**Press release**

# Basilea reports new data for ceftobiprole (Zevtera®) presented at US IDWeek Congress 2023

– **Eight presentations on antibiotic ceftobiprole providing further evidence for its activity against methicillin-resistant *Staphylococcus aureus* (MRSA) and other clinically relevant pathogens**

**Allschwil, Switzerland, October 17, 2023**

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 scientific presentations with new data on its antibiotic ceftobiprole (Zevtera®) have been presented at Infectious Disease Week (IDWeek) 2023, highlighting its utility for the treatment of severe bacterial infections.

IDWeek is the annual meeting of the Infectious Diseases Society of America (IDSA), jointly held with other infectious diseases societies in the US, and took place in Boston, Massachusetts (USA) from 11 to 15 October 2023.

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, stated: "The data presented at IDWeek provide further evidence for the potent antimicrobial activity of ceftobiprole against MRSA and other clinically relevant pathogens. It also provides results of pharmacokinetic-pharmacodynamic modeling supporting the dosing regimens to treat severe bacterial infections from the successful clinical phase 3 studies. These studies were conducted in patients with *Staphylococcus aureus* bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP). These are the three indications included in our New Drug Application, which is currently under priority review with the US FDA, with a Prescription Drug User Fee Act (PDUFA) goal date of 03 April 2024."

Data from four presentations, building on pharmacokinetic-pharmacodynamic modeling, provided evidence that the exposure achieved with the applied dosing regimens was efficacious for the treatment of *Staphylococcus aureus* bacteremia (SAB) in the ERADICATE phase 3 study.[1] The same was also shown in analyses for the ceftobiprole phase 3 studies in acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP).[2, 3]

Four additional abstracts included data from large *in-vitro* susceptibility studies testing bacterial isolates from US patients, which confirmed that ceftobiprole exhibits potent *in-vitro* activity against methicillin-susceptible and methicillin-resistant *Staphylococcus aureus* (MSSA, MRSA), as well as against *Streptococcus pneumoniae and Enterococcus faecalis*, and retained its

potency over the surveillance period of several years against these clinically relevant pathogens.

The presented data were generated in collaboration with the Institute for Clinical Pharmacodynamics, Schenectady, New York (USA), JMI Laboratories, North Liberty, Iowa, (USA) and the Duke Clinical Research Institute, Durham, North Carolina (USA).

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 phase 3 studies in SAB and acute bacterial skin and skin structure infections (ABSSSI), regulatory activities and non-clinical work.

**Ceftobiprole data presented at IDWeek 2023**

- Abstract #1946 – *In Vitro* Activity of Ceftobiprole against *Staphylococcus aureus* Bacteremia Isolates from the United States (2018–2020) – L. Duncan, M. Castanheira, J. I. Smart, M. E. Jones, R. E. Mendes

- Abstract #2162 – *In Vitro* Antimicrobial Activity of Ceftobiprole against *Streptococcus pneumoniae* Isolates from the United States (2016–2020) – L. Duncan, M. Castanheira, J. I. Smart, M. E. Jones, R. E. Mendes

- Abstract #2173 – Activity of Ceftobiprole Against *Enterococcus faecalis* Clinical Isolates From the United States (2016–2020), Including Those From Difficult-to-Treat Infections – R. E. Mendes, L. Duncan, H. S. Sader, J. I. Smart, M. E. Jones, M. Castanheira

- Abstract #2530 – Pharmacokinetic-Pharmacodynamic (PK-PD) Target Attainment Analyses to Support Ceftobiprole Dose Selection for the Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) and Community-Acquired Bacterial Pneumonia (CABP) – S. M. Bhavnani, J. P. Hammel, A. J. Rinaldo, J. I. Smart, K. Litherland, L. Duncan, M. E. Jones, M. Engelhardt, P. G. Ambrose, C. M. Rubino

- Abstract #2531 – Pharmacokinetic-Pharmacodynamic (PK-PD) Target Attainment Analyses to Support Ceftobiprole Dosing Regimens for Patients with *Staphylococcus aureus* Bacteremia (SAB) – S. M. Bhavnani, J. P. Hammel, A. J. Rinaldo, J. I. Smart, K. Litherland, L. Duncan, M. E. Jones, M. Engelhardt, P. G. Ambrose, C. M. Rubino

- Abstract #2532 – Pharmacokinetic-Pharmacodynamic Analyses for Ceftobiprole Efficacy Based on Phase 3 Data from Patients with *Staphylococcus aureus* Bacteremia – S. M. Bhavnani, J. P. Hammel, K. Liolios, A. P. Cammarata, M. Saulay, C. M. Rubino, M. Engelhardt, J. I. Smart, M. E. Jones, P. G. Ambrose, K. Litherland

- Abstract #2561 – Population Pharmacokinetic Analyses for Ceftobiprole Using Data from Phase 1 and 3 Studies – A. P. Cammarata, K. Litherland, M. C. Safir, S. M. Bhavnani, M. Saulay, J. I. Smart, M. E. Jones, M. Engelhardt, C. M. Rubino

- Abstract #2785 - Characterization of Methicillin-resistant *Staphylococcus aureus* Bloodstream Isolates Recovered from Patients Enrolled in a Randomized, Double-blind, Multi-center Study to Establish the Efficacy and Safety of Ceftobiprole for Treatment of Bacteremia, Including Infective Endocarditis – R. E. Mendes, L. Duncan, J. H. Kimbrough, T. L. Holland, V. G. Fowler Jr, M. E. Jones, M. Engelhardt, J. I. Smart, M. Castanheira

## 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. Ceftobiprole was designated a Qualified Infectious Disease Product (QIDP) by the US Food and Drug Administration (FDA) for SAB, ABSSSI and CABP. Therefore, if approved, ceftobiprole would be eligible to receive ten years of market exclusivity in the US from the date of approval.

## 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 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 press release can be downloaded from www.basilea.com.

## References

1. ERADICATE (SAB): ClinicalTrials.gov identifier NCT03138733
T. L. Holland, S. E. Cosgrove, S. B. Doernberg et al. Ceftobiprole for treatment of complicated *Staphylococcus aureus* bacteremia. New England Journal of Medicine 2023 (389), 1390-1401; DOI: 10.1056/NEJMoa2300220
2. TARGET (ABSSSI): ClinicalTrials.gov identifier NCT03137173
J. S. Overcash, C. Kim, R. Keech R et al. Ceftobiprole compared with vancomycin plus aztreonam in the treatment of acute bacterial skin and skin structure infections: Results of a phase 3, randomized, double-blind trial (TARGET). Clinical Infectious Diseases 2021 (73), e1507-e1517
3. CABP study: ClinicalTrials.gov identifier NCT00326287
S. C. Nicholson, T. Welte, T. M. File Jr. et al. A randomised, double-blind trial comparing ceftobiprole medocaril with ceftriaxone with or without linezolid for the treatment of patients with community-acquired pneumonia requiring hospitalization. International Journal of Antimicrobial Agents 2012 (39), 240-246
4. Summary of Product Characteristics (SmPC) Zevtera: https://www.medicines.org.uk/emc/product/9164/smpc [Accessed October 16, 2023]