Press release

Basilea provides portfolio update and outlook

- **Clinical portfolio strengthened through the in-licensing of phase 3-ready antibiotic ceftibuten-ledaborbactam**
- **Fosmanogepix second phase 3 study initiated; two phase 3 studies in invasive fungal infections progressing as planned**
- **Two new preclinical collaborations to develop novel antibacterial and antifungal drugs**
- **Cresemba continued strong double-digit in-market sales growth**

Allschwil, Switzerland, January 08, 2026

Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, reported today on the progress within its R&D and commercial portfolio during 2025 and outlined the upcoming milestones and timelines.

David Veitch, Chief Executive Officer, highlighted: "We entered 2025 from a position of strength and closed the year even stronger, thanks to outstanding execution and significant progress across all fronts. During 2025, we delivered on every goal we set."

He continued: "Cresemba celebrated its 10th year on the market with continued commercial success, achieving strong global in-market sales and expanding its reach to more than 75 countries. Zevtera was successfully launched in the US, its commercially most important market, while our R&D pipeline advanced toward next milestones. This included fosmanogepix entering its second phase 3 study and the in-licensing of ceftibuten-ledaborbactam, a novel oral antibiotic for complicated urinary tract infections (cUTI). These programs are designed to drive medium-term growth and are progressing fully in line with our plan."

He concluded: "Our business model is anchored in strong partnerships. Recently, we forged two new collaborations in preclinical development: one focused on artificial intelligence (AI)-driven antibacterial drug design and the other on antifungal drug development. These partnerships combine our expertise in anti-infectives with our partners' specialized capabilities to strengthen our early-stage pipeline. At the same time, existing partnerships remained robust. We secured substantial non-dilutive funding through the Other Transactions Agreement (OTA) with the Biomedical Advanced Research and Development Authority (BARDA)[1] for our antifungals fosmanogepix and BAL2062, and a prior BARDA contract was novated to Basilea following the in-licensing of the antibiotic ceftibuten-ledaborbactam. Commercial partnerships also delivered multiple milestone payments from Europe, China/Asia-Pacific, and Japan, underscoring the success of our commercial products as they address patients' needs worldwide."

Portfolio key highlights 2025 and outlook 2026

Cresemba® (isavuconazole): Reinforcing position as global market leader by value

- In April, Cresemba marked its 10-year anniversary since first commercial launch, reaffirming its position as the global market leader by value.
- Over the past decade, about half a million patients worldwide have been treated with Cresemba.[2]
- This achievement reflects the strong collaboration with our commercial partners, now having Cresemba available in more than 75 countries.
- According to the latest available market data, total global in-market sales of Cresemba in the twelve-month period between October 2024 and September 2025 amounted to USD 693 million, reflecting a 27 percent growth year-on-year, making it the largest branded antifungal for invasive fungal infections worldwide.[3]

Zevtera® (ceftobiprole): Establishing a novel treatment option for *Staphylococcus aureus* bacteremia (SAB) in the US

- Zevtera is now available in the US[4, 5], already achieving important hospital formulary wins and is also now included in major hospital purchasing organizations contracts.
- Secured US reimbursement and access pathways, New Technology Add-On Payment (NTAP) designation as innovative inpatient treatment, as well as Medicaid and 340B pricing and J-code for outpatient billing programs to support affordability and patient access.
- Repeat orders from major hospitals reflecting positive clinical experience with Zevtera among early adopters.

Fosmanogepix: Advancing phase 3 program in invasive mold and yeast infections

- FORWARD-IM, a phase 3 registrational study evaluating the efficacy and safety of the broad-spectrum antifungal fosmanogepix in adult patients with invasive mold infections, was initiated in July.[6] This phase 3 study is currently active at 15 sites, with about 40 additional sites planned to initiate during H1 2026.
- FORWARD-IM is the second phase 3 study for fosmanogepix, following the initiation of FAST-IC in September 2024, which evaluates fosmanogepix in invasive yeast infections. FAST-IC is currently active at more than 100 sites worldwide, with additional sites planned to initiate during Q1 2026, including 22 new sites in China.[7]
- Together, the two phase 3 studies are designed to support a broad treatment label to maximize patient reach, reflecting the broad-spectrum activity of fosmanogepix across both invasive mold and yeast infections. Both studies are progressing as planned, with

topline results anticipated in H1 2028, and the regulatory submission to follow shortly afterwards.
- The development of Basilea's antifungals fosmanogepix and BAL2062 is largely supported through an OTA agreement with BARDA.[8] In 2025, BARDA committed USD 64 million in two tranches following the successful achievement of predefined development milestones.

