Zai Lab Announces Acceptance of NDA Submission of Omadacycline in China by the NMPA

February 10, 2020

SHANGHAI, China and SAN FRANCISCO, Feb. 10, 2020 (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 its New Drug Application (NDA) for omadacycline for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

“This is another important step in the development of Zai as a fully-integrated biopharmaceutical company,” said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. “This NDA is our third submission accepted for review by the China NMPA and our first anti-infective NDA and demonstrates our capabilities in therapeutic areas outside of oncology. The Chinese infectious disease market is significantly underserved, and innovation is desperately needed more than ever due to the rise in bacterial resistance.”

Dr. Harald Reinhart, Chief Medical Officer for Autoimmune and Infectious Diseases at Zai Lab added, “Omadacycline is particularly well positioned for the China market due to its broad activity covering a wide spectrum of pathogens (including multi-drug resistance) associated with CABP and ABSSSI. As it is available in intravenous (IV) and oral (PO) formulations, omadacycline provides the option for IV-to-PO step down therapy thus allowing physicians to discharge patients earlier and reduce exposure to hospital pathogens. There are limited treatment options against drug-resistant bacteria in China, and omadacycline is an innovative drug that can address such unmet medical needs.”

Omadacycline was originally developed by Zai’s partner Paratek Pharmaceuticals. It was approved by the U.S. Food and Drug Administration (FDA) for both CABP and ABSSSI in October 2018 based on a comprehensive clinical trial program involving more than 2,000 patients. Zai’s omadacycline filing with the NMPA was accepted as a Category 1 drug and omadacycline will be locally manufactured in China.

About Omadacycline

Omadacycline (NUZYRA®) is a novel tetracycline, specifically designed to overcome tetracycline resistance and improve activity across a broad spectrum of bacterial infections such as those caused by Gram-positive, Gram-negative, atypical, and many other problem pathogens. NUZYRA was launched in the United States in February 2019 as a once-daily oral and intravenous antibiotic for the treatment of adults with CABP and ABSSSI.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a China and U.S.-based innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious and autoimmune 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 of omadacycline for the greater China territory. 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.

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