# Zai Lab Announces NDA Acceptance of Sulbactam-Durlobactam (SUL-DUR) for Infections Caused by Acinetobacter baumannii in China by the NMPA

February 22, 2023

SHANGHAI and CAMBRIDGE, Mass., Feb. 22, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the National Medical Products Administration (NMPA) in China has accepted the New Drug Application (NDA) for sulbactam-durlobactam (SUL-DUR), an investigational drug that combines sulbactam, a β-lactam antibiotic, and durlobactam, a novel broad-spectrum β-lactamase inhibitor for the treatment of infections caused by *Acinetobacter baumannii,* including multidrug-resistant and carbapenem-resistant (CRAB) strains.

"We are pleased to obtain the NMPA's acceptance of our submission for the registration of SUL-DUR, an intravenous (IV) antibiotic combination for patients with *Acinetobacter* infections including multidrug and carbapenem-resistant strains. SUL-DUR is poised to address a clear unmet medical need as patients face very limited treatment options with this pathogen, which causes serious infections with high mortality. The World Health Organization considers CRAB a top-priority resistant bacteria presenting a serious threat to the public[1], as one of the most significant biologic threats in the hospital setting," said Harald Reinhart, M.D., President and Head of Global Development, Neuroscience, Autoimmune and Infectious Diseases, Zai Lab. "The ATTACK trial has shown SUL-DUR treated patients have lower mortality and less renal toxicity compared to standard-of-care colistin therapy. Zai is committed to working with the NMPA to advance this promising antibiotic that has the potential to address an urgent need in China where approximately two-thirds of *Acinetobacter* bacterial strains are carbapenem-resistant."

In January 2023, Zai Lab announced that the NMPA has granted priority review status to the NDA for SUL-DUR for the treatment of infections caused by *Acinetobacter baumannii*, including multidrug-resistant and CRAB strains.

In November 2022, Zai Lab partner Entasis Therapeutics, a wholly owned subsidiary of Innoviva, announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the NDA for SUL-DUR, an investigational drug that combines sulbactam, a β-lactam antibiotic, and durlobactam, a novel broad-spectrum β-lactamase inhibitor for the treatment of infections caused by *Acinetobacter baumannii,* including CRAB. The Prescription Drug User Fee Act (PDUFA) target date is May 29, 2023.

In October 2021, Zai Lab and Entasis Therapeutics announced positive topline results from the ATTACK trial, a global Phase 3 registrational trial evaluating the safety and efficacy of SUL-DUR versus colistin in patients with infections caused by *Acinetobacter baumannii*. In October 2022, additional safety and efficacy data from the ATTACK trial was presented, further reinforcing the positive safety and efficacy findings from the topline data analysis. Zai Lab participated in the global ATTACK study by enrolling trial patients in China.

Note: (1) Tacconelli, E., Carrara, E., Savoldi, A., Harbarth, S., Mendelson, M., Monnet, D. L., et al. (2018). Discovery, research, and development of new antibiotics: the WHO priority list of antibiotic-resistant bacteria and tuberculosis. *Lancet Infect. Dis*. 18, 318–327. doi: 10.1016/S1473-3099(17)30753-3.

**About sulbactam-durlobactam (SUL-DUR)**
SUL-DUR is an intravenous, or IV, investigational drug developed by Entasis Therapeutics that is a combination of sulbactam, an IV β-lactam antibiotic, and durlobactam, a rationally designed broad-spectrum IV β-lactamase inhibitor, or BLI, being developed for the treatment of infections caused by ABC, including multidrug and carbapenem-resistant strains. SUL-DUR has been designated a Qualified Infectious Disease Product by the FDA, a designation that aims to spur development of new antibiotics for difficult-to-treat infections. The FDA has accepted the SUL-DUR NDA for priority review with an action date of May 29, 2023.

Zai Lab has an exclusive license to develop and commercialize SUL-DUR in Greater China (mainland China, Hong Kong, Taiwan and Macau), Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan.

**About Acinetobacter**
Acinetobacter are Gram-negative, opportunistic human pathogens that predominantly infect critically ill patients often causing severe pneumonia and bloodstream infections. They can also infect other body sites, such as the urinary tract and the skin. ABC is considered a global threat in the healthcare setting due in part to their ability to acquire multidrug resistance. Based on current carbapenem resistance rates, we estimate there are more than 300,000 hospital-treated carbapenem-resistant ABC infections each year globally. These patients often succumb to this infection, and treatment options are very limited[2].

**About *Acinetobacter baumannii* Infections in China**
Based on the 2020 Annual Report of CARSS (China Antimicrobial Resistance Surveillance System), there were around 220,000 Acinetobacter infections reported in 2020 in China, although the actual incidence is estimated to be much larger. The resistance of *Acinetobacter baumannii* to the carbapenem class of antibiotics was estimated at 54% in 2020 across China, with some provinces as high as 70-80%. Acinetobacter is also the most common pathogen that leads to hospital-acquired pneumonia and ventilator-acquired pneumonia in China[3]. With best available therapy, the mortality rate is estimated to be 50% in China[4].

Note: (2) Innoviva analysis; (3) China Diagnosis and Treatment Guideline for hospital-acquired pneumonia and ventilator-associated pneumonia, 2018; (4) Chung DR, et al; Asian Network for Surveillance of Resistant Pathogens Study Group. Am J Respir Crit Care Med 2011; Du, et al. American Journal of Infection Control 00 (2019).

**About Zai Lab**

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases, and neurological disorders to patients in China and around the world. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, including our products, business activities and partnerships, research, and other events or developments, 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 our future expectations, plans, and prospects, including, without limitation, statements relating to the benefits of SUL-DUR; the treatment of infections caused by *Acinetobacter baumannii,* including carbapenem-resistant strains in mainland China; clinical trial data, data readouts, and presentations; regulatory discussions, submissions, filings, and approvals and the timing thereof; the potential benefits, safety, and efficacy of our collaboration partners' products and of our pipeline therapies; and our future financial and operating results. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and can be identified by 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 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. We may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products, (2) our ability to obtain funding for our operations and business initiatives, (3) the results of our clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic, including any government actions or lockdown measures taken in response, on our business and general economic, regulatory, and political conditions, (6) risks related to doing business in China, and (7) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and 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.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC's website at www.sec.gov.

**For more information, please contact:**

**Investor Relations:** Lina Zhang
+86 136 8257 6943
lina.zhang@zailaboratory.com

**Media:** Jennifer Chang / Xiaoyu Chen
+1 (917) 446-3140 / +86 185 0015 5011
jennifer.chang@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Source: Zai Lab Limited