Ad hoc announcement pursuant to Art. 53 LR

Basilea announces in-licensing of a novel clinical phase 3-ready oral antibiotic

Allschwil, Switzerland, August 14, 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 it has entered into an exclusive license agreement with Venatorx Pharmaceuticals, Inc., to acquire the global rights to ceftibuten-ledaborbactam etzadroxil, a clinical phase 3-ready oral beta-lactam/beta-lactamase inhibitor (BL/BLI) combination for the potential treatment of complicated urinary tract infections (cUTI), including pyelonephritis.

Ceftibuten-ledaborbactam etzadroxil is the combination of ceftibuten, an orally bioavailable cephalosporin antibiotic, and ledaborbactam etzadroxil, the orally bioavailable prodrug of the novel beta-lactamase inhibitor ledaborbactam. The combination demonstrates bactericidal activity against Enterobacterales, including multidrug-resistant pathogens, the major cause of cUTI.[1] In the USA, cUTI account for more than 600,000 hospital admissions each year.[2] This underscores the significant clinical burden and need for effective oral treatment options, which may shorten or entirely avoid hospitalization. In preclinical and clinical phase 1 studies, ceftibuten and ledaborbactam etzadroxil were shown to be safe and well tolerated.[3]

David Veitch, Chief Executive Officer of Basilea, said: “This agreement allows us to strengthen our late-stage clinical pipeline and supports our strategy of ensuring that we have a continuous stream of potential new product launches in the near-term future, positioning us for sustainable substantial revenue growth. Ceftibuten-ledaborbactam etzadroxil holds strong promise in addressing the critical unmet need for the oral treatment of cUTI caused by multidrug-resistant Gram-negative bacteria and represents a compelling global commercial opportunity. We expect starting a registrational phase 3 program in cUTI in about 18 months.”

Under the terms of the agreement, Basilea will make an upfront payment and potential milestone payments in 2025. Following the successful completion of the phase 3 clinical development program and after the grant of regulatory approval and start of commercialization, Venatorx is eligible to receive tiered mid-single-digit royalties and additional potential milestone payments of up to USD 325 million in total, if all agreed commercial milestone events are triggered over the term of the contract.

The transaction is expected to result in approximately CHF 15 million of additional research and development expenses in 2025, including the full upfront payment, all potential pre-commercial milestone payments and expected R&D expenses in 2025. Basilea will provide updated financial guidance for the full-year 2025, reflecting this transaction, with the half-year earnings report on August 19, 2025.

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 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.[4] 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.[1] 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 Venatorx Pharmaceuticals, Inc.

Venatorx is a private, late-stage clinical pharmaceutical company focused on improving health outcomes for patients with multidrug-resistant bacterial infections and hard-to-treat viral infections. Venatorx also developed cefepime-taniborbactam, an intravenous-only antibiotic that successfully completed a Phase 3 study in adults with complicated urinary tract infections (cUTI), including pyelonephritis. The ceftibuten-ledaborbactam etzadroxil project has been funded in whole or in part with Federal funds from National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201600029C and the Department of Health and Human Services; Office

of the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50123C00050. For more information about Venatorx and its anti-infectives portfolio, please visit www.venatorx.com.

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.

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements, such as "believe", "assume", "expect", "forecast", "project", "may", "could", "might", "will" or similar expressions concerning Basilea Pharmaceutica Ltd, Allschwil and its business, including with respect to the progress, timing and completion of research, development and clinical studies for product candidates. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd, Allschwil to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd, Allschwil is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

For further information, please contact:

Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations
Basilea Pharmaceutica International Ltd, Allschwil
Hegenheimermattweg 167b
4123 Allschwil
Switzerland

Phone +41 61 606 1102

E-mail media_relations@basilea.com
investor_relations@basilea.com

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

References

1. 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.
2. M. D. Zilberberg, B. H. Nathanson, K. Sulham et al. Descriptive Epidemiology and Outcomes of Hospitalizations With Complicated Urinary Tract Infections in the United States, 2018. Open Forum Infectious Diseases 2022, Jan 10;9(1):ofab591
3. C. F. de Oliveira, M. B. Dorr, K. Lowe et al. Evaluation of Single and Multiple Dose Safety and Pharmacokinetics of Ledaborbactam Etzadroxil and Ceftibuten-Ledaborbactam Etzadroxil in Healthy Volunteers. Open Forum Infectious Diseases 2025, Jan 29;12(Suppl 1):ofae631.1425
4. J. A. Karlowsky, M. G. Wise, M. A. Hackel et al. Ceftibuten-Ledaborbactam Activity against Multidrug-Resistant and Extended-Spectrum-β-Lactamase-Positive Clinical Isolates of *Enterobacterales* from a 2018–2020 Global Surveillance Collection. Antimicrobial Agents and Chemotherapy 2022, Nov 15;66(11):e0093422