Press release

Basilea initiates phase 3 study with antifungal fosmanogepix in invasive mold infections

- **Study to evaluate the efficacy and safety of fosmanogepix in adults with invasive mold infections**
- **Study completion expected in Q1 2028**

Allschwil, Switzerland, July 29, 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 the initiation of FORWARD-IM, a phase 3 registrational study evaluating the efficacy and safety of its broad-spectrum antifungal fosmanogepix for the treatment of adult patients with invasive mold infections.[1]

Fosmanogepix is a first-in-class antifungal with a novel mechanism of action and is available in both intravenous and oral formulations. It has been evaluated for efficacy and safety in a phase 1 and phase 2 program, including three open-label phase 2 studies for the treatment of Candidemia, including *Candida auris*, and invasive mold infections.[2, 3, 4, 5, 6]

The FORWARD-IM study is the second phase 3 study for fosmanogepix, following the initiation of FAST-IC in September 2024, a randomized, double-blind phase 3 registrational study in adult patients with candidemia and/or invasive candidiasis.[7]

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, said: "Our phase 3 program with fosmanogepix allows us to fully explore the clinical benefit of this important new treatment option for invasive fungal infections. Its broad-spectrum activity against multidrug-resistant molds and yeasts highlights the unique potential of fosmanogepix to address significant gaps in current antifungal therapies. Fosmanogepix has shown promising efficacy in earlier clinical studies and in the ongoing expanded access program. The initiation of our second phase 3 study is a significant milestone for fosmanogepix and demonstrates our commitment to advancing our innovative pipeline for the benefit of patients."

FORWARD-IM is an interventional, open-label, two-cohort phase 3 study in adult patients with invasive mold infections caused by *Aspergillus* spp., *Fusarium* spp., *Lomentospora prolificans*, Mucorales fungi, or other multidrug-resistant molds. The first cohort will enroll approximately 160 patients, randomized in a 2:1 ratio to receive either fosmanogepix or current standard-of-care therapy. The second cohort will enroll approximately 60 patients who have developed intolerance, toxicities, lack of clinical response, or whose fungal isolate is resistant to standard-of-care therapy. All patients in the second cohort will receive fosmanogepix. The completion of

the study and publication of results are expected in 2028. The Swiss-based global company PSI CRO AG is managing the phase 3 program.

Basilea acquired fosmanogepix from Amplyx Pharmaceuticals, Inc., an affiliate of Pfizer Inc. Pfizer retains a right of first negotiation for commercializing fosmanogepix, once phase 3 development is successfully completed.

This project is funded in part with federal funds from the U.S. Department of Health and Human Services (HHS); Administration of 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.

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., *Lomentospora prolificans*, *Scedosporium* spp., and some fungi from the Mucorales order.[2] Fosmanogepix intravenous and oral formulations have been evaluated in phase 2 studies for the treatment of patients with Candidemia, including *Candida auris*, and invasive mold infections.[4, 5, 6] Fosmanogepix has received Fast Track and Orphan Drug designations from the US Food and Drug Administration (FDA) for seven separate indications, and is designated as a Qualified Infectious Disease Product (QIDP).

About invasive mold infections

Invasive aspergillosis and invasive infections with rare molds (e.g., *Fusarium* spp., *Lomentospora prolificans*, *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 immuno-deficiency 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 unfavorable, with a reported mortality rate 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.

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This press release can be downloaded from www.basilea.com.

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