

Ad hoc announcement pursuant to Art. 53 LR

Basilea announces agreement with Innoviva Specialty Therapeutics for the commercialization of antibiotic Zevtera[®] (ceftobiprole) in the United States

Allschwil, Switzerland, December 16, 2024

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 it has entered into an exclusive distribution and license agreement with Innoviva Specialty Therapeutics, Inc., a wholly owned subsidiary of Innoviva Inc. (NASDAQ: INVA), for the commercialization of Basilea's hospital anti-MRSA antibiotic Zevtera[®] (ceftobiprole) in the United States (US). Innoviva Specialty Therapeutics is a US-based biopharmaceutical company with an established hospital sales force and a core competence in commercializing anti-infective medicines.

David Veitch, Chief Executive Officer of Basilea, stated: "We are very pleased with our collaboration with Innoviva Specialty Therapeutics for the commercialization of Zevtera in the US. The company is a highly committed, focused and capable partner that shares our vision and ambitions for Zevtera in the US. They also have recent experience of launching a hospital antibiotic in the US. We are looking forward to working with Innoviva Specialty Therapeutics towards a successful launch and bringing Zevtera to patients in need in the US."

"With this agreement, Zevtera will become an important asset in our company's portfolio, allowing us to advance our strategy of providing differentiated therapies in infectious disease and critical care," said Pavel Raifeld, Chief Executive Officer, Innoviva, Inc. "There is a significant medical need for treatments targeting complicated *Staphylococcus aureus* infections, particularly *Staphylococcus aureus* bacteremia. We are therefore excited to bring this important new medicine to patients who are suffering from these severe infections."

Under the terms of the agreement, Basilea will receive a USD 4 million upfront payment and 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 of Zevtera drug product from Basilea.

About Zevtera[®] (ceftobiprole medocaryl sodium for injection)

Ceftobiprole, the active moiety of the prodrug ceftobiprole medocaryl, 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). Basilea has entered into license and distribution agreements covering more than 80 countries.

In the United States, Zevtera is indicated for the treatment of adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) (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).²

Basilea's ceftobiprole phase 3 program is 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. Basilea has been awarded approximately USD 112 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.

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.

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.



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This ad hoc announcement can be downloaded from www.basilea.com.

References

1. Summary of Product Characteristics (SmPC) Zevtera: <https://www.medicines.org.uk/emc/product/9164/smpc> [Accessed: December 15, 2024]
2. Full US prescribing information: https://www.basilea.com/ZEVTERA_US_prescribing_information_46b9y4wk