



## Entasis Therapeutics and Zai Lab Announce Exclusive License Agreement in Asia-Pacific and Global Strategic Development Collaboration for ETX2514

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### Collaboration will facilitate enrollment of pivotal global Phase 3 trial of ETX2514 in combination with sulbactam for the treatment of carbapenem-resistant *Acinetobacter baumannii* infections

WALTHAM, Mass. and SHANGHAI, China, April 25, 2018 (GLOBE NEWSWIRE) -- Entasis Therapeutics Holdings Inc., a clinical-stage biopharmaceutical company focused on the discovery and development of novel antibacterial products, and Zai Lab Limited (NASDAQ:ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced an exclusive license agreement for ETX2514 in the Asia-Pacific region and a global strategic development collaboration. Entasis' ETX2514 is a novel broad-spectrum intravenous inhibitor of  $\beta$ -lactamases, which are a major cause of antibiotic resistance. Entasis is developing ETX2514SUL, a fixed-dose combination of ETX2514 and sulbactam, for the treatment of a variety of serious multidrug-resistant infections caused by *Acinetobacter baumannii*, representing a healthcare challenge of global importance with over 200,000 occurrences estimated in China each year. ETX2514SUL is currently in Phase 2 development with plans to move into global Phase 3 clinical trials in the first quarter of 2019. Zai Lab will manage the portion of the Phase 3 trial conducted in China.

"Entasis remains committed to building a pipeline of life-saving treatments for patients affected by drug-resistant bacterial infections around the world. We are thrilled to partner with Zai Lab on the further development and potential commercialization of ETX2514SUL in the Asia-Pacific region, most notably in Greater China, where the rate of *A. baumannii* infections rank among the highest in the world," said Manos Perros, Chief Executive Officer of Entasis. "With their experienced leadership team, focus on innovation and established expertise and network within the infectious diseases arena, Zai Lab is the ideal partner to help bring ETX2514SUL to the numerous patients in the region who need a new effective treatment option. The collaboration will offset costs and enable enrollment of patients from China into our global Phase 3 clinical trial, further supporting our plans to rapidly progress ETX2514SUL to market."

"Infectious diseases are a key focus area for Zai Lab due to the serious problem of multidrug-resistant infections both in China and globally. We are excited to collaborate with Entasis, a company that has extensive expertise and know-how in developing anti-infective products that address multidrug-resistant infections, and we look forward to working together to accelerate the global development of this potential life-saving therapy. We expect ETX2514SUL will be a positive addition to Zai Lab's anti-infective portfolio, and we remain committed to developing a drug to combat multidrug-resistance, which currently poses a serious global threat to our society," stated Samantha Du, Ph.D., Chairman and Chief Executive Officer of Zai Lab. "This collaboration reinforces the strength of the Zai Lab team both in China and globally, and we believe will help us further progress on our mission to establish Zai Lab as an innovative, fully integrated, global pharmaceutical company."

Under the terms of the agreement, Entasis has granted Zai Lab an exclusive license to develop and commercialize ETX2514SUL in specified countries in the Asia-Pacific region, including Japan. Entasis and Zai Lab will cooperate in conducting a pivotal Phase 3 trial in China, with Zai Lab taking the lead by conducting the screening, enrollment and treatment of patients, and coordinating development, registration and commercialization of ETX2514SUL in the territory. In addition, Entasis and Zai Lab have an option to collaborate on the development and commercialization of ETX2514 in combination with other active ingredients. A joint steering committee will be formed between the companies to oversee development, regulatory and commercialization activities in the Asia-Pacific territory. In addition to financial support for the portion of the Phase 3 trial conducted in China, Entasis will receive a \$5 million upfront payment and is eligible to receive up to an aggregate of \$7.6 million in near-term development milestones and up to an aggregate of \$91.0 million in additional development, regulatory and sales milestone payments related to ETX2514SUL and other combinations, plus royalties.

#### 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, it has also become an increasingly significant challenge for physicians. Due to the high rates of multidrug-resistant infections, the Chinese government has identified the goal of developing one to two innovative anti-infective drugs by 2020.

#### About ETX2514

ETX2514 is a novel broad-spectrum intravenous inhibitor of class A, C and D beta-lactamases. ETX2514 restores the *in vitro* activity of multiple  $\beta$ -lactams against Gram-negative, multidrug-resistant pathogens. Entasis is initially developing ETX2514SUL, a fixed-dose combination of ETX2514 and sulbactam, for the treatment of a variety of serious multidrug-resistant infections caused by *A. baumannii*. Sulbactam is a generic  $\beta$ -lactam that has intrinsic activity against *A. baumannii* but suffers from widespread  $\beta$ -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. The U.S. Food and Drug Administration has granted Qualified Infectious Disease Product (QIDP) designation and Fast Track designation to ETX2514SUL for the

treatment of hospital-acquired and ventilator-acquired bacterial pneumonia and bloodstream infections due to *A. baumannii*.

#### **About Entasis**

Entasis is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel antibacterial products to treat serious infections caused by multidrug-resistant Gram-negative bacteria. Entasis' targeted-design platform has produced a pipeline of product candidates, including ETX2514SUL (targeting *A. baumannii* infections), ETX0282CPDP (targeting *Enterobacteriaceae* infections), and zoliflodacin (targeting *Neisseria gonorrhoeae*). Entasis is also using its platform to develop a novel class of antibiotics, non- $\beta$ -lactam inhibitors of the penicillin-binding proteins (NBPs) (targeting Gram-negative infections). For more information, visit [www.entasistx.com](http://www.entasistx.com).

#### **About Zai Lab**

Zai Lab (NASDAQ:ZLAB) is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. The company'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 global 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.

#### **Entasis Forward-looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Entasis' expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements about (i) the timing of the initiation, progress and scope of the Phase 3 clinical trial of ETX2514SUL; (ii) potential regulatory approval and commercialization of ETX2514SUL; (iii) the potential use of ETX2514SUL to treat a variety of serious multi-drug resistant infections caused by *Acinetobacter baumannii*; and (iv) Entasis' potential receipt of milestone payments and royalties. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during non-clinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected and changes in expected or existing competition. Except as required by law, Entasis assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

#### **Zai Lab Forward-Looking Statements**

This press release includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding the timing of the initiation, progress and scope of the Phase 3 clinical trial of ETX2514SUL, the potential use of ETX2514SUL to treat a variety of serious multidrug-resistant infections caused by *Acinetobacter baumannii*, Entasis' potential receipt of milestone payments and royalties from Zai Lab. You can identify forward-looking statements because they contain words such as "believes" and "expects." Forward-looking statements are based on Zai Lab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Zai Lab's filings with the Securities and Exchange Commission. Zai Lab 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.

#### **Entasis Company Contact**

Kyle Dow  
Entasis Therapeutics  
(781) 810-0114  
[kyle.dow@entasistx.com](mailto:kyle.dow@entasistx.com)

#### **Entasis Media Contact**

Kari Watson or Stefanie Tuck  
MacDougall Biomedical Communications  
(781) 235-3060  
[kwatson@macbiocom.com](mailto:kwatson@macbiocom.com) or [stuck@macbiocom.com](mailto:stuck@macbiocom.com)

#### **ZAI LAB CONTACTS:**

Zai Lab  
Billy Cho  
+86 21 6163 7322  
[billy.cho@zailaboratory.com](mailto:billy.cho@zailaboratory.com)

Solebury Trout  
John Graziano  
+1 646 378 2942  
[jgraziano@troutgroup.com](mailto:jgraziano@troutgroup.com)



Zai Lab Limited



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