# Zai Lab and Pfizer Announce Strategic Collaboration on the Novel Antibacterial Drug XACDURO® (Sulbactam-Durlobactam)

November 21, 2024

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 21, 2024-- Zai Lab (“Zai Lab”, NASDAQ: ZLAB; HKEX: 9688) and Pfizer (“Pfizer”, NYSE: PFE) announced today a strategic collaboration for the novel antibacterial drug XACDURO® (sulbactam-durlobactam) in mainland China. Pfizer’s affiliated companies will be exclusively authorized to undertake and perform certain commercialization activities for XACDURO ® in mainland China. Through this collaboration, Zai Lab will leverage the industry-leading commercialization infrastructure of Pfizer’s affiliated companies in the anti-infective therapeutic area to help accelerate access to this important therapy for patients in need in mainland China. The period of collaboration is for the imported product through November 2028, subject to early termination or extension.

XACDURO® is the only antimicrobial agent specifically developed for the treatment of carbapenem-resistant *Acinetobacter baumannii* (CRAB)[1]. It has been approved in the United States and in mainland China for the treatment of adult patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.
The Centers for Disease Control and Prevention (CDC) has identified carbapenem-resistant micro-organisms as an urgent threat[2]. Globally, *Acinetobacter baumannii* was among the top six leading pathogens for deaths associated with resistance in 2019[3], and CRAB is included in the highest priority category, the Critical Group category, in the list of bacterial priority pathogens published by the World Health Organization (WHO) in 2024[4]. In China, *Acinetobacter baumannii* was the leading cause of death attributable to antimicrobial resistance according to the global burden of disease study 2019[5]. Approximately 300,000 *Acinetobacter baumannii* isolates were reported in mainland China in 2022[6].Treatment options for HABP/VABP caused by CRAB infections are limited, and prior to approval of XACDURO®, there remains a lack of gold-standard therapy for CRAB infections[7].

“Drug resistance is becoming increasingly serious, with high clinical mortality rate and poor prognosis in critically ill patients, resulting in a serious disease burden. According to recent surveillance data from China[8], resistance of *Acinetobacter baumannii* to the carbapenem class of antibiotics has reached approximately 74%,” said Josh Smiley, President and Chief Operating Officer of Zai Lab. “Zai Lab was instrumental in the development of XACDURO, leading to its approval in China earlier this year. By joining forces with Pfizer, we seek to bring this innovative treatment to Chinese patients more quickly, saving the lives of those most at risk.”

“Pfizer has been deeply engaged in the anti-infective therapeutic area for many years. We have always been committed to addressing the challenges of multiple microbial infections, including bacterial, fungal as well as viral infections, and to reduce the burden of disease on patients,” said Jean-Christophe Pointeau, President of Pfizer China. “The collaboration with Zai Lab will help enable us to work together as we strive to address the growing problem of drug resistance in the treatment of *Acinetobacter baumannii*, and reflects the new quality productive forces in pharmaceutical companies, helping to achieve the goal of ‘Healthy China’ initiative.”

**About XACDURO® (sulbactam-durlobactam)**

XACDURO® (sulbactam-durlobactam) is an intravenous drug developed by Entasis Therapeutics Inc., an affiliate of Innoviva Specialty Therapeutics, which is a combination of sulbactam, a β-lactam antibiotic, and durlobactam, a β-lactamase inhibitor, or BLI. XACDURO® was approved by the U.S. Food and Drug Administration (FDA) in 2023 and China’s National Medical Products Administration (NMPA) in 2024 for the treatment of adult patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

The NMPA approval is based on positive results from the ATTACK trial (NCT03894046), a global, Phase 3 registrational trial evaluating the safety and efficacy of XACDURO® versus colistin in patients with infections caused by *A. baumannii*. In the pivotal study, XACDURO® demonstrated statistical non-inferiority versus colistin for the primary endpoint of 28-day all-cause mortality in patients with carbapenem-resistant *Acinetobacter* infections and a statistically significant improvement in clinical cure rates. XACDURO® was well tolerated and exhibited a favorable safety profile across the clinical program. Zai Lab participated in the global ATTACK study by enrolling patients in China. The Chinese patient cohort data confirm the findings of the global study regarding mortality and clinical response improvement.

