Innoviva Specialty Therapeutics' Antimicrobial Therapies, XACDURO®, ZEVTERA® and NUZOLVENCE® Designated Finalists for the 2026 Prix Galien USA Best Pharmaceutical Product Award

August 11, 2026

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 11, 2026-- Innoviva Specialty Therapeutics (IST), a subsidiary of Innoviva, Inc. (NASDAQ: INVA), announced today that three of the company's infectious disease therapies, XACDURO ® (sulbactam/durlobactam for injection), ZEVTERA® (ceftobiprole medocaril sodium for injection), and NUZOLVENCE® (zoliflodacin) are finalists for the 2026 Prix Galien USA Award in the *Best Pharmaceutical Product* category. This marks the third consecutive year an Innoviva Specialty Therapeutics product has been recognized by the renowned Galien Foundation.

"This is the broadest slate of IST products to be designated as Prix Galien finalists, which is a testament to the clinical significance of the IST portfolio," said Pavel Raifeld, Chief Executive Officer of Innoviva, Inc. "Each of these therapies addresses a distinct front in the fight against drug-resistant infections, and this nomination is further validation of our efforts to deliver life-saving medicines to patients."

The Prix Galien award is widely regarded as the industry's equivalent of the Nobel Prize, recognizing groundbreaking advancements in the biopharmaceutical and medical technology industries that demonstrate the potential to significantly improve human health. The 2026 Award winners will be announced during a ceremony on October 29, 2026, in New York City.

"As the public health crisis of antimicrobial resistance (AMR) further progresses, innovative therapeutics will continue to play an outsized role," said David Altarac, MD, Chief Medical Officer at Innoviva Specialty Therapeutics. "To that end, considering that AMR is estimated to be associated with significant morbidity and millions of deaths worldwide each year, we're privileged to be recognized for making notable strides in providing treatment for such difficult-to-treat infections."

XACDURO, approved by the FDA in May 2023, remains the only antibiotic specifically approved for hospital-acquired and ventilator-associated bacterial pneumonia caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex, a pathogen the World Health Organization classifies as a critical-priority drug-resistant threat.

ZEVTERA became in April 2024 the first cephalosporin approved by the FDA in nearly two decades for adults with *Staphylococcus aureus* bloodstream infections (bacteremia), including methicillin-resistant strains (MRSA), and is also indicated for acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia in adult and pediatric patients.

NUZOLVENCE, approved by the FDA in December 2025, is a first-in-class, single-dose oral therapy for drug-resistant urogenital gonorrhea, developed through IST's collaboration with the Global Antibiotic Research and Development Partnership (GARDP), a not-for-profit organization.

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*.

Current US FDA approved 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 NUZOLVENCE® (zoliflodacin) for oral suspension

NUZOLVENCE is a first-in-class, single-dose, oral antibiotic FDA-approved for the treatment of uncomplicated urogenital gonorrhea, including strains resistant to current first-line therapies. NUZOLVENCE is a spiropyrimidinetrione bacterial type II topoisomerase inhibitor indicated for the treatment of uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae in adults and pediatric patients 12 years of age and older, weighing at least 35 kg. The NUZOLVENCE mechanism of action is distinct from that of currently approved antibiotics and has demonstrated activity against drug-resistant *Neisseria gonorrhoeae*.

Important Safety Information (ISI)

Indication and Usage

Indication

NUZOLVENCE® is a spiropyrimidinetrione bacterial type II topoisomerase inhibitor indicated for the treatment of uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae in adults and pediatric patients 12 years of age and older, weighing at least 35 kg.

Usage to Reduce Development of Drug-Resistant Bacteria: To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZOLVENCE and other antibacterial drugs, NUZOLVENCE should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Contraindications

Known history of hypersensitivity to NUZOLVENCE.

Concomitant use with moderate or strong CYP3A4 inducers because this is predicted to result in decreased plasma concentrations of zoliflodacin and may reduce the NUZOLVENCE efficacy.

