Zai Lab Announces NDA Acceptance of Margetuximab for Patients with Pretreated Metastatic HER2-Positive Breast Cancer in China by the NMPA

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SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass., Jan. 06, 2022 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), a patient-focused, innovative, commercial-stage, global biopharmaceutical company, today announced that the China National Medical Products Administration (NMPA) has accepted the New Drug Application (NDA) for margetuximab, an investigational, Fc-engineered monoclonal antibody that targets HER2. The margetuximab NDA is for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease, in combination with chemotherapy.

"We are pleased to have NMPA's acceptance of our NDA for margetuximab, which is the only HER2-targeted agent to have shown a progression-free survival (PFS) improvement versus trastuzumab in SOPHIA, a head-to-head global Phase 3 clinical trial," said Alan Sandler, MD, President and Head of Global Development, Oncology, at Zai Lab. "Both SOPHIA and Zai Lab's registrational bridging trial support the potential use of margetuximab as an important new treatment option for a very difficult-to-treat patient population. The potential approval of margetuximab will also be an important addition to our growing women's oncology franchise and marks Zai Lab's sixth NDA acceptance by the NMPA."

"Early detection and treatment of breast cancer have had a positive impact on patient survival. However, we still need to improve the prognosis for people diagnosed with HER2-positive metastatic breast cancer, and additional anti-HER2 targeted therapies are needed," said Professor Zefei Jiang, Chairman of Chinese Society of Clinical Oncology (CSCO) Breast Cancer Expert Committee and Deputy Director of Department of Oncology, Chinese PLA General Hospital. "Zai Lab's bridging study confirmed the clinical benefit of margetuximab in Chinese patients. We are excited to see this potential new treatment option for patients living with metastatic breast cancer in China."

In December 2020, MacroGenics, Inc. announced that the U.S. Food and Drug Administration (FDA) approved margetuximab (brand name MARGENZA®) in combination with chemotherapy for the treatment of adult patients with metastatic HER2-positive breast cancer who received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. The approval was based on efficacy and safety results from the pivotal Phase 3 SOPHIA trial.

In October 2021, Zai Lab announced that the bridging study of margetuximab plus chemotherapy as compared with trastuzumab plus chemotherapy in advanced, previously treated HER2-positive breast cancer patients met its primary endpoint, median PFS evaluated by blinded independent central review (BICR). The safety profile was consistent with that seen in the SOPHIA study. Zai Lab is planning to present the detailed study results at an upcoming medical conference.

About Margetuximab

MARGENZA (margetuximab-cmkb) is an Fc-engineered monoclonal antibody that targets the HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors. Similar to trastuzumab, margetuximab-cmkb inhibits tumor cell proliferation, reduces shedding of the HER2 extracellular domain and mediates antibody-dependent cellular cytotoxicity (ADCC). However, through MacroGenics' Fc Optimization technology, margetuximab-cmkb has been engineered to enhance the engagement of the immune system. In vitro, the modified Fc region of margetuximab-cmkb increased binding to the activating Fc receptor FCGR3A (CD16A) and decreased binding to the inhibitory Fc receptor FCGR2B (CD32B). These changes led to greater in vitro ADCC and NK cell activation. The clinical significance of in vitro data is unknown.

About Breast Cancer in China

Breast cancer is the most common cancer in Chinese women, with 416,371 newly diagnosed cases and 117,174 deaths in 2020[1]. Approximately 25%-30% of all types of late-stage breast cancer are HER2-positive[2,3]. Monoclonal antibodies targeting HER2 have greatly improved outcomes; however, a significant number of patients progress to later lines of therapy. Effective treatments for metastatic HER2-positive breast cancer continue to remain an unmet need.

Source: (1) Globocan 2020; (2) The role of HER2 in cancer therapy and targeted drug delivery, Wanyi Tai, Rubi Mahato, and Kun Cheng; (3) Human Epidermal Growth Factor Receptor 2 (HER2) in Cancers: Overexpression and Therapeutic Implications, Nida Iqbal and Naveed Iqbal.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders, infectious diseases, and neuroscience. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing, and commercializing our portfolio in order to impact human health worldwide.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to our development and possible commercialization of margetuximab in China; reimbursement administration discussions, filings, approvals, and the timing thereof; and the potential benefits, safety, and efficacy of our collaboration partners' products and investigational therapies. These forward-looking statements may contain words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" 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 our 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) our ability to successfully commercialize and generate revenue from our approved products; (2) our ability to finance our operations and business initiatives and obtain funding for such activities, (3) our results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and general economic, regulatory and political conditions and (6) the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to 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 our views as of any date subsequent to the date of this press release.

For more investor-related information about Zai Lab, please go to www.SEC.gov or visit www.zailaboratory.com.

For more information, please contact:

Investor Relations: Ron Aldridge / Lina Zhang
+1 (781) 434-8465 / +86 136 8257 6943
ronald.aldridge@zailaboratory.com / lina.zhang@zailaboratory.com

Media: Danielle Halstrom / Xiaoyu Chen
+1 (215) 280-3898 / +86 185 0015 5011
danielle.halstrom@zailaboratory.com / xiaoyu.chen@zailaboratory.com

Zai Lab Limited

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