Ceftibuten-ledaborbactam: addressing unmet needs in cUTI

- In August, we secured global rights to ceftibuten-ledaborbactam (CTB-LEDA) through an exclusive licensing agreement with Venatorx Pharmaceuticals. CTB-LEDA is an oral beta-lactam/beta-lactamase inhibitor (BL/BLI) combination developed to treat cUTI, including certain kidney infections (acute pyelonephritis).
- In September, a prior BARDA contract was novated from Venatorx to Basilea, providing significant non-dilutive funding of up to USD 159 million to support the cUTI program.[9] The first tranche of USD 6 million has already been committed, with additional tranches expected upon achievement of predefined development milestones.
- We are on track to initiate the phase 3 clinical program in Q1 2027, following regulatory interactions planned during 2026. Given the anticipated high patient enrollment rates, we are also focusing during 2026 on securing drug-supply, enabling efficient trial execution in 2027 and 2028 and a topline readout in early 2029.

Early-stage pipeline programs: Completed preclinical profiling and advancing toward next inflection points

- We have successfully completed the preclinical profiling of the first-in-class LptA inhibitor antibiotic BAL2420[10] and expect to initiate a first in-human clinical study in the first half of 2026. BAL2420 is being developed to address severe infections caused by Gram-negative bacteria.
- Preclinical profiling of the antifungal BAL2062 has also been successfully completed. In 2026 we expect to conclude discussions with regulatory authorities to define the optimal phase 2 and phase 3 clinical development pathways for this drug-candidate.

New R&D partnerships: Driving long-term value creation

In December and January, we entered into two collaborations aimed at accelerating innovation and strengthening our early-stage pipeline with high-potential drug candidates to support long-term growth:

- Phare Bio partnership: This collaboration leverages cutting-edge technologies to transform antibiotic discovery by combining generative AI with Basilea's proven expertise in anti-infectives and clinical development. Using AI to design new molecules

will enable faster, more efficient development of novel antibiotics that address significant unmet medical needs.

- Prokaryotics Inc. collaboration: Focuses on developing a first-in-class, broad-spectrum antifungal drug-candidate targeting severe invasive fungal infections. This new class of antifungals will be designed to deliver effective, safe and easy-to-administer treatments, addressing significant market needs.

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.

References

1. The Biomedical Advanced Research and Development Authority (BARDA) is part of the Administration for Strategic Preparedness and Response (ASPR) within the US Department of Health and Human Services
2. Data on file, Basilea Pharmaceutica International Ltd, Allschwil
3. IQVIA Analytics Link, September 2025. In-market sales reported as moving annual total (MAT) in US dollar.
4. Full US prescribing information: https://innovivaspecialtytherapeutics.com/wp-content/uploads/2025/05/Prescribing-Information-Zevtera.pdf [Accessed: January 07, 2026]
5. Basilea's ceftobiprole phase 3 program is funded in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201600002C. Basilea has been awarded approximately USD 111 million, or approximately 75 percent of the costs related to the *Staphylococcus aureus* bacteremia (SAB) and acute bacterial skin and skin structure infections (ABSSSI) phase 3 studies, regulatory activities and non-clinical work
6. ClinicalTrials.gov ID NCT06925321
7. ClinicalTrials.gov ID NCT05421858
8. BARDA OTA number: 75A50124C00033
9. BARDA agreement number: 75A50123C00050
10. CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) funding for this project is provided in part by federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority; Antibacterials branch; under agreement number 75A50122C00028; and by awards from Wellcome (WT224842) and Germany's Federal Ministry of Education and Research (BMBF).