Innoviva Specialty Therapeutics' Antimicrobial Therapies ZEVTERA® and XACDURO® Nominated for the 2025 Prix Galien USA Best Pharmaceutical Product Award

August 13, 2025

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 13, 2025-- Innoviva Specialty Therapeutics, a subsidiary of Innoviva, Inc. (NASDAQ: INVA), announced today that two of the company's infectious disease therapies, ZEVTERA ® (ceftobiprole medocaril sodium for injection) and XACDURO® (sulbactam/durlobactam for injection) have been nominated for the prestigious 2025 Prix Galien USA Award, "*Best Pharmaceutical Product."*

"We are honored that both ZEVTERA and XACDURO have been recognized among the most innovative therapies of the year by The Galien Foundation," said Pavel Raifeld, Chief Executive Officer of Innoviva, Inc. "These nominations reflect the strength of our scientific innovation and the urgent clinical need our therapies address."

The Prix Galien USA is a prestigious award recognizing groundbreaking advancements in the biopharmaceutical and medical technology industries that significantly improve human health. Worldwide, the Prix Galien is regarded as the equivalent of the Nobel Prize in biopharmaceutical and medical technology research. The Prix Galien USA 2025 Award winners will be announced during a ceremony on October 30, 2025, in New York City.

"As antimicrobial resistance continues to rise globally, we remain committed to delivering therapies and life-saving solutions for these difficult-to-treat infections. This recognition reinforces the value of our portfolio and our mission to improve outcomes for patients while creating long-term value for our stakeholders," added David Altarac, MD, Chief Medical Officer at Innoviva Specialty Therapeutics.

In April 2024, the U.S. FDA approved ZEVTERA, marking a significant milestone in Innoviva Specialty Therapeutics' expanding antibiotic portfolio. ZEVTERA is the first and only advanced-generation cephalosporin approved to treat adults with *Staphylococcus aureus* bloodstream infections (bacteremia)(SAB), including those with right-side endocarditis caused by both methicillin-susceptible and methicillin-resistant strains (MRSA). Notably, ZEVTERA is the most recently FDA-approved therapy for MRSA-related SAB in nearly two decades, addressing a critical unmet need in serious bacterial infections.

ZEVTERA is also indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI), and adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP).

ZEVTERA was developed by Basilea Pharmaceutica Ltd, Allschwil, and in December 2024, Innoviva Specialty Therapeutics, Inc., acquired exclusive U.S. marketing rights through a licensing agreement with Basilea.

XACDURO is the first and only antibiotic approved in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*). The FDA approved XACDURO in May 2023.

Since its founding in 2022, Innoviva Specialty Therapeutics, Inc. has commercialized four therapies within its critical care and infectious disease portfolio, including the two nominated antimicrobial treatments launched in the past two years. In collaboration with the Global Antibiotic Research and Development Partnership (GARDP), the company is also awaiting a decision from the U.S. FDA on its investigational therapy, zoliflodacin, currently under review for the treatment of uncomplicated gonorrhea in adults and adolescents aged 12 and older. A decision is expected by the end of 2025.

About The Prix Galien USA Award

The Prix Galien was created in France in 1970 in honor of Galen, the father of medical science and modern pharmacology. The Galien Foundation oversees and directs activities in the U.S. for the Prix Galien Awards, which includes the biennial Prix Galien International Awards. To qualify for a Prix Galien USA Award, each candidate must have been an FDA-approved product for marketing within the last five years and demonstrate tremendous potential to improve human health. The nominating committee does not consider sales data when selecting award nominees; they consider science and health impact.

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.

About XACDURO®

XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use, is a combination of sulbactam, a beta-lactam antibacterial, and durlobactam, a beta-lactamase inhibitor, approved in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*). XACDURO is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter*.

XACDURO® INDICATION & USAGE

Indication

XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use is indicated in adults for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

Limitations of Use

XACDURO is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

Usage

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

IMPORTANT SAFETY INFORMATION

Contraindications: XACDURO is contraindicated in patients with a history of known severe hypersensitivity to the components of XACDURO or other beta-lactam antibacterial drugs.

Warnings and Precautions:

- Hypersensitivity was observed in patients treated with XACDURO in clinical trials. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before initiating therapy with XACDURO, careful inquiry should be made concerning previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta lactams, and other allergens. If an allergic reaction occurs, discontinue XACDURO.
- *Clostridioides difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs. If CDAD is suspected or confirmed, the risk/benefit of continuing treatment with XACDURO should be assessed.
- Prescribing XACDURO in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions: The most common adverse reactions reported in >10% of patients treated with XACDURO were liver test abnormalities (19%), diarrhea (17%), anemia (13%), and hypokalemia (12%).

To report SUSPECTED ADVERSE REACTIONS, contact Innoviva Specialty Therapeutics, Inc. at 1-800-651-3861 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before administering, please see the Full Prescribing Information for XACDURO.

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), a newly approved advanced-generation cephalosporin antibiotic is the latest addition to the Company's expanding antibiotic portfolio. ZEVTERA 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/20250813478127/en/

Media Contact:
David Patti
Corporate Communications
Innoviva, Inc.
david.patti@inva.com
908.421.5971

Source: Innoviva Specialty Therapeutics, Inc.