Warnings and Precautions

- **Embryo-Fetal Toxicity: Potential Risk for Pregnant Females**
  - Based on data from animal studies, NUZOLVENCE may cause fetal harm when administered to a pregnant female at clinically relevant doses. Avoid use during pregnancy. Advise pregnant females about the potential risk to the fetus with maternal exposure to NUZOLVENCE. Obtain a pregnancy test prior to initiation in persons of reproductive potential.
- **Embryo-Fetal Toxicity: Potential Risk Related to Males with Female Partners of Reproductive Potential:**
  - Based on data from an animal toxicity study, the risk of early pregnancy loss may be increased in female partners of males treated with NUZOLVENCE. Advise males with female partners of reproductive potential to use effective contraception for at least 3 months after NUZOLVENCE administration.
- **Testicular Toxicity and Risks to Male Fertility:**
  - Based on findings from animal studies, NUZOLVENCE may cause testicular toxicity and impair male fertility. An assessment of spermatogenesis has not been conducted in humans. Advise males that NUZOLVENCE may cause testicular toxicity and impair male fertility.
- **Hypersensitivity Reactions:**
  - Hypersensitivity reactions, including rash and pruritus, have been reported in patients receiving NUZOLVENCE.

Before therapy with NUZOLVENCE is instituted, carefully inquire about previous hypersensitivity reactions to NUZOLVENCE. If an allergic reaction to NUZOLVENCE occurs, discontinue NUZOLVENCE and institute appropriate supportive measures.

- **Clostridioides difficile Infection (CDI):**
  - CDI 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.
- **Development of Drug-Resistant Bacteria:**
  - Prescribing NUZOLVENCE in the absence of a proven or strongly suspected bacterial infection or 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 (≥2%) are headache, dizziness, nausea, and diarrhea. Laboratory abnormalities (neutropenia, leukopenia) were also observed.

Drug Interactions

Concomitant use with moderate or strong CYP3A4 inducers is contraindicated.

Use in Specific Populations

- **Pregnancy:** Based on findings from animal studies, NUZOLVENCE may cause fetal malformations or increased embryo-fetal loss when administered to a pregnant female. A postmarketing descriptive pregnancy safety study is available for NUZOLVENCE. If exposure occurs during pregnancy, pregnant females or their healthcare providers should report the pregnancy to Entasis Therapeutics at 1-800-651-3861.
- **Lactation:** There are no data on the presence of zoliflodacin in either human or animal milk, effects on the breastfed infant, or effects on milk production. If NUZOLVENCE is present in breast milk, intestinal flora alteration in the breastfed infant could occur.
- **Females and Males of Reproductive Potential:** Based on animal studies, NUZOLVENCE may cause fetal malformations when administered to a pregnant female at clinically relevant doses. Additionally, based on data from an animal study, the risk of early pregnancy loss may be increased in partners of males treated with NUZOLVENCE.
- **Pregnancy Testing:** Obtain a pregnancy test in females of reproductive potential prior to initiating treatment with NUZOLVENCE.
- **Contraception:** Advise males with female partners of reproductive potential to use effective contraception for at least 3 months after their single-dose treatment of NUZOLVENCE.
- **Infertility:** Based on data from repeat-dose animal toxicity and fertility studies, NUZOLVENCE may cause testicular toxicity and impair male fertility.
- **Pediatric Use:** The safety and effectiveness of NUZOLVENCE in pediatric patients younger than 12 years of age or weighing less than 35 kg have not been established.
- **Geriatric Use:** Clinical studies of NUZOLVENCE did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently than younger patients.

Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. To report SUSPECTED ADVERSE REACTIONS, please contact:

Innoviva Specialty Therapeutics™	U.S. Food and Drug Administration
1-800-651-3861	1-800-FDA-1088
medinfo@istx.com	www.fda.gov/medwatch

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 affiliates, include GIAPREZA ® (angiotensin II), XERAVA® (eravacycline), XACDURO® (sulbactam for injection; durlobactam for injection), and NUZOLVENCE® (zoliflodacin). Innoviva Specialty Therapeutics also markets ZEVTERA (ceftobiprole), an advanced-generation cephalosporin antibiotic, in the U.S. through an exclusive license from Basilea Pharmaceutica International Ltd, Allschwil. For more information about Innoviva Specialty Therapeutics, please visit www.innovivaspecialtytherapeutics.com.

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®, GIAPREZA®, XERAVA®, XACDURO®, ZEVTERA® and NUZOLVENCE® 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); the timing, manner, and amount of potential capital returns to shareholders; the development of the LYNX® platform; 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 timing, manner and amount of capital deployment, including potential capital returns to stockholders; and risks related to the Company's growth strategy. 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, 2025 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.

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