# ZEVTERA® (ceftobiprole), an Advanced-Generation Cephalosporin Antibiotic Now Commercially Available in the U.S. to Treat Three Types of Bacterial Infections

May 20, 2025

- ZEVTERA is the first and only U.S. Food and Drug Administration-approved cephalosporin indicated to treat *Staphylococcus aureus* bacteremia (SAB), including right-sided endocarditis, caused by the methicillin-resistant *Staphylococcus aureus* (MRSA).

WALTHAM, Mass.--(BUSINESS WIRE)--May 20, 2025-- Innoviva Specialty Therapeutics, Inc., a subsidiary of Innoviva, Inc. (Nasdaq: INVA), today announced the United States commercial availability of ZEVTERA® (ceftobiprole medocaril sodium for injection), the newest addition to the Company's growing antibiotic portfolio. ZEVTERA is the only U.S. Food and Drug Administration (FDA) approved advanced-generation cephalosporin indicated to treat adult patients with *Staphylococcus aureus* bloodstream infection (bacteremia) (SAB), including those with right-side endocarditis caused by methicillin-susceptible and methicillin-resistant isolates.[i] ZEVTERA is the latest approved MRSA SAB therapy since 2006.

"The availability of ZEVTERA in the U.S. marks the introduction of our second novel therapy in two years, addressing drug-resistant pathogens that pose significant health risks, particularly in hospitals and out-patient settings," said Pavel Raifeld, Chief Executive Officer, Innoviva, Inc. "This portfolio expansion demonstrates our commitment to delivering therapies that offer physicians new options for treating some of the most challenging and potentially deadly diseases by leveraging our market-leading hospital platform."

MRSA, a strain of *Staphylococcus aureus*, has developed resistance to methicillin and many other commonly used antibiotics. Infections with MRSA have a high morbidity and mortality rate. Each year, over one hundred thousand individuals in the U.S. experience bacteremia caused by *Staphylococcus aureus*, with nearly 20,000 of these cases resulting in death.

In April 2024, the U.S. FDA approved ZEVTERA for three indications. It is the only FDA-approved MRSA cephalosporin antibiotic for treating adult patients with SAB and right-side endocarditis. In addition to *Staphylococcus aureus* bacteremia, ZEVTERA is 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).[ii]

Unlike earlier-generation cephalosporins, ZEVTERA retains effectiveness against Gram-negative bacteria and provides activity against MRSA and methicillin-susceptible *Staphylococcus aureus* (MSSA). In the Phase 3 ERADICATE study, ceftobiprole met the primary endpoint by demonstrating non-inferiority versus daptomycin, with or without aztreonam. The overall success rate was 69.8% with ceftobiprole, compared to 68.7% with daptomycin, in the Modified Intention-to-Treat (mITT) population at 70 days post-randomization. Both treatments were well tolerated. The overall rate of adverse events was similar between the ceftobiprole and daptomycin groups.[iii]

"ZEVTERA is an excellent addition to our antibiotics portfolio and its market availability further underscores our strategic commitment to deliver meaningful innovations in infectious diseases," said David Altarac, M.D., Chief Medical Officer, Innoviva Specialty Therapeutics, Inc. "With the approval of ZEVTERA for three different indications, physicians and other health care providers will have a new option for serious bacterial infections, including *Staphylococcal aureus* bacteremia caused by methicillin-susceptible and methicillin-resistant isolates. Through our collaboration with specialty pharmacies and pharmacy distributors nationwide, ZEVTERA is available for immediate access."

Despite the availability of standard-of-care therapies, the mortality rate for SAB remains high, with approximately 30% of patients succumbing to the infection at 90 days.[iv] Patients with MRSA are three times more likely to experience prolonged bacteremia compared to those with methicillin-sensitive *Staphylococcus aureus*. Furthermore, MRSA bacteremia increased hospital length of stay and systemic infection vs. *methicillin-susceptible Staphylococcus aureus* (MSSA) bacteremia.[v]

ZEVTERA is supplied in a single-dose vial containing 667 mg of ceftobiprole medocaril sodium (equivalent to 500 mg of ceftobiprole) as a lyophilized powder for intravenous infusion after reconstitution. Please visit www.innovivaspecialtytherapeutics.com for more information.

ZEVTERA was developed by Basilea Pharmaceutica Ltd, Allschwil ("Basilea") and received Priority Review, Fast Track, and Qualified Infectious Disease Product designations for the CABP, ABSSSI, and SAB indications. In December 2024, Innoviva Specialty Therapeutics, Inc., acquired exclusive U.S. marketing rights through a licensing agreement with Basilea.

"We congratulate our partner Innoviva Specialty Therapeutics on making ZEVTERA available in the U.S., which marks a significant milestone for the brand," said David Veitch, Chief Executive Officer of Basilea. "The U.S. is the most critical commercial market for newer antibacterials, and there is a substantial medical need for treatments targeting *Staphylococcus aureus* infections, particularly *Staphylococcus aureus* bacteremia. We are excited to support Innoviva Specialty Therapeutics in bringing ZEVTERA to patients in the U.S. who are suffering from these severe infections."

