Innoviva Specialty Therapeutics to Deliver Six Presentations from its Infectious Diseases and Critical Care Portfolio at IDWeek 2025

October 7, 2025

Highlights include an oral presentation of a subset analysis from the Phase 3 clinical trial of zoliflodacin, an investigational single-dose oral treatment for uncomplicated gonorrhea due to *Neisseria gonorrhoeae*

WALTHAM, Mass.--(BUSINESS WIRE)--Oct. 7, 2025-- Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (NASDAQ: INVA), today announced that it will deliver data from six presentations at IDWeek 2025, including clinical data, pharmacokinetic-pharmacodynamic (PK-PD) analyses, and microbiologic surveillance from its growing portfolio of antibiotics and critical care medicines. IDWeek will be held in Atlanta, GA, from October 19-22, 2025.

Highlights include two oral presentations: a subset analysis from the Phase 3 trial of zoliflodacin, an investigational single-dose oral antibiotic for the treatment of uncomplicated gonorrhea, and an evaluation of the PK-PD profile of ZEVTERA® (ceftobiprole medocaril sodium for injection) infusion dosing regimens in patients with *Staphylococcus aureus* bacteremia (SAB). Innoviva Specialty Therapeutics will deliver the subset analysis of the zoliflodacin Phase 3 trial data in collaboration with its not-for-profit development partner, the Global Antibiotic Research & Development Partnership (GARDP), which sponsored and led the study.

“The breadth and depth of data we’re presenting reflects our strong commitment to addressing serious infectious diseases through innovation and scientific rigor,” said David Altarac, M.D., Chief Medical Officer at Innoviva Specialty Therapeutics. “From advancing novel therapies like zoliflodacin, to optimizing the use of antibiotic agents such as ceftobiprole, our presentations underscore our focus on improving outcomes for patients facing high-risk infections, including drug-resistant pathogens and critical care challenges.”

IDWeek is a joint annual meeting organized by a collaboration of professional organizations: the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA), the Pediatric Infectious Diseases Society (PIDS), and the Society of Infectious Diseases Pharmacists (SIDP).

ID Week 2025 Abstracts and Presentations

Zoliflodacin

Oral presentation

Abstract Title:	Subgroup Analyses of Microbiological Cure Rates by Baseline Zoliflodacin MIC and Susceptibility to Ciprofloxacin in Participants from the Global Zoliflodacin Phase 3 Randomized Controlled Trial
Presenter:	Sarah McLeod
Date:	Wednesday, October 22, 2025
Session:	Transmission Interrupted: New Approaches to STI Care
Time:	1:45 PM – 3:00 PM
Location:	B211-B212

Poster presentation:	P-1206 / Novel Agents
Abstract Title:	Association of Sex Assigned at Birth and Sexual Orientation with Antimicrobial Susceptibility of Baseline *Neisseria gonorrhoeae* Isolates from Participants Recruited in the Global Zoliflodacin Phase 3 Randomized Controlled Trial
Presenter:	Sarah McLeod
Date:	Tuesday, October 21, 2025
Time:	12:15 PM - 1:30 PM ET
Location:	Poster Hall B4-B5

Poster presentation:	P-1207 / Novel Agents
Abstract Title:	In Vitro Activity of Zoliflodacin against *Neisseria gonorrhoeae* Isolates Collected in 2022 from The United States
Presenter:	Sarah McLeod
Date:	Tuesday, October 21, 2025
Time:	12:15 PM - 1:30 PM ET
Location:	Poster Hall B4-B5

Sulbactam-Durlobactam

Poster presentation:	P-444 / Pediatric Bacterial Studies
Abstract Title:	Population Pharmacokinetics (PPK) Analysis of Sulbactam-Durlobactam (SUD) to Support Dose Selection for Evaluation in a Clinical Trial in Pediatric Patients with *Acinetobacter baumannii*-Calcoaceticus Complex (ABC) Infections
Presenter:	Angela Tanudra

