Zai Lab Announces Margetuximab Achieved Primary Objective in Bridging Study in Advanced HER2+ Breast Cancer in Greater China

October 5, 2021

-- Demonstrated efficacy and safety consistent with global SOPHIA study
-- Company expects to file BLA in China in advanced HER2+ breast cancer by approximately year end 2021

SHANGHAI and SAN FRANCISCO, Oct. 05, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced that the bridging study of margetuximab plus chemotherapy in advanced, previously treated HER2+ breast cancer met its primary endpoint, with acceptable safety and tolerability. The study showed that efficacy of this combination in Chinese patients was consistent with that seen in the global population in the SOPHIA trial conducted by Zai Lab's partner MacroGenics, Inc.

The study was a randomized, open-label, multi-center, Phase II clinical study to evaluate the efficacy and safety of margetuximab plus chemotherapy compared with trastuzumab plus chemotherapy in 123 Chinese patients in mainland China, Hong Kong, and Taiwan with advanced HER2+ breast cancer who had received at least two prior lines of anti-HER2-directed therapy in the metastatic setting, including trastuzumab. The primary endpoint of the study was median progression-free survival (mPFS) evaluated by blinded independent central review (BICR) as defined by the achievement of at least 50% of the efficacy of margetuximab plus chemotherapy in the SOPHIA study (hazard ratio (HR) < 0.88). The secondary endpoints included overall survival (OS), mPFS evaluated by investigator, and objective response rate (ORR).

In this study, the HR for PFS in the intent-to-treat population evaluated by BICR was 0.69 favoring the margetuximab combination, thus achieving the primary endpoint. The safety profile of margetuximab plus chemotherapy was acceptable and consistent with the safety profile of margetuximab plus chemotherapy seen in the SOPHIA trial. Zai Lab is planning to present the detailed study results at an upcoming medical conference. Based on these positive results, Zai Lab expects to file a BLA in China for this indication by approximately year end 2021.

"We are pleased to see that the results of our bridging study are consistent with those of the SOPHIA trial that were the basis for the approval of Margenza® in the United States," said Alan Sandler, M.D., President and Head of Global Development, Oncology. "Both trials support the potential use of margetuximab as another treatment option for a very difficult-to-treat patient population. The successful completion of our bridging study further demonstrates Zai Lab's capabilities to produce clinical data of global quality to support regulatory approval in China in collaboration with our partners."

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders and infectious disease. 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 the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements including but not limited to statements relating to our strategy and plans; potential of and expectations for our business and pipeline programs; capital allocation and investment strategy; clinical development programs and related clinical trial data; risks and uncertainties associated with drug development and commercialization; regulatory approvals for our pipeline programs and the timing thereof; the potential benefits, safety and efficacy of our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments, collaborations and business development activities; and our future financial and operating results. These forward-looking statements include, without limitation, statements containing 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 information, please contact:

ZAI LAB CONTACTS:

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

Source: Zai Lab Limited