Zai Lab Announces First Chinese Patient Dosed in the Global Phase 3 ATTACK Trial of Sulbactam-Durlobactam for Patients with Carbapenem-Resistant Acinetobacter Infections

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SHANGHAI and SAN FRANCISCO, May 18, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), an innovative commercial stage biopharmaceutical company, today announced dosing of the first Chinese patient in the global ATTACK (Acinetobacter Treatment Trial Against Colistin) Phase 3 registrational trial evaluating the combination of sulbactam and durlobactam (SUL-DUR) for the treatment of carbapenem-resistant *Acinetobacter baumannii* infections.

"With over 200,000 occurrences estimated each year, China ranks among the countries with the highest incidence of *A. baumannii* infections in the world. Most cases are caused by strains resistant to carbapenem antibiotics which are very difficult organisms to treat. For these patients where mortality rates are approaching 50%, new antibiotics replacing colistin are clearly needed," said Harald Reinhart, M.D., Chief Medical Officer, Autoimmune and Infectious Diseases. "Given the excellent in-vitro activity of sulbactam/durlobactam against MDR *Acinetobacter* and the demonstrated safety of the combination in clinical trials, we look forward to collaborating with our partner, Entasis Therapeutics, in the ATTACK trial."

ATTACK is a global, two-part Phase 3 registrational trial enrolling approximately 300 patients with pneumonia and bloodstream infections caused by carbapenem-resistant *Acinetobacter baumannii*. The data readout is expected in early 2021. Zai Lab and its partner, Entasis Therapeutics, will cooperate in conducting the trial in China with Zai Lab taking the operational lead by conducting the screening, enrollment and treatment of patients and coordinating development, registration and commercialization of SUL-DUR in specified countries in the Asia-Pacific region including Japan.

About *Acinetobacter baumannii* Infections

A. baumannii is a Gram-negative bacterium causing severe infections associated with high mortality and has emerged as a cause of numerous global outbreaks, displaying ever-increasing rates of antibiotic resistance, which greatly limits treatment options. Consequently, the World Health Organization (WHO) has placed carbapenem-resistant *A. baumannii* at the top of its list of "Critical" priority pathogens for new antibiotics. The U.S. Centers for Disease Control (CDC) also recognizes *A. baumannii* as a serious public health threat and estimates that 63% of A. baumannii are multidrug-resistant.

In China, *A. baumannii* accounts for approximately 11% of total Gram-negative infections. Based on a national surveillance of over 1,300 hospitals in China, there are over 200,000 *A. baumannii* infections per year, although the actual incidence is estimated to be much larger. The resistance of *A. baumannii* to the carbapenem class of antibiotics has increased significantly, estimated at 60% in 2016, with some provinces as high as 70-80%. In other Asia-Pacific countries, such as Japan and Korea, this pathogen has also become an increasingly significant challenge for physicians. Due to the high rates of multidrug-resistant infections, the Chinese government has announced the goal of developing one to two innovative anti-infective drugs by 2020.

About Sulbactam-Durlobactam (SUL-DUR)

Durlobactam (DUR; previously designated ETX2514) is a novel broad-spectrum intravenous inhibitor of class A, C and D beta-lactamases. Sulbactam (SUL) is a generic β-lactam antimicrobial with activity against *Acinetobacter baumannii*; however, β-lactamase-mediated resistance to sulbactam is now widespread rendering it generally ineffective. In preclinical studies, durlobactam inhibits the β-lactamases commonly found in *A. baumannii* thus restoring sulbactam's antimicrobial activity. Entasis Therapeutics is developing SUL-DUR (previously designated ETX2514SUL), a fixed-dose combination of durlobactam and sulbactam, as a novel intravenous antibiotic for the treatment of a variety of serious multidrug-resistant infections caused by *A. baumannii*. A Phase 2 trial and several Phase 1 trials of SUL-DUR have recently been completed with positive results for pharmacokinetics and safety/tolerability. SUL-DUR has been designated a Qualified Infectious Disease Product (QIDP) by the U.S. Food and Drug Administration and awarded Fast Track status.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is an innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious and autoimmune diseases to patients in China and around the world. To quickly target the large, fast-growing segments of China's pharmaceutical market and address unmet medical needs, Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates. Zai Lab has also built an in-house team with strong drug discovery and translational research capabilities, aiming to establish a global pipeline of proprietary drug candidates against targets in our focus areas. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing SUL-DUR in China. 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 nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's 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 but not limited to (1) Zai Lab's ability to obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to generate revenue from its drug candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on general economic, regulatory and political conditions and (6) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed on April 29, 2020, and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and undertakes no obligation to publicly 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 Zai Lab's views as of any date subsequent to the date of this press release.

For more information, please contact:

ZAI LAB CONTACTS:

Zai Lab
Billy Cho, CFO
+86 137 6151 2501
billy.cho@zailaboratory.com

Media: Ryo Imai / Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006 ext. 315 / 364
rimai@burnsmc.com / rflamm@burnsmc.com

Investors: Pete Rahmer / Mike Zanoni
Endurance Advisors, on behalf of Zai Lab
415-515-9763 / 610-442-8570
prahmer@enduranceadvisors.com / mzanoni@enduranceadvisors.com

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