

Ad hoc announcement pursuant to Art. 53 LR

Basilea receives USD 39 million funding under BARDA agreement to continue to advance novel antifungals fosmanogepix and BAL2062

Allschwil, Switzerland, July 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, announced today that the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services, committed the next USD 39 million to Basilea to continue to advance the development of Basilea's novel antifungals fosmanogepix and BAL2062. This additional funding is based on the successful completion of a milestone within the "Other Transaction Agreement" (OTA, agreement number 75A50124C00033) that was awarded on September 30, 2024, and which allows for potential funding of up to approximately USD 268 million in total to develop antifungal and antibacterial assets.

David Veitch, Chief Executive Officer of Basilea, said: "We are very pleased to receive the continued funding under the OTA with BARDA to support the development of our antifungal drug candidates fosmanogepix and BAL2062. Both compounds offer a novel mechanism of action and represent new therapeutic options for patients with aspergillosis, candidiasis or other life-threatening fungal infections. These infections primarily affect patients with weakened immune systems, such as cancer or transplant patients. Infections with difficult-to-treat rare molds or with resistance to current therapies are increasing. Hence, there continues to be a high medical need for new innovative antifungals."

He added: "This second tranche of funding within the BARDA OTA will support the ongoing phase 3 study with fosmanogepix in yeast infections and the second phase 3 study, in mold infections, which is expected to start soon. It also provides funding for the preparation for the start of the phase 2 study for our antifungal BAL2062."

The USD 39 million is in addition to the initial USD 29 million BARDA committed at the signing of the OTA in September 2024. BARDA's financial contribution is about 60% of the total costs of the supported projects over the term of the OTA, which could provide a total potential non-dilutive funding of up to approximately USD 268 million, over up to 12 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.

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 intravenous and oral formulations have been evaluated in clinical phase 2 studies for the treatment of patients with Candidemia, including *Candida auris* infections, and invasive mold infections.¹ A phase 3 study evaluating fosmanogepix in the treatment of adult patients with candidemia and/or invasive candidiasis is ongoing and the initiation of a second phase 3 study, in the treatment of adult patients with invasive mold infections, is expected soon.² Fosmanogepix has received Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration for a number of indications, and is designated as a Qualified Infectious Disease Product (QIDP).

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.³ Safety and tolerability have been demonstrated in a previously completed phase 1 study with single and multiple ascending intravenous (i.v.) doses.⁴ The drug candidate has Qualified Infectious Disease Product (QIDP), Orphan Drug and Fast Track designation from the US Food and 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.^{5,6}

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.⁷ 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.⁸

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.

This project has been funded in part with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under OT number: 75A50124C00033. The contract and federal funding are not an endorsement of the study results, product, or company.

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. K. J. Shaw, A. S. Ibrahim. Fosmanogepix: A Review of the First-in-Class Broad Spectrum Agent for the Treatment of Invasive Fungal Infections. *Journal of Fungi (Basel)* 2020 (6), 239
2. FAST study (candidemia/invasive candidiasis): ClinicalTrials.gov identifier NCT05421858; FORWARD study (invasive mold infections): ClinicalTrials.gov identifier NCT06925321

3. K. J. Shaw. GR-2397: Review of the Novel Siderophore-like Antifungal Agent for the Treatment of Invasive Aspergillosis. *Journal of Fungi (Basel)* 2022 (8), 909
4. ClinicalTrials.gov identifier NCT02956499: M. P. Mammen, D. Armas, F. H. Hughes et al. First-in-Human Phase 1 Study To Assess Safety, Tolerability, and Pharmacokinetics of a Novel Antifungal Drug, VL-2397, in Healthy Adults. *Antimicrobial Agents and Chemotherapy* 2019 (63), e00969-19
5. J. Cadena, G. R. Thompson 3rd, T. F. Patterson. Aspergillosis: Epidemiology, Diagnosis, and Treatment. *Infectious Disease Clinics of North America* 2021 (35), 415-434
6. M. Slavin, S. van Hal, T. C. Sorrell et al. Invasive infections due to filamentous fungi other than *Aspergillus*: epidemiology and determinants of mortality. *Clinical Microbiology and Infection* 2015 (21), 490.e1-490.e10
7. Candidemia (Blood Infection) and Other *Candida* Infections. 2019 Factsheet by the American Thoracic Society: <https://www.thoracic.org/patients/patient-resources/resources/candidemia.pdf> (Accessed: July 07, 2025)
8. B. J. Kullberg, M. C. Arendrup. Invasive Candidiasis. *The New England Journal of Medicine* 2015 (373), 1445-1456