

Press release

Basilea reports presentation of new data for fosmanogepix, isavuconazole (Cresemba[®]) and ceftobiprole (Zevtera[®]) at ESCMID Global 2025

Allschwil, Switzerland, April 16, 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 scientific presentations on Basilea's clinical-stage novel antifungal fosmanogepix given at ESCMID Global 2025, the annual meeting of the European Society of Clinical Microbiology and Infectious Diseases, which took place from April 11 to 15, 2025 in Vienna, Austria. Further presentations covered the antifungal isavuconazole (Cresemba[®]) and the antibiotic ceftobiprole (Zevtera[®]).

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, said: "Invasive fungal infections are an increasing global health problem and novel antifungals are urgently needed. To date more than 250 patients suffering from difficult-to-treat invasive fungal infections have received fosmanogepix via expanded access. The data presented at ESCMID highlight the potential of fosmanogepix as a life-saving treatment option in severe fungal infections, based on the results from a large cohort of patients with invasive fusariosis, as well as from patients with mucormycosis, who received fosmanogepix via expanded access. We look forward to the start of our second phase 3 study with fosmanogepix covering a broad range of mold infections, including aspergillosis, fusariosis and mucormycosis."

More than 250 patients from 11 countries with serious or life-threatening invasive fungal infections, who progressed on antifungal standard-of-care treatment, experienced treatment-limiting toxicities, or had infections with resistant fungal pathogens, received fosmanogepix via expanded access to date (NCT06433128). As presented at ESCMID, treatment with fosmanogepix resulted in favorable response rates of 70% or higher in patients with invasive fusariosis or mucormycosis and it was tolerated for long treatment durations.

Further presentations reported on the activity of fosmanogepix against diverse yeast and mold species collected as part of a worldwide surveillance program.

Fosmanogepix data presented at ESCMID Global 2025

- Presentation IPT13: Fosmanogepix – a novel clinical phase 3 stage antifungal agent – M. Engelhardt
- Presentation O0419: Fosmanogepix expanded access in patients with *Fusarium* infections – S. Dadwal, A. Baluch, J. Dickter, J. R. Newman, M. H. Nguyen, R. Weihe, H. Schlamm, L. Ostrosky-Zeichner
- Poster P4164: Fosmanogepix expanded access case series in patients with mucormycosis – A. Puing, A. Kaur, Y. J. Lee, P. Chang, A. Koff, D. Tyungu, M. Oldham, M. Shaughnessy, A. Tande, H. Schlamm, J. Maertens
- Poster E0237: Activity of manogepix against a worldwide collection of mould isolates from 2023 – M. Winkler, S. Edeker, A. Klauer, P. R. Rhomberg, M. Castanheira
- Poster P2891: Activity of manogepix against a worldwide collection of yeast isolates from 2023 – M. Winkler, S. Edeker, A. Klauer, P. R. Rhomberg, M. Castanheira

Isavuconazole (Cresemba) data presented at ESCMID Global 2025

- Poster P2944: Deciphering Connections between Isavuconazole (ISAV) Drug Exposures and Responses Among Different Infections: Mucorales – L. Kovanda, A. Desai
- Poster P2945: Deciphering Connections Between Isavuconazole Drug Exposures and Responses Among Different Infections: Dimorphic Fungi/Mould/Other Filamentous Fungi and Mixed Infections – A. Desai, L. Kovanda
- Poster P2946: Deciphering Connections Between Isavuconazole Drug Exposures and Responses Among Different Infections: Invasive Candidiasis – L. Kovanda, A. Desai
- Poster E0050: Enhancing Isavuconazole Pharmacokinetics: A Comprehensive Population (PPK) Model from Three Phase 3 Trials and Covariate Exploration – A. Desai, L. Kovanda

- Poster E0055: High-dose isavuconazole therapy is well-tolerated and significantly improves survival in a fruit fly model of invasive mucormycosis – S. Wurster, N. D. Albert, N. P. Wiederhold, R. E. Lewis, D. P. Kontoyiannis

Ceftobiprole (Zevtera) data presented at ESCMID Global 2025

- Poster E0792: Ceftobiprole alone versus in combination with ampicillin against borderline penicillin-resistant, vancomycin-resistant *Enterococcus faecalis* – O. Funk, I. Khan, J. Li, J. Cusumano

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.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).

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 Cresemba® (isavuconazole)

Cresemba, with the active ingredient isavuconazole, is an intravenous (i.v.) and oral azole antifungal. In the 27 European Union member states, as well as in Iceland, Liechtenstein and Norway, isavuconazole is approved for patients aged from 1 year of age and older for the treatment of invasive aspergillosis and for the treatment of mucormycosis in patients for whom amphotericin B is inappropriate.³ Isavuconazole is also approved in the United States (US)⁴ and several additional countries in Europe and beyond, including the United Kingdom⁵, the Middle East and North Africa region, the Asia Pacific region, China and Japan.⁶ It has orphan drug designation in the US, Europe and Australia for its approved indications.

About Zevtera® (ceftobiprole medocartil sodium for injection)

Ceftobiprole, the active moiety of the prodrug ceftobiprole medocartil, is an advanced generation cephalosporin antibiotic for intravenous administration, with rapid bactericidal activity against a wide range of Gram-positive bacteria, such as *Staphylococcus aureus*, including methicillin-resistant strains (MRSA), and Gram-negative bacteria.⁷ In several countries in Europe and beyond, the brand is currently approved and marketed as Zevtera® and Mabelio® for the treatment of adult patients with hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated bacterial pneumonia (VABP), and for the treatment of community-acquired bacterial pneumonia (CABP).⁷ In the United States, ZEVTERA® is indicated for the treatment of adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) (SAB), including right-sided infective endocarditis, and adult patients with acute bacterial skin and skin structure infections (ABSSSI) and for adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP).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](https://www.basilea.com).

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

References

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4. Full US prescribing information: <https://www.astellas.us/docs/cresemba.pdf> [Accessed: April 15, 2025]
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