

Ad hoc announcement pursuant to Art. 53 LR

Basilea awarded BARDA contract for the development of novel oral phase 3-ready antibiotic ceftibuten-ledaborbactam

- **Total non-dilutive funding of up to USD 159 million upon completion of predefined milestones, including near-term committed funding of USD 6 million**

Allschwil, Switzerland, September 25, 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 US Department of Health and Human Services, has novated a contract from Venatorx Pharmaceuticals, Inc. (Venatorx) to Basilea to support the development of the novel oral antibiotic ceftibuten-ledaborbactam etzadroxil, a beta-lactam/beta-lactamase inhibitor (BL/BLI) combination, for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis. Basilea recently acquired the global rights to ceftibuten-ledaborbactam etzadroxil from Venatorx.

David Veitch, Chief Executive Officer of Basilea, said: "We thank BARDA for their continued collaboration and support for the development of novel anti-infectives to help patients with severe infections. The funding helps us to further advance our newly in-licensed novel antibiotic ceftibuten-ledaborbactam, which we believe holds a strong promise in addressing the critical unmet need for the oral treatment of cUTIs caused by multidrug-resistant Gram-negative bacteria."

The existing funding agreement between BARDA and Venatorx was novated, with Basilea replacing Venatorx as a contracting party. Under the terms of the contract, Basilea will be reimbursed for a portion of the development costs required to bring ceftibuten-ledaborbactam etzadroxil to market, including the planned Phase 3 clinical studies. The non-dilutive funding comprises an initial amount of approximately USD 6 million and options to provide up to USD 153 million of additional non-dilutive funding upon completion of predefined milestones.

About beta-lactam/beta-lactamase inhibitor (BL/BLI) combinations

Many Gram-negative bacteria express enzymes such as extended spectrum beta-lactamases (ESBL) that confer resistance against commonly used antibiotics. Beta-lactamase inhibitors block these enzymes and restore the activity of beta-lactam antibiotics against initially resistant Gram-negative bacteria, therefore BL/BLI combinations are an important addition to the armamentarium for the treatment of infections caused by multidrug-resistant bacterial pathogens.

About ceftibuten-ledaborbactam etzadroxil

Ledaborbactam etzadroxil is the orally bioavailable prodrug of ledaborbactam, a novel broad-spectrum boronic acid beta-lactamase inhibitor, which is being developed in combination with ceftibuten, an oral cephalosporin antibiotic, which is approved in the US for the treatment of upper and lower respiratory tract infections and for urinary tract infections outside the US. *In vitro* and *in vivo* studies demonstrated that ledaborbactam etzadroxil restores the activity of ceftibuten against strains of Enterobacterales expressing Ambler class A extended spectrum beta-lactamases (ESBLs), class C cephalosporinases, and class A and D carbapenemases (KPC and OXA-48, respectively) as well as multidrug-resistant (MDR) Enterobacterales.^[1] Ceftibuten-ledaborbactam etzadroxil has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the US Food and Drug Administration (FDA) for cUTI and uncomplicated urinary tract infections. Ceftibuten-ledaborbactam etzadroxil is an investigational drug and is not yet approved in any country for commercial use.

About complicated urinary tract infections (cUTI)

Complicated UTIs, which include pyelonephritis (kidney infections), are defined as urinary tract infections ascending from the bladder accompanied by local and systemic signs and symptoms and are one of the most common bacterial infections in hospital and community settings.

Increasing resistance of bacteria causing complicated urinary tract infections has led to limited availability of effective oral antibiotic treatment options.^[2] Currently, there are no approved oral beta-lactam or beta-lactam/beta-lactamase inhibitor combinations that are effective against Enterobacterales expressing Ambler class A ESBLs, class C cephalosporinases, and class A & D serine carbapenemases (KPC and OXA-48).

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 ad hoc announcement can be downloaded from www.basilea.com.

References

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2. T. P. Lodise, T. Chopra, B. H. Nathanson et al. Epidemiology of Complicated Urinary Tract Infections due to *Enterobacterales* Among Adult Patients Presenting in Emergency Departments Across the United States. *Open Forum Infectious Diseases* 2022, Jun 24;9(7):ofac315.