Ad hoc announcement pursuant to Art. 53 LR

Basilea reports preliminary 2022 revenues, exceeding guidance, and provides portfolio update

- **Continued commercial success of Cresemba and Zevtera in 2022 generated revenue contributions of approx. CHF 122 million, exceeding guidance by more than 17%**
- **Significant proceeds from oncology transactions**
- **Following pre-NDA (New Drug Application) meeting held with FDA in Q4 2022 for ceftobiprole (Zevtera), NDA submission for three indications planned within two to three months**
- **Building a balanced R&D portfolio of antibacterial and antifungal drug candidates to support sustainable long-term growth in line with strategic refocus**

Basel/Allschwil, Switzerland, January 11, 2023

Basilea Pharmaceutica Ltd (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, announced today the unaudited preliminary revenues for the financial year 2022 and provided an update on the progress made with its commercial brands Cresemba® (isavuconazole) and Zevtera® (ceftobiprole), as well as in advancing its R&D portfolio in 2022.

Revenue contributions from the antifungal Cresemba and the antibiotic Zevtera are expected to amount to approximately CHF 122 million (full-year 2022 guidance: CHF 98 million – 104 million). Total revenue, which includes BARDA reimbursements[1], proceeds from the oncology transactions and other revenue contributions in addition to the Cresemba and Zevtera contributions, is expected to amount to approximately CHF 148 million (full-year 2022 guidance: CHF 116 million – 122 million).

David Veitch, Chief Executive Officer, commented: “We achieved significant milestones in 2022 and will continue to focus on delivering on our strategy to drive value creation going forwards. This is supported by the continued commercial success, especially of Cresemba and, subject to receiving a marketing approval in the U.S, the anticipated increasing revenue contributions from Zevtera. We are also planning to in-license further preclinical and clinical assets in 2023 and beyond. Our goal is to maintain a balanced portfolio of innovative drug candidates for the treatment of severe bacterial and fungal infections to support the long-term growth of Basilea, beyond Cresemba and Zevtera, and in so doing execute on our strategic goal of becoming a leading anti-infectives company.”

The strong global commercial performance of Cresemba triggered a number of separate sales milestone payments to Basilea from its partners, related to Cresemba in-market sales; in the United States, Asia Pacific & China, Canada and the Nordics. By year-end 2022, Cresemba was approved in 73 countries and marketed in 63 countries, including the United States, most

EU member states, China and additional countries inside and outside of Europe. According to the latest available market data, total global in-market sales of Cresemba in the twelve-month period between October 2021 and September 2022 amounted to USD 363 million, a 19 percent growth year-on-year.[2]

Anti-infectives key highlights 2022

Cresemba

- The intravenous and oral formulations of Cresemba were launched in China for the treatment of adult patients with invasive aspergillosis and invasive mucormycosis, marking the entry into one of the most important markets for novel antifungals.
- Patient recruitment was completed for the pediatric program. The completion of the pediatric program is a requirement for gaining an additional two years of marketing exclusivity in Europe and six months in the United States.
- In December, Basilea's partner Asahi Kasei Pharma received the marketing approval for Cresemba in Japan for the treatment of adult patients with aspergillosis, mucormycosis, and cryptococcosis.

Zevtera

- In June, Basilea announced positive topline results for the phase 3 ERADICATE study, evaluating ceftobiprole in the treatment of adult patients with bacterial bloodstream infections caused by *Staphylococcus aureus* (SAB).[3] The ERADICATE study complements the TARGET phase 3 study in acute bacterial skin and skin structure infections (ABSSSI), which achieved positive results in 2019.[4]
- In July, Zevtera received the marketing authorization in Brazil.

Dr. Marc Engelhardt, Chief Medical Officer, said: "In Q4 2022 we had a pre-NDA meeting with the U.S. Food and Drug Administration, which allowed us to finalize our regulatory strategy for ceftobiprole in the U.S. We will be seeking approval not only for *Staphylococcus aureus* bacteremia and acute bacterial skin and skin structure infections but also for community-acquired bacterial pneumonia. We aim to submit the corresponding New Drug Application within the next two to three months. While *Staphylococcus aureus* bacteremia is the indication of highest unmet medical need, we believe that a broader range of indications would further support the utility of ceftobiprole in a clinical practice setting."

Preclinical programs

- The work on an in-licensed DXR inhibitor program against multi drug-resistant Gram-negative bacteria progressed and Basilea expects to reach the next preclinical decision point in 2023.
- Progress on advancing earlier internal programs continues.

- Basilea has completed the profiling of a lead compound from a recently in-licensed preclinical program of broad-spectrum antifungals with a new mode of action. The candidate did not meet Basilea's stringent criteria for progressing into the development stage and the company decided to return the program to the licensor.

Dr. Laurenz Kellenberger, Chief Scientific Officer, commented: "We made good progress advancing our pipeline with promising programs, from both internal and external innovation. Our competencies and know-how in research and development of anti-infectives, combined with a data-driven approach and decision making process allows us to quickly identify and then focus on the most promising candidates for further development and for in-licensing."

Oncology transactions successfully completed in 2022

In February 2022, Basilea announced the strategic decision to focus exclusively on anti-infectives going forwards and to exit oncology by the end of 2022. By November 2022, Basilea had entered into three separate transactions with innovative oncology companies. These transactions related to novel preclinical stage inhibitors of PARG and CLK as well as BAL0891, a potential first-in-class mitotic checkpoint inhibitor. They were structured to provide upfront and near-term milestone payments, while also ensuring that Basilea maintains an ongoing participation in the long-term value creation potential of these promising programs.

On the oncology assets which were not transacted, Basilea decided to transfer the rights for the FGFR inhibitor derazantinib back to Merck & Co. For the tumor checkpoint controller lisavanbulin, Basilea concluded the study program last year, following a decision not to expand glioblastoma patient cohorts, retaining the option to explore partnering opportunities in the future. Basilea will not incur material costs related to any oncology activities in 2023.

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 several 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 ad hoc announcement can be downloaded from www.basilea.com.

References

1. 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 U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201600002C.
2. IQVIA Analytics Link, September 2022. In-market sales reported as moving annual total (MAT) in U.S. dollar.
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