Press release

Basilea announces commercial availability of antibiotic Zevtera® (ceftobiprole) in the United States

Allschwil, Switzerland, May 20, 2025

Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, announced today that its antibiotic Zevtera® (ceftobiprole medocaril for injection) is now commercially available in the United States through Basilea's partner Innoviva Specialty Therapeutics, Inc., a wholly owned subsidiary of Innoviva, Inc. (NASDAQ: INVA). Zevtera is used in hospitals for the treatment of bacterial infections, such as those caused by *Staphylococcus aureus* bacteria, including methicillin-resistant strains (MRSA). It is the only advanced-generation cephalosporin approved by the United States Food and Drug Administration (FDA) for the treatment of adult patients with *Staphylococcus aureus* bacteremia (SAB), including those with right-sided infective endocarditis. It is also indicated in the United States to treat adult patients with acute bacterial skin and skin structure infections (ABSSSI) and for the treatment of adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP).

David Veitch, Chief Executive Officer of Basilea, stated: "We congratulate our partner Innoviva Specialty Therapeutics on making Zevtera commercially available in the United States, which is a significant milestone for the brand. We are proud of Zevtera being the first MRSA active antibiotic approved for SAB in the US in more than a decade. There is a high medical need for treatments targeting *Staphylococcus aureus* infections, particularly *Staphylococcus aureus* bacteremia. Our team is pleased to be supporting Innoviva Specialty Therapeutics in bringing Zevtera to patients in the US who are suffering from these severe infections."

"The availability of Zevtera in the US 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 of Innoviva. "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."

Basilea entered into an exclusive distribution and license agreement with Innoviva Specialty Therapeutics in December 2024. Under the terms of the agreement, Basilea will receive tiered royalties on net sales in the high-teens to mid-twenties percentage range. Basilea will be eligible to receive sales milestones of up to USD 223 million. In addition, Innoviva Specialty Therapeutics will purchase its demand for Zevtera drug product from Basilea.

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.[1] In several countries in Europe and beyond, the brand is currently approved and marketed 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). In the United States, Zevtera is approved and marketed for the treatment of adult patients with *Staphylococcus aureus* bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI) and for adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP)[2]. Basilea's ceftobiprole phase 3 program was funded in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201600002C. The contract and federal funding are not an endorsement of the study results, product, or company. Basilea has been awarded approximately USD 111 million, or approximately 75 percent of the costs related to the *Staphylococcus aureus* bacteremia (SAB) and acute bacterial skin and skin structure infections (ABSSSI) phase 3 studies, regulatory activities and non-clinical work.

Important US safety information for Zevtera (US trade name: ZEVTERA®)

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.

For full US prescribing information, please visit: https://innovivaspecialtytherapeutics.com/wp-content/uploads/2025/05/Prescribing-Information-Zevtera.pdf

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

About *Staphylococcus aureus* bacteremia (SAB)

Staphylococcus aureus bacteremia (SAB) is a serious bloodstream infection associated with significant morbidity and mortality.[3] 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.[4]

About acute bacterial skin and skin structure infections (ABSSSI)

Acute bacterial skin and skin structure infections (ABSSSI) are common infections in the healthcare setting. *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.[5]

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.[6]

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 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 US.

About Basilea

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

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements, such as "believe", "assume", "expect", "forecast", "project", "may", "could", "might", "will" or similar expressions concerning Basilea Pharmaceutica Ltd, Allschwil and its business, including with respect to the progress, timing and completion of research, development and clinical studies for product candidates. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd, Allschwil to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd, Allschwil is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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This press release can be downloaded from www.basilea.com.

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