Zai Lab Announces First Patients Treated in Separate Phase 1b and Registrational Bridging Studies

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- *Phase 1b Study of Niraparib in Combination with MGD013 in Advanced or Metastatic Gastric Cancer in China*
- *Registrational Bridging Study in China of Margetuximab plus Chemotherapy in HER2-Positive Metastatic Breast Cancer*

SHANGHAI, China and SAN FRANCISCO, Feb. 04, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a China and U.S.-based innovative commercial stage biopharmaceutical company, today announced that the first patients have been dosed in two separate clinical studies:

- Phase 1b dose escalation and expansion clinical study of niraparib, in combination with MGD013, for the treatment of patients with advanced or metastatic gastric adenocarcinoma or gastroesophageal junction adenocarcinoma (collectively as gastric cancer) who failed prior treatment, and

- Registrational bridging study of margetuximab, in combination with chemotherapy, for the treatment of patients with metastatic HER2-positive breast cancer, respectively.

Niraparib plus MGD013 Gastric Cancer Phase 1b Study

The Phase 1b clinical study is a single-arm, open-label, dose escalation and expansion study assessing the safety and antitumor activity of niraparib, an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor, in combination with MGD013, a first-in-class, bispecific PD-1 x LAG-3 DART® molecule, in patients with advanced or metastatic gastric cancer who failed prior treatment.

The primary endpoint of the study is assessing the safety of niraparib in combination with MGD013 in patients with advanced gastric cancer and determining the recommended phase 2 dose. Secondary endpoints include objective response rate (ORR), disease control rate (DCR), progression-free survival (PFS), and overall survival (OS).

Margetuximab plus Chemotherapy HER2-Positive Metastatic Breast Cancer Registrational Bridging Study

The registrational bridging trial is a randomized, open-label study evaluating the efficacy and safety of margetuximab, an Fc-engineered, monoclonal antibody that targets HER2, plus chemotherapy compared to trastuzumab plus chemotherapy in patients with metastatic HER2-positive breast cancer who have received prior anti-HER2 therapies.

The primary endpoint of the study is PFS. Secondary endpoints include OS, ORR, duration of response (DoR) and clinical benefit rate (CBR), as well as safety and pharmacokinetic profile of margetuximab in Chinese patients.

Zai Lab's partner MacroGenics has submitted a Biologics License Application (BLA) for margetuximab for the treatment of patients with metastatic HER2-positive breast cancer in combination with chemotherapy in December 2019. The submission is based on the safety and efficacy results of the pivotal Phase 3 SOPHIA study. Pending acceptance of the BLA, MacroGenics anticipates a Prescription Drug User Fee Act (PDUFA) date by the end of 2020.

About Gastric Cancer in China

Gastric cancer is the second most common cancer in China (679,100 newly diagnosed cases in 2015) and the second leading cause of death in China (498,000 deaths in 2015). The 5-year overall survival rate of gastric cancer is only 35.9%. Current therapies include surgery, chemotherapy, radiotherapy and targeted therapy. There is limited effective treatment option for patients with advanced or metastatic gastric cancer who have failed prior treatment in China and globally.

About Breast Cancer in China

Breast cancer is the most common cancer in Chinese women, with 272,400 newly diagnosed cases and 70,700 deaths in 2015. Approximately 25%~30% of all types of late stage breast cancer are HER2-positive. The 5-year overall survival rate of breast cancer is 83%. However, after treatment failure or disease progression after second-line anti-HER2 treatment, there is no approved effective treatment in last-line setting in China and globally.

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. 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 plans for commercializing niraparib, MGD013 and margetuximab in China. 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.

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