

Press release

Basilea initiates clinical phase 3 study with antifungal fosmanogepix in candidemia and invasive candidiasis

Allschwil, Switzerland, September 24, 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 it has initiated the Fosmanogepix Against Standard-of-care Treatment in Invasive Candidiasis (FAST-IC) phase 3 study. This registrational study evaluates the efficacy and safety of Basilea's broad-spectrum antifungal fosmanogepix in the treatment of adult patients with candidemia and/or invasive candidiasis, that is *Candida* yeast bloodstream or deep-seated tissue infections.¹

Fosmanogepix is a first-in-class antifungal treatment candidate with a novel mechanism of action. It 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.^{2, 3, 4, 5}

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, said: "We are very pleased to have activated the first study center in the phase 3 program for fosmanogepix and look forward to enrolling patients into FAST-IC. Invasive *Candida* infections are life-threatening complications for many hospitalized patients and associated with high mortality, and fosmanogepix offers a potential new treatment option in this high medical need area. In addition, we are working towards starting the second phase 3 study investigating fosmanogepix in the treatment of adult patients with invasive mold infections around year-end."

FAST-IC is a global, multi-center, randomized, active-controlled, double-blind phase 3 study and investigates intravenous (i.v.) fosmanogepix versus a standard-of-care regimen of i.v. caspofungin in adult patients with candidemia and/or invasive candidiasis. The study is expected to enroll approximately 450 patients, who will be randomized in a 2:1 ratio to either fosmanogepix or caspofungin. There is an optional oral switch to fosmanogepix in the fosmanogepix group and to fluconazole in the caspofungin group. The Swiss-based global company PSI CRO AG will manage the phase 3 program.

Basilea acquired fosmanogepix from Amplyx Pharmaceuticals, Inc., an affiliate of Pfizer Inc., in November 2023. Under the terms of the asset purchase agreement, Basilea assumed all rights and obligations from previous agreements, and will make a USD 6.0 million milestone payment under these obligations, upon the enrolment of the first patient, which is fully reflected in Basilea's most recent financial guidance for the full year 2024.



This project has been 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., *Scedosporium* spp., and some fungi from the Mucorales order.² Fosmanogepix intravenous and oral formulations have been evaluated in clinical phase 2 studies for the treatment of patients with Candidemia, including *Candida auris*, and invasive mold infections.² 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).

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.^{6,7}

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.⁸ The prognosis of invasive candidiasis remains difficult, with a reported mortality rate as high as 40%, even when patients receive antifungal therapy.⁹

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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