Date:	Monday, October 20, 2025
Time:	12:15-1:30 pm ET
Location:	Poster Hall B4-B5

Ceftobiprole

Oral Presentation	
Abstract Title:	Pharmacokinetic-Pharmacodynamic (PK-PD) Target Attainment Analyses to Support Ceftobiprole Continuous Infusion Dosing Regimens for Patients with *Staphylococcus aureus* Bacteremia (SAB)
Session:	570 PK/PD
Presenter:	Sujata M. Bhavnani
Date:	Wednesday, October 22, 2025
Time:	11:18-11:30 am ET
Location:	B211-B212

Eravacycline

Poster presentation:	P-443 / Pediatric Bacterial Studies
Abstract Title:	Population Pharmacokinetics (PPK) Analysis of Eravacycline (ERV) to Support Dose Selection for a Trial in Pediatric Patients Aged 8 to Less Than 18 Years with Complicated Intra-Abdominal Infection (cIAI).
Presenter:	Kajal B. Larson
Date:	Monday, October 20, 2025
Time:	12:15-1:30 pm
Location	Poster Hall B4-B5

For additional information or to speak with a Medical Affairs or Commercial team representative, please stop by **ID Week booth #1231** or go to, www.innovivaspecialtytherapeutics.com, and follow us on LinkedIn and X.

About ZEVTERA® (ceftobiprole medocaril sodium for injection)

Ceftobiprole, the active moiety of the prodrug ceftobiprole medocaril, is an advanced-generation cephalosporin antibiotic for intravenous administration, with rapid bactericidal activity against a wide range of Gram-positive bacteria, such as *Staphylococcus aureus*, including methicillin-resistant strains (MRSA), and Gram-negative bacteria. Outside the U.S., the brand is currently approved and marketed in several European countries and beyond as ZEVTERA® and Mabelio® for the treatment of adult patients with hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated bacterial pneumonia (VABP), and for the treatment of community-acquired bacterial pneumonia (CABP). Basilea has entered into license and distribution agreements covering more than 80 countries.

INDICATIONS & USAGE

Indications

ZEVTERA® (ceftobiprole medocaril sodium for injection), for intravenous use, is indicated for the treatment of:

- Adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates.
- Adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive and gram-negative microorganisms: *Staphylococcus aureus* (methicillin-susceptible and methicillin-resistant isolates), *Streptococcus pyogenes,* and *Klebsiella pneumoniae*.
- Adult and pediatric patients (3 months to less than 18 years) with community-acquired bacterial pneumonia (CABP) caused by susceptible isolates of the following gram-positive and gram-negative microorganisms: *Staphylococcus aureus* (methicillin-susceptible isolates), *Streptococcus pneumoniae, Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Escherichia coli*, and *Klebsiella pneumoniae*.

Usage

- To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZEVTERA and other antibacterial drugs, ZEVTERA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

Contraindications:

- ZEVTERA is contraindicated in patients with a known history of severe hypersensitivity to ZEVTERA, or to other members of the cephalosporin class.

Warnings and Precautions:

- Increased mortality with unapproved use in ventilator-associated bacterial pneumonia (VABP) Patients: **The safety and effectiveness of ZEVTERA for the treatment of VABP has not been established and the use of ZEVTERA for VABP is not approved.**

- Serious hypersensitivity reactions, including anaphylaxis, were observed in ZEVTERA-treated patients in clinical trials. Serious and occasionally fatal hypersensitivity reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before therapy with ZEVTERA is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or other beta-lactam antibacterial drugs should be made. Maintain clinical supervision if this product is to be given to a penicillin- or other beta-lactam-allergic patient, because cross sensitivity among beta-lactam antibacterial agents has been established. Discontinue ZEVTERA if a hypersensitivity reaction occurs, and institute appropriate treatment.

- Seizures and other adverse central nervous system (CNS) reactions have been reported during treatment with ZEVTERA and other cephalosporins. If CNS adverse reactions, including seizures, occur, evaluate patients to determine whether ZEVTERA should be discontinued.