**About MRSA**

According to the Centers for Disease Control and Prevention (CDC), methicillin-resistant *Staphylococcus aureus* (MRSA) is considered a serious public health threat. MRSA is a type of staph infection that has become resistant to commonly used antibiotics, including methicillin, oxacillin, penicillin, and amoxicillin. This resistance has contributed to MRSA's status as a significant public health concern.

MRSA infections can lead to severe complications both in healthcare settings and in the community, including pneumonia, sepsis, surgical site infections, and endocarditis. Individuals at highest risk for contracting MRSA include those who have prolonged hospital stays, have been admitted to intensive care, underwent recent invasive procedures, or reside in nursing homes. Healthcare workers who come into direct contact with patients infected with MRSA are also at increased risk.

**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.

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

Innoviva Specialty Therapeutics, Inc.™

1-800-651-3861

medinfo@istx.com

U.S. Food and Drug Administration

1-800-FDA-1088

www.fda.gov/medwatch

**For smaller pieces, AE language can be:**

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 *Staphylococcus aureus* bacteremia (SAB)**

*Staphylococcus aureus* bacteremia (SAB) is a serious bloodstream infection associated with significant morbidity and mortality. Complications include concomitant infections such as bone, joint or heart valve infections, persistent bacteremia or bacteremia in patients on dialysis. With a 30-day all-cause mortality of around 20% there is a high medical need for improved therapies for SAB.[vi]

**About acute bacterial skin and skin structure infections (ABSSSI)**

Acute bacterial skin and skin structure infections (ABSSSI) are common infections in healthcare settings. *Staphylococcus aureus* is the most common pathogen associated with these infections, which can be difficult to treat if methicillin-resistant *Staphylococcus aureus* (MRSA) is involved.[vii]

**About community-acquired bacterial pneumonia (CABP)**

Community-acquired bacterial pneumonia (CABP) is a leading cause of morbidity and mortality worldwide. It is the leading cause of infectious disease-related death in the US.[viii]

**About Basilea**

Basilea is a commercial-stage biopharmaceutical company founded in 2000 and headquartered in Switzerland. Basilea is committed to discovering, developing and commercializing innovative drugs to meet the needs of patients with severe bacterial and fungal infections. Basilea has successfully launched two hospital brands, Cresemba (isavuconazonium sulfate), for the treatment of invasive fungal infections and ZEVTERA for the treatment of bacterial infections. In addition, the Company has preclinical and clinical anti-infective assets in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit www.basilea.com.

**About Innoviva**

Innoviva is a diversified holding company with a core royalties portfolio, a leading critical care and infectious disease platform known as Innoviva Specialty Therapeutics ("IST"), and a portfolio of strategic investments in healthcare assets. Innoviva's royalty portfolio includes respiratory assets partnered with Glaxo Group Limited ("GSK"). Innoviva is entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. Innoviva's other innovative healthcare assets include infectious disease and critical care assets stemming from acquisitions of Entasis Therapeutics, including 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 and the investigational zoliflodacin currently being developed for the treatment of uncomplicated gonorrhea, and La Jolla Pharmaceutical Company, including 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. On December 14, 2024, Innoviva entered into an exclusive distribution and license agreement with Basilea Pharmaceutica Ltd, Allschwil for the commercialization of ZEVTERA® (ceftobiprole), an advanced-generation cephalosporin antibiotic, in the U.S.

ANORO®, RELVAR® and BREO® are trademarks of the GSK group of companies. ZEVTERA® is a trademark of Basilea Pharmaceutica Ltd, Allschwil.

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[i] Full US prescribing information: https://www.basilea.com/ZEVTERA_US_prescribing_information_46b9y4wk

[ii] U.S. Food and Drug Administration. (2024, April 3). FDA approves new antibiotic for three different uses. [FDA News Release] https://www.fda.gov/news-events/press-announcements/fda-approves-new-antibiotic-three-different-uses

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[iv] Van der Vaart, Thomas; All-Cause and Infection-Related Mortality in *Staphylococcus aureus* Bacteremia, a Multicenter Prospective Cohort Study; *Open Forum Infectious Diseases;* December 2022, Volume 9, Issue 12; https://academic.oup.com/ofid/article/9/12/ofac653/6854726

[v] Minejima, E., Mai, N., Bui, N., Mert, M., Mack, W. J., She, R. C., Nieberg, P., Spellberg, B., & Wong-Beringer, A. (2020). Defining the Breakpoint Duration of Staphylococcus aureus Bacteremia Predictive of Poor Outcomes. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*, *70*(4), 566–573. https://doi.org/10.1093/cid/ciz257

[vi] K. Hamed, M. Engelhardt, M. E. Jones et al. Ceftobiprole versus daptomycin in Staphylococcus aureus bacteremia: a novel protocol for a double-blind, Phase III trial. Future Microbiology 2020 (1), 35-48

[vii] J. Edelsberg, C. Taneja, M. Zervos et al. Trends in US hospital admissions for skin and soft tissue infections. Emerging Infectious Diseases 2009 (15), 1516-1518

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