Ad hoc announcement pursuant to Art. 53 LR

Basilea reports progress on the implementation of its strategy to focus on anti-infectives

- **ERADICATE phase 3 study exploring ceftobiprole for the treatment of patients with *Staphylococcus aureus* bacteremia (SAB) expected to report results shortly**
- **Separate transactions for TTK/PLK1 inhibitor (BAL0891) and preclinical oncology projects expected to be concluded in H2 2022**
- **No expansion of ongoing lisavanbulin clinical studies; exploring partnering opportunities**
- **Derazantinib rights to be transferred back to Merck & Co. by the end of 2022**
- **No material expenses related to oncology activities beyond 2022 and sustainable profitability expected in 2023**
- **Strategy implementation on track**

Basel/Allschwil, Switzerland, June 27, 2022

Basilea Pharmaceutica Ltd (SIX: BSLN), a commercial-stage biopharmaceutical company, announced today an update on the progress made in the implementation of its strategic focus on anti-infectives.

David Veitch, Chief Executive Officer, stated: “We have made significant progress in the implementation of our new strategy. With regard to our oncology business, we have run a broad partnering process, whilst continuing to generate clinical data from the ongoing clinical trials. This allows us now to make informed decisions on each asset in order to ensure that we can focus our resources on our anti-infectives business as of 2023. The ERADICATE phase 3 study exploring ceftobiprole for the treatment of patients with *Staphylococcus aureus* bacteremia, or SAB, is on track to report results shortly and the preclinical profiling of the recently in-licensed potential first-in-class antifungal has also been initiated.”

Partnering discussions for the TTK/PLK1-inhibitor (BAL0891) and preclinical oncology assets are well advanced and expected to be concluded in H2 2022. In line with its strategic priorities and based on data from the ongoing open-label studies, Basilea has decided not to expand the studies for the tumor checkpoint controller lisavanbulin. Ongoing patients will be offered continued access to lisavanbulin, whilst partnering opportunities continue to be explored. With regard to the FGFR inhibitor derazantinib, the company has decided to terminate the license agreement and return the rights to Merck & Co, Inc. by the end of the year.[1]

Adesh Kaul, Chief Financial Officer, added: “Our broad partnering outreach has resulted, as intended, in discussions on a variety of possible partnering structures. We concluded that entering into separate transactions for our oncology assets would generate most long-term

value. With regard to derazantinib, the changing competitive landscape and the evolving clinical data from our open-label studies led us to conclude that a transaction could not be closed at the terms and within the timelines required. We believe that based on the partnering progress and our portfolio decisions we are now well on track to ensure that Basilea generates sustainable positive operating cash flow and profits as of 2023."

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) and susceptible *Pseudomonas* spp.[2] The brand is currently approved and marketed as Zevtera and Mabelio in a number of countries in Europe and beyond. Basilea has entered into license and distribution agreements in Europe, Eurasian countries, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA) regions.

About the ERADICATE phase 3 study

The ERADICATE study[3] is a randomized, double-blind, multicenter phase 3 study in patients with SAB to assess the safety and efficacy of intravenous ceftobiprole medocaril compared with intravenous daptomycin, plus optional intravenous aztreonam for coverage of Gram-negative pathogens.[4]

About *Staphylococcus aureus* bacteremia (SAB)

Staphylococcus aureus bacteremia is a leading cause of bloodstream infections, responsible for a broad variety of complications and has been associated with significant morbidity and a mortality of 20 to 40%.[5, 6] Several studies have demonstrated that MRSA bacteremia is associated with a significantly higher mortality rate compared with MSSA bacteremia.[7, 8] Infections of the inner lining of the heart or heart valves (infective endocarditis) and bone infections (osteomyelitis) are common complications of SAB.

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 medical needs of patients with 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 severe bacterial infections. In addition, we have several preclinical 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. Derazantinib, lisavanbulin and BAL0891 and their uses are investigational and have not been approved by a regulatory authority for any use. Efficacy and safety have not been established. The information presented should not be construed as a recommendation for use. The relevance of findings in nonclinical/preclinical studies to humans is currently being evaluated.

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. Basilea has in-licensed derazantinib from ArQule Inc., a wholly-owned subsidiary of Merck & Co., Inc., Kenilworth, N.J., U.S.A.
2. Summary of Product Characteristics (SmPC) Zevtera: https://www.medicines.org.uk/emc/product/9164/smpc [Accessed: June 24, 2022]
3. ERADICATE: ClinicalTrials.gov identifier NCT03138733
   K. Hamed, M. Engelhardt, M. E. Jones et al. Ceftobiprole versus daptomycin in Staphylococcus aureus bacteremia: a novel protocol for a double-blind, Phase III trial. Future Microbiology. 2020 (1), 35-48
4. Basilea's ceftobiprole phase 3 program is funded in part (up to USD 134.2 million, which is approximately 70% of the total potential program costs) with federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201600002C.

5. A. G. Jensen, C. H. Wachmann, F. Espersen et al. Treatment and outcome of Staphylococcus aureus bacteremia: a prospective study of 278 cases. Archives of Internal Medicine 2002 (162), 25-32
6. J.-L. Wang, S.-Y. Chen, J.-T. Wang et al. Comparison of both clinical features and mortality risk associated with bacteremia due to community-acquired methicillin-resistant Staphylococcus aureus and methicillin-susceptible S. aureus. Clinical Infectious Diseases 2008 (46), 799-806
7. S. I. Blot, K. H. Vandewoude, E. A. Hoste et al. Outcome and attributable mortality in critically ill patients with bacteremia involving methicillin-susceptible and methicillin-resistant Staphylococcus aureus. Archives of Internal Medicine 2002 (162), 2229-2235
8. S. E. Cosgrove, G. Sakoulas, E. N. Perencevich et al. Comparison of mortality associated with methicillin-resistant and methicillin-susceptible Staphylococcus aureus bacteremia: a meta-analysis. Clinical Infectious Diseases 2003 (36), 53-59