- *Clostridioides difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including ZEVTERA, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, the risk/benefit of continuing treatment with ZEVTERA should be assessed.

Adverse Reactions:

- SAB (adult patients): The most common adverse reactions occurring in ≥ 2% of adult patients were anemia, nausea, hypokalemia, vomiting, hepatic enzyme and bilirubin increased, diarrhea, blood creatinine increased, hypertension, leukopenia, pyrexia, abdominal pain, fungal infection, headache, and dyspnea.

- ABSSSI (adult patients): The most common adverse reactions occurring in ≥ 2% of adult patients were nausea, diarrhea, headache, injection site reaction, hepatic enzyme increase, rash, vomiting, and dysgeusia.

- CABP (adult and pediatric patients 3 months to less than 18 years of age):

- Adult Patients: The most common adverse reactions occurring in ≥ 2% of adult patients were nausea, hepatic enzyme increased, vomiting, diarrhea, headache, rash, insomnia, abdominal pain, phlebitis, hypertension, and dizziness.

- Pediatric Patients: The most common adverse reactions occurring in ≥ 2% of pediatric patients were vomiting, headache, hepatic enzyme increased, diarrhea, infusion site reaction, phlebitis, and pyrexia.

- To report suspected adverse reactions, contact Innoviva Specialty Therapeutics, Inc. at 1-800-651-3861 (medinfo@istx.com) or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

- **For full prescribing information, go to:** https://innovivaspecialtytherapeutics.com/wp-content/uploads/2025/05/Prescribing-Information-Zevtera.pdf

About Innoviva Specialty Therapeutics

Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc., is focused on delivering innovative therapies in critical care and infectious disease. Innoviva Specialty Therapeutics' products, through its affiliate, La Jolla Pharmaceutical Company, include GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock, and XERAVA® (eravacycline) for the treatment of complicated intra-abdominal infections in adults. Innoviva Specialty Therapeutics' products, through its affiliate, Entasis Therapeutics Inc., include XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use approved for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*). ZEVTERA® (ceftobiprole) is the only FDA-approved cephalosporin specifically designed to treat adult patients with acute bacterial skin and skin structure infections (ABSSSI), adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) including those with right-sided infective endocarditis, and adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP). The Company's clinical pipeline includes zoliflodacin, an investigational antibiotic for uncomplicated gonorrhea, which is being developed in collaboration with the Global Antibiotic Research and Development Partnership (GARDP), and is currently under review by the U.S. Food and Drug Administration.

For more information about Innoviva Specialty Therapeutics, please visit here.

Forward-Looking Statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives, and future events. Innoviva intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. The words "anticipate," "expect," "goal," "intend," "objective," "opportunity," "plan," "potential," "target" and similar expressions are intended to identify such forward-looking statements. Such forward-looking statements involve substantial risks,

uncertainties, and assumptions. These statements are based on the current estimates and assumptions of the management of Innoviva as of the date of this press release and are subject to known and unknown risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Innoviva to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: expected cost savings; lower than expected future royalty revenue from respiratory products partnered with GSK; the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, formerly, TRELEGY® ELLIPTA® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of Innoviva (including Innoviva's growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner, and amount of potential capital returns to shareholders; the status and timing of clinical studies, data analysis and communication of results; the potential benefits and mechanisms of action of product candidates; expectations for product candidates through development and commercialization; the timing of regulatory approval of product candidates; and projections of revenue, expenses and other financial items; the impact of the novel coronavirus (COVID-19). Other risks affecting Innoviva are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Innoviva's Annual Report on Form 10-K for the year ended December 31, 2022 and Quarterly Reports on Form 10-Q, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Past performance is not necessarily indicative of future results. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The information in this press release is provided only as of the date hereof, and Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

View source version on businesswire.com: https://www.businesswire.com/news/home/20251007432274/en/

Media Contact:
David Patti
Corporate Communications
Innoviva, Inc.
908.421-5971
david.patti@inva.com

Source: Innoviva Specialty Therapeutics