Press release

Basilea provides portfolio status update

- **Clinical portfolio substantially strengthened through business development in 2023; two phase 3 studies expected to start in 2024**
- **Cresemba in-market sales of USD 445 million, increased 22% year-on-year, in 12-month period ending September 2023; 6-months market exclusivity extension granted in the US**
- **FDA PDUFA target action date on ceftobiprole US NDA April 3; US commercialization partner expected to be announced prior to FDA decision**

Allschwil, Switzerland, January 5, 2024

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 within its R&D portfolio in 2023 and upcoming milestones and timelines.

David Veitch, Chief Executive Officer, said: “We have achieved significant milestones in 2023 and remain committed to executing our strategy to drive long-term value creation. With the addition of three new assets to our clinical development pipeline, led by the very promising antifungal fosmanogepix, we are delivering on our goal of creating a balanced portfolio of innovative drug candidates for the treatment of severe bacterial and fungal infections. Furthermore, we have established ourselves as the partner of choice for companies seeking support in the development of their assets, with a focus on differentiation and commercial positioning. The continued commercial success of Cresemba and, pending US approval, the increasing revenue contributions from Zevtera, provide us with the financial strength to both advance our new programs and continue to expand our exciting R&D portfolio, supporting us in achieving our strategic goal of becoming a leading anti-infectives company.”

Maintaining its strong momentum, the commercial performance of Cresemba triggered a number of milestone payments to Basilea. By year-end 2023, 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 2022 and September 2023 amounted to USD 445 million, a 22 percent growth year-on-year.[1]

Portfolio key highlights 2023

Cresemba® (isavuconazole) commercial lifespan extension

- In December, the US Food and Drug Administration (FDA) approved the expanded use of Cresemba in children with invasive aspergillosis and invasive mucormycosis.[2] The FDA also granted pediatric exclusivity, which extends the period of market exclusivity for Cresemba in the United States by an additional six months to September 2027.
- In August, Basilea submitted a similar application for a pediatric label extension of Cresemba in the European Union and anticipates a decision by the European Commission around mid-2024. If the pediatric extension is granted, Cresemba would be eligible to an additional two years of market exclusivity in the European Union, until October 2027.

Zevtera® (ceftobiprole) US NDA under review

- In September, data from the successful phase 3 study, ERADICATE, which evaluated ceftobiprole for the treatment of bacterial bloodstream infections (bacteremia) caused by *Staphylococcus aureus* in adult patients, were published in the New England Journal of Medicine, supporting its potent activity in treating serious bacterial infections.[3]
- In August, Basilea submitted a New Drug Application (NDA) to the FDA, seeking approval of ceftobiprole for the treatment of 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).[4] The FDA accepted the submission in October and set April 3, 2024, as the Prescription Drug User Fee Act (PDUFA) target action date, i.e. the regulatory decision date.

Basilea expects to enter into a commercialization partnership agreement for ceftobiprole in the US prior to the FDA decision.

Pipeline broadened with promising new clinical drug candidates

- In November, Basilea acquired the rights to the phase-3-ready, first-in-class, broad-spectrum antifungal fosmanogepix, one of the most attractive agents currently in clinical development, with activity against both yeasts, including *Candida auris*, classified as acritical priority pathogen by the World Health Organization (WHO), and molds that are resistant to other antifungal agents.
- Acquisition of another potential first-in-class antifungal, now named BAL2062, with activity against *Aspergillus* molds, including azole-resistant strains and other fungi
- Acquisition of evaluation license for the novel antibiotic, tonabacase, for the treatment of infections caused by *Staphylococcus aureus*, including multi-drug resistant strains and those forming difficult-to-eradicate biofilms.

For fosmanogepix, Basilea anticipates to start a phase 3 study in invasive yeast infections mid-2024 and a phase 3 study in invasive mold infections, by year-end 2024. For BAL2062 and tonabacase, the focus for 2024 will be on preclinical profiling in order to define the optimal positioning and clinical development plans for these assets. Following a re-prioritization of its earlier stage research pipeline and re-allocation of resources, Basilea decided at year-end 2023 to discontinue the preclinical program on inhibitors of DXR, an enzyme in the bacterial isoprenoid biosynthesis pathway.[5]

Throughout 2024, we aim to continue expanding our R&D portfolio, through the identification of innovative, commercially attractive assets, addressing unmet medical needs in the treatment of severe fungal and bacterial diseases.

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.

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