated and Uncomplicated Urinary Tract Infection
Sept 3-6, 2019	ASM-ESCMID	W-62	Mendes	Omacycline is Not a Substrate for Clinically Relevant β-Lactamase Enzymes
June 20-24, 2019	ASM Microbe	FRIDAY-CIV-155	Armstrong	Analysis of Pooled Microbiological Data from Two Phase 3 Studies of Omadacycline Treatment for Acute Bacterial Skin and Skin Structure Infections
June 20-24, 2019	ASM Microbe	FRIDAY-AAR-540	Huband	<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
June 20-24, 2019	ASM Microbe	SATURDAY-AAR-608	Thwaites	Investigating the Interaction between Omadacycline and Other Antibacterial Agents against Gram-Positive and Gram-Negative Bacteria
May 14-17, 2019	SAEM	88	Pollack	Omacycline Treatment of Acute Bacterial Skin and Skin Structure Infections in Intravenous Drug Users
Apr 13-16, 2019	ECCMID	O0304	Cornely	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

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Date	Conference	Presentation / Abstract Number	First Author	Title
Apr 13-16, 2019	ECCMID	O0306	Pai	Safety and Efficacy of Omadacycline for Treatment of Acute Bacterial Skin and Skin Structure Infections by Patient Body Mass Index
Apr 13-16, 2019	ECCMID	P1876	Huband	<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
Apr 13-16, 2019	ECCMID	P1918	Pai	Safety and Efficacy of Omadacycline by Body Mass Index in Patients with Community-acquired Bacterial Pneumonia
Apr 13-16, 2019	ECCMID	P1943	Lakota	Omacycline Pharmacokinetics: Impact of Comorbidities
Apr 13-16, 2019	ECCMID	P1944	Bhavnani	Assessment of Pharmacokinetics-Pharmacodynamics to Support Omacycline Dosing Regimens for the Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections (ABSSI)
Apr 13-16, 2019	ECCMID	P2011	Tzanis	Omacycline Hepatic Safety: Integrated Analysis of Randomized Controlled Phase III Trials
Apr 13-16, 2019	ECCMID	P2288	LaPensee	Incidence of Emergency Department Visits and Hospitalizations after Outpatient Treatment with an Oral Antibiotic among Patients with Acute Bacterial Skin and Skin Structure Infections