Zai Lab Announces NDA for Omadacycline Granted Priority Review by China's NMPA

May 6, 2020

SHANGHAI, China, and SAN FRANCISCO, May 06, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), an innovative commercial stage biopharmaceutical company, today announced that the Center for Drug Evaluation of China's National Medical Products Administration (NMPA) has granted priority review status to the New Drug Application (NDA) for omadacycline for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

"The NMPA's decision to grant priority review to our NDA for omadacycline underscores the importance of addressing a growing unmet need of bacterial resistance in China with an innovative medicine," said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. "We believe omadacycline is particularly well positioned for the China market due to its broad activity covering a wide spectrum of pathogens, including multi-drug resistant bacteria, associated with CABP and ABSSSI. We look forward to working closely with the agency to move our first anti-infective therapeutic toward approval."

"CABP is a common secondary infection associated with respiratory viruses like influenza and coronavirus, and recent influenza outbreaks and coronavirus epidemics are a reminder of the need for antibiotics like omadacycline. We believe few intravenous/oral antibiotics exist which are as potent as omadacycline in this indication," added Dr. Harald Reinhart, Chief Medical Officer for Autoimmune and Infectious Diseases of Zai Lab.

Priority review was established in China to facilitate drug registration and accelerate the development of new drugs with clinical value under the guidance of Opinions on Encouraging Pharmaceutical Innovation via Priority Review & Approval issued by the NMPA in December 2017. According to these guidelines, the NMPA will prioritize the review of and evaluation resources for applications under priority review, which are expected to result in reduced review and approval timelines.

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. The NMPA accepted our NDA for omadacycline for the treatment of CABP and ABSSSI on February 10, 2020.

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.

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 prospects 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, 2019 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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