



Zai Lab Presents Interim Results of its ongoing Phase 2 study of ZL-2301 (brivanib) in Chinese Patients with Advanced Hepatocellular Carcinoma (HCC) at the 21st Annual Meeting of the Chinese Society of Clinical Oncology

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Results demonstrate anti-tumor activity and manageable safety profile of the two dosing regimens of ZL-2301 tested in the trial

Plan to pursue study to evaluate ZL-2301 in combination with anti-PD-1 therapy

SHANGHAI, China, Sept. 26, 2018 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative biopharmaceutical company, presented interim results of its Phase 2 study of ZL-2301 (brivanib) in Chinese patients with previously-treated advanced hepatocellular carcinoma (HCC). Results from the study show ZL-2301 continues to demonstrate evidence of anti-tumor activity with a manageable safety profile in Chinese patients. The interim data were presented at the 21st Annual Meeting of the Chinese Society of Clinical Oncology (CSCO) on Sept. 22, 2018, at the Xiamen International Conference and Exhibition Center (XICEC) in Xiamen, China.

In the multi-center, open-label Phase 2 trial, 90 patients were enrolled to receive either 800 mg of ZL-2301 once-daily (QD) or 400 mg of ZL-2301 twice-daily (BID), administered orally. The primary endpoints in the trial are: (1) disease control rate (DCR) at 12 weeks from randomization, defined as the percentage of patients with a complete response, partial response or stable disease, and (2) time to disease progression (TTP).

The interim analysis was based on 75 patients (36 on 800mg QD; 39 on 400mg BID). The 12 weeks DCR was 41.7% in the 800mg QD arm and 35.9% in the 400mg BID arm. TTP was 4.2 months (95% CI, 2.8-4.2) in 800mg QD arm and 2.8 months (95% CI, 1.4-4.2) in the 400mg BID arm. ZL-2301 was relatively well-tolerated in the study; its toxicity profile appears in-line with that of the VEGFR inhibitor drug class.

Dr. Shukui Qin, Executive Member of the Asian Clinical Oncology Society, Senior Vice President of Chinese Society of Clinical Oncology and Lead Investigator for ZL-2301 study, commented, "This is a well conducted clinical trial that produced additional data to better characterize the clinical profile of ZL-2301 in Chinese patients. The data helped to set the foundation for further development of ZL-2301 as a potential therapy for HCC which are still in dire need of additional treatment options."

The efficacy and tolerability results of the study are in-line with our expectations in this heavily pre-treated HCC population. Given the large, unmet needs in HCC, a common, difficult to treat cancer, primarily driven by hepatitis B infection in China, and the rapidly changing landscape in HCC, Zai Lab plans to conduct a combination study to evaluate ZL-2301 with anti-PD1 therapy for HCC patients in China.

About ZL-2301 (brivanib)

ZL-2301 (brivanib) is an oral, small molecule dual target tyrosine kinase inhibitor, or TKI. Zai Lab licensed exclusive rights for China, Hong Kong, Macau and Taiwan from Bristol Myers Squibb. ZL-2301 has been tested in four Phase III studies in hepatocellular cancer (HCC) and showed anti-tumor activity and a manageable safety profile. Based on Zai Lab's review of the results from Bristol-Myers Squibb's development program for ZL-2301, its understanding of the etiology and current standard of care of HCC in Chinese patients and its ongoing research, Zai Lab believes that ZL-2301 has the potential to be an effective treatment option for Chinese HCC patients and merits further clinical development. In the second quarter of 2017 Zai Lab initiated a Phase II trial of ZL-2301 as a second-line treatment for advanced HCC patients in China.

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 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 and other statements containing words such as "anticipates", "believes", "expects", "plans" 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, 2017 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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