Ad hoc announcement pursuant to Art. 53 LR

Basilea announces FDA acceptance of New Drug Application for antibiotic ceftobiprole

- **Seeking approval for *Staphylococcus aureus* bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI), and community-acquired bacterial pneumonia (CABP)**
- **Prescription Drug User Fee Act (PDUFA) goal date set for April 03, 2024**

Allschwil, Switzerland, October 02, 2023

Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial or fungal infections, announced today that the US Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for the antibiotic ceftobiprole, which was submitted to the FDA on August 3rd this year. With this NDA, Basilea is seeking approval for treating patients in three indications: *Staphylococcus aureus* bacteremia (SAB), including right-sided infective endocarditis, acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP). The FDA has set April 03, 2024, as the Prescription Drug User Fee Act (PDUFA) goal date.

The PDUFA goal date indicates the date for the FDA to complete its review of the NDA, which is supported by clinical efficacy and safety data from the phase 3 studies ERADICATE (SAB),[1] TARGET (ABSSSI),[2] and a phase 3 study in CABP.[3] The ERADICATE study was the largest double-blind randomized registrational study conducted for a new antibiotic treatment in SAB.

Dr. Marc Engelhardt, Chief Medical Officer, said: “We are pleased with the FDA's acceptance of our New Drug Application, which is another important step towards bringing ceftobiprole to patients with severe bacterial infections in the US, as there is a high medical need for new antibiotic treatment options, especially in complicated SAB. We look forward to working closely with the FDA throughout their review process.”

Ceftobiprole has been designated a Qualified Infectious Disease Product (QIDP) under the US Generate Antibiotics Incentives Now (GAIN) Act; hence, subject to approval, ceftobiprole would be eligible to receive ten years of market exclusivity in the US from the date of approval. Basilea is planning to commercialize ceftobiprole in the US through a partner and intends to enter into such a partnership prior to the PDUFA goal date.

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 SAB and ABSSSI phase 3 studies, regulatory activities and non-clinical work.

About ceftobiprole

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.[4] The brand is currently approved and marketed as Zevtera® and Mabelio® in several countries in Europe and beyond, 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. Ceftobiprole is currently not approved or partnered 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 or 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 anti-infective assets in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit basilea.com.

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For further information, please contact:

Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations
Basilea Pharmaceutica Ltd, Allschwil
Hegenheimermattweg 167b
4123 Allschwil
Switzerland

Phone +41 61 606 1102

E-mail media_relations@basilea.com
investor_relations@basilea.com

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

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