Innoviva Specialty Therapeutics Signs Exclusive Distribution and Licensing Agreement to Acquire U.S. Marketing Rights for Zevtera® (ceftobiprole)

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BURLINGAME, Calif.--(BUSINESS WIRE)--Dec. 16, 2024-- Innoviva Specialty Therapeutics, Inc., ("IST") a subsidiary of Innoviva, Inc. (Nasdaq: INVA), today announced it has entered into an exclusive distribution and license agreement with Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), for the commercialization of Zevtera® (ceftobiprole), an advanced-generation cephalosporin antibiotic, in the United States.

"The licensing of Zevtera expands IST's diverse yet complementary portfolio of differentiated treatments that address substantial unmet medical needs," said Pavel Raifeld, Chief Executive Officer, Innoviva, Inc. "We are excited to leverage our operating platform to deliver this important drug to patients. The transaction reinforces the significant opportunity for growth we see in our therapeutics business, building on the momentum and success we have had with our existing marketed products."

In April 2024, the U.S. Food and Drug Administration (FDA) approved Zevtera for three specific treatment indications, and it is the only FDA-approved methicillin-resistant *Staphylococcus aureus* (MRSA) cephalosporin antibiotic for treating adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) (SAB) and endocarditis. Zevtera is indicated for the treatment of adult patients with SAB, including right-sided infective endocarditis, and adult patients with 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).[1]

"Zevtera strengthens our role as a provider of essential therapeutics for infectious diseases and critical care within our primary customer base," stated David Altarac, Chief Medical Officer of Innoviva Specialty Therapeutics, Inc. "Drug-resistant pathogens, like MRSA, pose significant challenges for patients in hospitals and other healthcare facilities with a high mortality rate and huge cost burden. Zevtera will enable physicians to treat this important pathogen more effectively, as it is the only approved cephalosporin specifically for MRSA bloodstream infections."

Under the terms of the agreement, Innoviva, Inc., will be granted exclusive marketing rights to Zevtera in the U.S. Basilea will receive a $4 million upfront payment in addition to tiered royalties and milestones on net sales in the U.S. Innoviva Specialty Therapeutics anticipates commercializing Zevtera in mid-year 2025.

Reference

1. Full US prescribing information: https://www.basilea.com/ZEVTERA_US_prescribing_information_46b9y4wk

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] Outside the U.S., the brand is currently approved and marketed in several countries in Europe 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.

Important US safety information for ZEVTERA (ceftobiprole medocaril sodium for injection)

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.
- Hypersensitivity Reactions: Discontinue ZEVTERA if a hypersensitivity reaction occurs, and institute appropriate treatment.
- Seizures and other adverse central nervous system (CNS) reactions have been associated with the use of ZEVTERA. If seizures or other CNS adverse reactions 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. Evaluate if diarrhea occurs.

Adverse reactions

- SAB (adult patients): The most common adverse reactions occurring in ≥ 4% of adult patients were anemia, nausea, hypokalemia, vomiting, hepatic enzyme and bilirubin increased, diarrhea, blood creatinine increased, hypertension, leukopenia and pyrexia.
- ABSSSI (adult patients): The most common adverse reactions occurring in ≥ 2% of adult patients were nausea, diarrhea, headache, injection site reaction, hepatic enzyme increased, 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 here: www.basilea.com/ZEVTERA_US_prescribing_information_46b9y4wk

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.

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.

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.

For full prescribing information go to https://www.basilea.com/ZEVTERA_US_prescribing_information_46b9y4wk

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.

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