Zai Lab Announces NDA for Sulbactam-Durlobactam (SUL-DUR) Granted Priority Review by China's NMPA

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SHANGHAI and CAMBRIDGE, Mass., Jan. 30, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has granted priority review status to the New Drug Application (NDA) for sulbactam-durlobactam (SUL-DUR) for the treatment of infections caused by *Acinetobacter baumannii,* including multidrug-resistant and carbapenem-resistant (CRAB) strains.

"The CDE's decision to grant priority review to our NDA for SUL-DUR underscores the importance of addressing the urgent need for new treatment options for patients with life-threatening infections caused by *Acinetobacter* species including multidrug and carbapenem-resistant strains," said Harald Reinhart, M.D., President and Head of Global Development, Neuroscience, Autoimmune and Infectious Diseases, Zai Lab. "CRAB infections are among the worst bacterial infections, and safe and effective treatment options are limited. We thank the agency for their commitment and continued support to patients in need and look forward to working closely with them to advance this important therapy toward approval in China, where CRAB infections are still frequently seen in ICUs and result in high mortality rates."

Priority review was established in China to encourage innovative drug development with significant clinical value and urgent clinical need. It is implemented under the Drug Registration Rules (Bureau Order 27) and the Working Procedure for Priority Review and Approval of Drug Marketing Authorization (Tentative, NMPA 2020 No. 82) effective on July 1, 2020 and July 7, 2020, respectively. According to these guidelines, the regulatory authority will prioritize the evaluation resources for applications under priority review to help reduce review and approval timelines.

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 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[1]. With best available therapy, the mortality rate is estimated to be 50% in China[2].

Note: (1) China Diagnosis and Treatment Guideline for hospital-acquired pneumonia and ventilator-associated pneumonia, 2018; (2) 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; regulatory discussions, submissions, filings, and approvals and the timing thereof; 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.

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