Ad hoc announcement pursuant to Art. 53 LR

Basilea enters into agreement with BARDA to develop novel antifungals and antibacterials and receives initial funding

- **Initial funding of USD 29 million to support development of Basilea's clinical stage first-in-class antifungals, fosmanogepix and BAL2062**
- **Multi-year Other Transaction Agreement (OTA) allows for potential funding of up to approximately USD 268 million to develop antifungal and antibacterial assets**
- **Increasing FY 2024 financial guidance on total revenue, operating result and net profit**

Allschwil, Switzerland, September 19, 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, announced today that the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the US Department of Health and Human Services, has awarded Basilea an Other Transaction Agreement (OTA), under OTA number 75A50124C00033. As a result, Basilea increases its financial guidance for the full year 2024.

David Veitch, Chief Executive Officer of Basilea, said: "Basilea has been working with BARDA since 2013. In continuing this partnership through an OTA, we will be leveraging our strong portfolio and the capabilities of our organization to develop urgently needed novel antifungals and antibacterials. We believe this long-term partnership will also lead to the successful implementation of our strategy to become a leading anti-infectives company."

Under the terms of the OTA, BARDA will support the development of designated novel, first-in-class antifungals and antibacterials in Basilea's portfolio with a total potential non-dilutive funding of up to approximately USD 268 million over up to twelve years, if all additional options to extend the contract are exercised by BARDA upon successful completion of pre-defined milestones, including clinical and regulatory activities.

With the signing of the OTA, initial BARDA funds of USD 29 million have been committed to support the development of the antifungals fosmanogepix and BAL2062. BARDA's financial contribution is assumed to be about 60% of the total costs over the term of the OTA.

Under the OTA, BARDA and Basilea can jointly decide to move candidates into and out of the portfolio based on product performance, technical risk, and programmatic need. This flexibility results in significant time, effort, and cost savings to both partners.

Increasing full-year (FY) 2024 financial guidance

Reflecting the near-term impact of the OTA, Basilea updates its financial guidance for the full year 2024. Development costs under the OTA will continue to be reported under research and development expenses. The BARDA reimbursements will be reported under other revenue, resulting in increased total revenue and unchanged operating expenses. Also, additional deferred taxes are recognized due to the expected positive effect of the OTA on the company's medium-term financial outlook. This results in a higher operating result and net profit for FY 2024.

(In CHF million)	FY 2024e (new)	FY 2024e (previous)	FY 2023
Cresemba and Zevtera-related revenue	~190	~190	150.3
of which royalty income	*~92*	*~92*	*78.9*
Total revenue	~203	~196	157.6
Cost of products sold	~40	~40	26.8
Operating expenses	~120	~120	111.7
Operating result	~43	~36	19.2
Net profit	~60	~42	10.5

About fosmanogepix

Fosmanogepix is a clinical-stage broad-spectrum antifungal. It has a novel mechanism of action and its active moiety has shown activity against common species of *Candida* and *Aspergillus*, including multi-drug-resistant strains, such as *Candida auris* and *Candida glabrata*, as well as rare difficult-to-treat molds including *Fusarium* spp., *Scedosporium* spp., and some fungi from the Mucorales order.[1] Fosmanogepix is available in intravenous and oral formulations and has been evaluated for efficacy and safety in a phase 1 / phase 2 program, including three open-label phase 2 studies for the treatment of Candidemia, including *Candida auris*, and invasive mold infections.[1, 2, 3, 4] Basilea will initiate shortly a double-blind non-inferiority phase 3 study in invasive yeast infections.[5] Fosmanogepix has received Fast Track and Orphan Drug designations from the US Food and Drug Administration for seven separate indications, and is designated as a Qualified Infectious Disease Product (QIDP) for the treatment of four indications.

About BAL2062

BAL2062 is a first-in-class antifungal, derived from a natural product, and has demonstrated fungicidal activity against clinically important molds such as *Aspergillus* spp., including azole-resistant strains.[6] Safety and tolerability have been demonstrated in a previously completed phase 1 study with single and multiple ascending intravenous (i.v.) doses.[7] The drug candidate has Qualified Infectious Disease Product (QIDP), Orphan Drug and Fast Track designation from the US Food & Drug Administration (FDA) for invasive aspergillosis.

About invasive mold infections

Invasive aspergillosis and invasive infections with rare molds (e.g., *Fusarium* spp., *Scedosporium* spp., and Mucorales fungi) are life-threatening infections that predominantly affect immunocompromised patients, including patients with hematologic malignancies (blood cancer), transplant patients, or patients with other immunodeficiency disorders. These infections are associated with high morbidity and mortality.[8, 9]

About invasive candidiasis

Invasive candidiasis, including deep-seated tissue candidiasis and candidemia, is an increasingly important nosocomial infection, especially in patients hospitalized in intensive care units. *Candida* species are ranked as the fourth main cause of bloodstream infections in hospitals in the US.[10] The prognosis of invasive candidiasis remains difficult, with a reported mortality rate for invasive candidiasis as high as 40%, even when patients receive antifungal therapy.[11]

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.

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, Allschwil 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, Allschwil to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd, Allschwil 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.

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

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