Zai Lab has an exclusive license to develop and commercialize XACDURO® in Greater China (mainland China, Hong Kong, Taiwan and Macau, collectively), Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan from Entasis Therapeutic Inc.

**About Zai Lab**

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide. For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

**Zai Lab Forward-Looking Statements**

This press release contains forward-looking statements relating to Zai Lab's future expectations, plans, and prospects, including, without limitation, statements regarding our plans for commercializing XACDURO®, the potential benefits of XACDURO®; and the potential treatment of certain infections caused by *Acinetobacter baumannii*, including carbapenem-resistant strains. These forward-looking statements may contain words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would," and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact or guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC), which can be found on our website at www.zailaboratory.com and on the SEC's website at www.sec.gov. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

**About Pfizer: Breakthroughs That Change Patients' Lives**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development, and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments, and local communities to support and expand access to reliable, affordable health care around the world. For more than 175 years, we have worked to make a difference for all who rely on us. To learn more, please visit us on our website at www.pfizer.com.cn.

**Pfizer Disclosure Notice**

The information contained in this release is as of November 21, 2024. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a strategic collaboration between Pfizer and Zai Lab for the novel antibacterial drug XACDURO® in mainland China, and Pfizer's efforts to address the challenges of multiple microbial infections, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, risks related to the ability to realize the anticipated benefits of the strategic collaboration, including the possibility that the expected benefits from the strategic collaboration will not be realized or will not be realized within the expected time period; whether XACDURO® will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of XACDURO®; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

**Notes:**


1. El-Ghali A, Kunz Coyne AJ, Caniff K, Bleick C, Rybak MJ. Sulbactam-durlobactam: A novel β-lactam-β-lactamase inhibitor combination targeting carbapenem-resistant Acinetobacter baumannii infections. Pharmacotherapy. 2023;43(6):502-513. doi:10.1002/phar.2802
2. Centers for Disease Control and Prevention, "Carbapenem-resistant Acinetobacter baumannii (CRAB): An urgent public health threat in United States healthcare facilities," August 2021: https://arpsp.cdc.gov/story/cra-urgent-public-health-threat
3. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2022; 399(10325):629-655. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext
4. WHO Bacterial Priority Pathogens List, 2024
5. Zhang C, Fu X, Liu Y, Zhao H, Wang G. Burden of infectious diseases and bacterial antimicrobial resistance in China: a systematic analysis for the global burden of disease study 2019. Lancet Reg Health West Pac. 2023;43:100972. Published 2023 Nov 22. doi:10.1016/j.lanwpc.2023.100972
6. 2022 Annual Report of China Antimicrobial Resistance Surveillance System (CARSS)
7. Zhang S, Di L, Qi Y, Qian X, Wang S. Treatment of infections caused by carbapenem-resistant *Acinetobacter baumannii*.

*Front Cell Infect Microbiol*. 2024;14:1395260. Published 2024 Jul 18. doi:10.3389/fcimb.2024.1395260
8. 2023 Annual Report of China Antimicrobial Surveillance Network (CHINET)

View source version on businesswire.com: https://www.businesswire.com/news/home/20241121825806/en/

**For more information, please contact:**

**Investor Relations:**
Christine Chiou / Lina Zhang
+1 (917) 886-6929 / +86 136 8257 6943
christine.chiou1@zailaboratory.com / lina.zhang@zailaboratory.com

**Media:**
Shaun Maccoun / Xiaoyu Chen
+1 (415) 317-7255 / +86 185 0015 5011
shaun.maccoun@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Source: Zai Lab