Ad hoc announcement pursuant to Art. 53 LR

Basilea provides update on New Drug Application to the US Food and Drug Administration for antibiotic ceftobiprole

Basel/Allschwil, Switzerland, April 18, 2023

Basilea Pharmaceutica Ltd (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial or fungal infections, provided an updated timeline for its New Drug Application (NDA) submission for its antibiotic ceftobiprole to the US Food and Drug Administration (FDA).

Basilea estimates that an additional three to six months of preparatory work will be required to ensure that one of its third-party contract manufacturing organizations (CMOs) is ready for inspection by the FDA, which is a prerequisite for an NDA review. Basilea, therefore, now expects to submit the NDA for the three indications of *Staphylococcus aureus* bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI), and community-acquired bacterial pneumonia (CABP) in the third quarter of 2023.

David Veitch, Basilea's CEO, said: "We have compiled our NDA dossier and are ready to make a submission to the FDA. However, after completion of the FDA inspection-readiness preparations within our supply chain, it became clear that the quality systems of one of our CMOs need to be adapted prior to an FDA inspection. We estimate this process to require between three to six months, with the NDA submission planned to occur immediately afterwards in the third quarter of 2023, leading to an expected regulatory decision by the FDA in the second quarter of 2024. Importantly, ceftobiprole, if approved in the US, will have ten years of market exclusivity from approval, based on its Qualified Infectious Disease Product (QIDP) status designated by the FDA."

The updated timelines for the NDA submission in the US do not have any impact on Basilea's financial guidance.

Basilea's ceftobiprole phase 3 program is funded in part (up to USD 136.4 million, which is approximately 70% of the total potential program costs) 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.

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).[1] The brand is currently approved and marketed as Zevtera and Mabelio in a number of 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). Ceftobiprole is not approved in the US. Basilea has entered into several license and distribution agreements for ceftobiprole covering more than 80 countries.

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.

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 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 to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd 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.

For further information, please contact:

Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations
Basilea Pharmaceutica International 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.

References

1. Summary of Product Characteristics (SmPC) Zevtera: https://www.medicines.org.uk/emc/product/9164/smpc [Accessed: April 17, 2023]