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Press release

Basilea announces approval of antibiotic Zevtera® in China to treat community-acquired pneumonia and hospital-acquired pneumonia

- **National Medical Products Administration (NMPA) granted Drug Approval License to Basilea's partner CR Gosun**
- **Basilea will receive CHF 3 million milestone payment from CR Gosun**

Basel, Switzerland, November 06, 2020

Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that its license partner Shenzhen China Resources Gosun Pharmaceuticals Co. Ltd. (CR Gosun) has received a Drug Approval License from the National Medical Products Administration (NMPA) in China for Basilea's antibiotic Zevtera® (ceftobiprole). With the Drug Approval License Authorization, Zevtera is now approved in China for the treatment of adult patients with community-acquired pneumonia (CAP) and adult patients with hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP). The granting of the Drug Approval License triggered a milestone payment of CHF 3 million, from CR Gosun to Basilea.

David Veitch, Basilea's CEO, said: "The approval of Zevtera in China is an important milestone for the brand. We believe that China represents the second largest global commercial opportunity. Our focus will now be on supporting our partner, CR Gosun, to make Zevtera available to patients in China with bacterial lung infections."

Zevtera is currently approved and marketed in major European countries and a number of countries in Latin America, the Middle East and North Africa (MENA) regions as well as in Canada for the treatment of adult patients with CAP or HAP, excluding VAP.[1] It is not approved in the United States. In order to support a potential registration in the U.S., Basilea is conducting a phase 3 program, with a successfully completed study in acute bacterial skin and skin structure infections (ABSSSI) and an ongoing study in *Staphylococcus aureus* bacteremia (bloodstream infections), which is anticipated to complete patient enrolment in the second half of 2021.[2]

Basilea entered into the agreement with CR Gosun in September 2017. Under the terms of the agreement, CR Gosun was granted an exclusive license to develop, manufacture and commercialize ceftobiprole in China mainland, Hong Kong and Macao. Basilea will initially supply CR Gosun at a transfer price and will be eligible for tiered double-digit royalties on product sales, once CR Gosun manufactures ceftobiprole itself. Basilea is also eligible for pre-specified sales milestone payments.

About ceftobiprole

Ceftobiprole medocaril, the prodrug of the active moiety ceftobiprole, is a cephalosporin antibiotic for intravenous administration with rapid bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria. This includes methicillin-susceptible and resistant *Staphylococcus aureus* (MSSA, MRSA) and susceptible *Pseudomonas* spp.[1] The drug is approved and marketed as Zevtera® and Mabelio® in a number of countries in Europe and beyond. Basilea has entered into license and distribution agreements for the brand in Europe, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA) regions.

About Basilea

Basilea Pharmaceutica Ltd. is a commercial-stage biopharmaceutical company, focused on the development of products that address the medical challenges in the therapeutic areas of oncology and infectious diseases. With two commercialized drugs, the company is committed to discovering, developing and commercializing innovative pharmaceutical products to meet the medical needs of patients with serious and life-threatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Additional information can be found at Basilea's website www.basilea.com.

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This press release 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: November 05, 2020]
2. The ceftobiprole phase 3 program is funded in part (up to USD ~130 million, which is approximately 70% of the total estimated program costs) with federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201600002C.