Press release

Basilea provides portfolio update and outlook

Allschwil, Switzerland, January 08, 2025

Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, reported today on the progress of its Research & Development portfolio in 2024 and upcoming milestones.

David Veitch, Chief Executive Officer, said: "We have achieved several significant milestones in 2024. We partnered with a highly committed, focused and capable company for the commercialization of our anti-MRSA antibiotic, Zevtera, in the United States, following its approval earlier in the year. For our leading antifungal Cresemba, the European Commission expanded the approved uses to include treatment for pediatric patients. This not only made Cresemba available to children, but also extended its protection from generic competition in the EU until late 2027. We are also pleased to have been awarded very significant non-dilutive funding from BARDA and CARB-X to support the development of novel, first-in-class antifungals and antibacterials within our R&D portfolio. Finally, we laid the foundation for future growth by commencing a phase 3 study in invasive yeast infections with our potential next lead product, the broad-spectrum antifungal fosmanogepix. Throughout 2025, we aim to continue both progressing our current R&D assets and expanding our portfolio through targeted in-licensing and acquisition of innovative, commercially attractive, pre-clinical and clinical assets, addressing unmet medical needs in the treatment of severe fungal and bacterial diseases."

Maintaining its strong momentum, the commercial performance of Cresemba triggered several milestone payments to Basilea in 2024. By year-end 2024, Cresemba was marketed in more than 70 countries, including the United States (US), most EU member states, China and Japan. According to the latest available market data, total global in-market sales of Cresemba in the twelve-month period between October 2023 and September 2024 amounted to USD 533 million, a 20 percent growth year-on-year, making it the largest branded antifungal for invasive fungal infections worldwide.[1]

Portfolio key highlights 2024 and outlook 2025

Cresemba® (isavuconazole): Indications expanded to pediatric patients

- In August, the European Commission approved the use of Cresemba in children with invasive aspergillosis or mucormycosis,[2] following a similar decision by the US Food and Drug Administration (FDA) in December 2023; the market exclusivity of Cresemba was extended to October 2027 in the EU and September 2027 in the US.

Zevtera® (ceftobiprole): US approval and commercialization progress; Chinese NRDL inclusion

- In April, the US FDA approved Zevtera for SAB, ABSSSI and CABP, i.e. all three submitted indications.[3, 4]
- In September, Zevtera has been approved for New-Technology Add-On Payment (NTAP) in the US, which will provide hospitals an incremental payment in addition to standard reimbursement, by the Centers for Medicare & Medicaid Service (CMS).[5]
- In December, we announced Innoviva Specialty Therapeutics (IST) as commercialization partner for the US market. The US launch is expected mid-2025.
- In China, ceftobiprole (Chinese trade name: Sibipre®) has been included in the National Reimbursement Drug List (NRDL) at the end of 2024, making it eligible for reimbursement under the Chinese national basic medical insurance program from 2025.

Clinical and preclinical pipeline: Substantial progress made and significant funding secured

- The "Other Transaction Agreement" (OTA)[6] with the Biomedical Advanced Research and Development Authority (BARDA) signed in September provides up to approximately USD 268 million non-dilutive funding over up to 12 years for the development of novel antifungals and antibacterials. An initial commitment of USD 29 million supports the development of our antifungals fosmanogepix and BAL2062.
- In September, we commenced a phase 3 study with fosmanogepix in the treatment of adult patients with candidemia and/or invasive candidiasis, i.e. severe invasive yeast infections. A second phase 3 study, in invasive mold infections, is expected to start in the coming months.
- The Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) awarded non-dilutive funding of USD 7.3 million in December for the first-in-class LptA inhibitor antibiotic, BAL2420, which we acquired in January 2024.[7] This was new funding on top of USD 0.9 million awarded in April. The extended funding supports the progression of the drug candidate towards a first-in-human clinical study which is expected to start mid-2026. BAL2420 is being developed for the potential treatment of severe infections caused by Gram-negative bacteria.
- Preclinical evaluations for the antibacterial tonabacase and the antifungal BAL2062 are well advanced. We expect to take the decision whether to exercise our option to initiate exclusive contract negotiations to license tonabacase for further clinical development and commercialization in the next few weeks. For BAL2062, our focus in 2025 will be on the completion of the preclinical profiling and the preparation of the phase 2 program so that we can start the clinical study in early 2026.

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

References

1. IQVIA Analytics Link, September 2024. In-market sales reported as moving annual total (MAT) in US dollar.
2. European Public Assessment Report (EPAR): https://www.ema.europa.eu/en/medicines/human/EPAR/cresemba [Accessed: January 07, 2025]
3. Full US prescribing information: https://www.basilea.com/ZEVTERA_US_prescribing_information_46b9y4wk; SAB: *Staphylococcus aureus* bacteremia; ABSSSI: Acute bacterial skin and skin structure infections; CABP: Community-acquired bacterial pneumonia.
4. 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
5. Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes: https://federalregister.gov/d/2024-17021 (Accessed: January 07, 2025)
6. BARDA OTA number: 75A50124C00033
7. CARB-X's funding for this project is provided in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority; Antibacterials branch; under agreement number 75A50122C00028; and by awards from Wellcome (WT224842) and Germany's Federal Ministry of Education and Research (BMBF). The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of CARB-X or any of its funders.