



Zai Lab Announces CTA Acceptance for a Phase 3 Clinical Trial of ETX2514SUL for the Treatment of Carbapenem-Resistant *Acinetobacter* Infections

May 17, 2019

More than 200,000 cases of A. baumannii infections in China annually - Approximately 60% are carbapenem-resistant - High mortality rate (30-60%) highlights serious medical need

SHANGHAI, China, May 17, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced that the China National Medical Products Administration (NMPA) has accepted the Company's Clinical Trial Application (CTA) to allow for the initiation of a Phase 3 clinical trial to evaluate the safety and efficacy of ETX2514SUL, a fixed-dosed combination of a broad spectrum β -lactamase inhibitor with sulbactam, for the treatment of patients with pneumonia and blood stream infections caused by carbapenem-resistant *A. baumannii*.

"Carbapenem-resistant *A. baumannii* infections are a very serious public health problem in China because options to treat them are quite limited leading to a high mortality rate," said Harald Reinhart, M.D., Chief Medical Officer of Zai Lab. "ETX2514SUL has shown very promising *in vitro* and *in vivo* activity against this serious pathogen, and was the reason for our partnering with Entasis to bring this drug candidate to China and to participate in their global clinical trial."

The *Acinetobacter* Treatment Trial Against Colistin (ATTACK) is a global, two-part Phase 3 clinical trial that will enroll approximately 300 patients from 18 countries. Zai Lab will be responsible for patient enrollment in China, and potentially provide early access for patients in Asia-pacific countries. Entasis Therapeutics will be responsible for patient enrollment in the U.S. and Europe. For more information about the ATTACK trial, please visit www.clinicaltrials.gov (NCT03894046).

"In-licensing ETX2514SUL was part of our strategy to build a de-risked clinical stage pipeline that is highly differentiated and addresses serious unmet medical needs in China and beyond," said Samantha Du, Ph.D., Founder and Chief Executive Officer of Zai Lab. "We look forward to contributing a large contingent of Chinese patients to the ATTACK study and starting clinical activities this year."

About ETX2514

ETX2514 is a novel, broad-spectrum inhibitor of class A, C, and D β -lactamases. ETX2514 restores the *in vitro* activity of multiple β -lactams against Gram-negative, multidrug-resistant (MDR) pathogens. Entasis Therapeutics is initially developing ETX2514SUL, the combination of ETX2514 and sulbactam, for the treatment of severe *A. baumannii* infections. Sulbactam is a generic β -lactam which has intrinsic antibacterial activity against *A. baumannii* but suffers from widespread β -lactamase-mediated resistance. In preclinical studies, ETX2514 restored sulbactam antibacterial activity against *A. baumannii*. ETX2514 has completed single- and multi-ascending dose Phase 1 trials and a Phase 2 trial, in combination with sulbactam, in complicated urinary tract infections.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a China and US-based innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding business strategy, plans and objectives for future operations, including statements about the initiation of a Phase 3 clinical trial to evaluate the safety and efficacy of ETX2514SUL. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and are identified by words such as "anticipates", "believes", "expects", "plan" 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 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, and (5) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2018 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: Nancie Steinberg / Robert Flamm, Ph.D.

Burns McClellan, on behalf of Zai Lab

212-213-0006

nsteinberg@burnsmc.com / rflamm@burnsmc.com

Investors: Jill Steier

Burns McClellan, on behalf of Zai Lab

212-213-0006

jsteier@burnsmc.com



Zai Lab Limited