Zai Lab to Highlight New Data from its Oncology Pipeline at 2023 ASCO Annual Meeting

June 1, 2023

Three poster presentations to provide updates on Zai Lab's oncology programs focused on unresectable solid tumors, ovarian cancer and gastrointestinal stromal tumors

Early Phase 1/2 study data from Zai Lab's internally developed ZL-1211 program support a solid safety/tolerability profile and preliminary antitumor activity

SHANGHAI, China and CAMBRIDGE, Mass., June 01, 2023 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) will present three poster presentations with new data, including preliminary results from a clinical study evaluating its internal oncology research and development program ZL-1211, at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. ZL-1211 is an anti-Claudin (CLDN) 18.2 monoclonal antibody currently being evaluated for the treatment of unresectable or metastatic solid tumors.

"We have been steadily expanding our oncology pipeline to include in-house research and development programs that are designed to reach patients globally, and we are pleased to share initial findings from our ZL-1211 program at this year's ASCO meeting," said Rafael Amado, MD, President, Head of Global Oncology Research and Development, Zai Lab. "Patients with advanced and refractory solid tumors require expanded treatment options, and we are committed to becoming an integral part of this treatment landscape."

ZL-1211 is an anti-CLDN18.2 antibody that targets CLDN18.2 to induce cancer cell death through antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC). This report will highlight preliminary results from the ongoing dose-escalation portion of a first-in-human, Phase 1/2, multicenter study of ZL-1211 administered intravenously to adults with CLDN18.2-positive advanced solid tumors (Poster #379). The first phase of the study aims to assess the single agent safety, tolerability, and early anti-tumor activity of ZL-1211 in patients with unresectable or metastatic solid tumors, as well as to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose of ZL-1211 in this patient population.

Among the 10 evaluable patients included in the data analysis, the results showed ZL-1211 demonstrated a tolerable safety profile and preliminary antitumor effects. For example:

- There were no dose limiting toxicities (DLTs) as of the data cut-off date.
- The most common treatment-related adverse events (TRAEs) were gastrointestinal (GI) disorders, including nausea, vomiting, and abdominal pain.
- Six patients achieved stable disease with three patients having some evidence of tumor regression.

Researchers will also present results from a *post hoc* sub-group analysis from the PRIME study, which explored the efficacy and safety of niraparib maintenance therapy among Chinese patients with advanced ovarian cancer who had measurable residual disease after first-line platinum-based chemotherapy (Poster #257). The data indicate that, in these patients, niraparib maintenance therapy tended to induce additional antitumor activity and led to a clinically meaningful increase in progression free survival (PFS) versus placebo. Zai Lab has a collaboration and license agreement with GSK for the development and commercialization of ZEJULA® (niraparib) in Greater China (mainland China, Hong Kong and Macau).

Zai Lab's third presentation (Poster #477) will provide a long-term update to the Phase 2 trial evaluating the efficacy and safety of ripretinib as fourth-line (or beyond) therapy in a single arm study of Chinese patients with advanced gastrointestinal stromal tumors (GIST). The long-term follow up results continue to support the clinically meaningful benefit in PFS, which is comparable to results seen in the global randomized INVICTUS trial, and demonstrate clinically meaningful overall survival (OS) in Chinese ≥4L GIST patients, while the safety profile remains acceptable. Zai Lab has a licensing agreement with Deciphera for the development and commercialization of QINLOCK® (ripretinib) in Greater China (mainland China, Hong Kong, Macau and Taiwan).

Details regarding the Zai Lab presentations at the 2023 ASCO meeting are as follows:

Title:	Preliminary results of a phase 1/2, first-in-human, open-label, dose escalation study of ZL-1211 (anti-Claudin 18.2 mAb) in patients with unresectable or metastatic solid tumors
Abstract #:	2537 (Poster #379)
Presenter:	Sunil Sharma, MD, Honor Health
Date/Time:	Saturday, June 3, 8:00 a.m. CT
Location:	McCormick Place, Hall A
Abstract link:	https://meetings.asco.org/abstracts-presentations/221710

Title:	Efficacy and safety of ripretinib in Chinese patients with advanced gastrointestinal stromal tumors (GIST) as ≥4th line therapy: Long-term update from a single-arm, phase 2 trial.
Abstract #:	11543 (Poster #477)
Presenter:	Jian Li, DPhil, Peking University Cancer Hospital & Institute
Date/Time:	Saturday, June 3, 1:15 p.m. CT
Location:	McCormick Place, Hall A
Abstract link:	https://meetings.asco.org/abstracts-presentations/220669

Title:	Efficacy and safety of niraparib maintenance therapy in patients with newly diagnosed advanced ovarian cancer who had measurable residual disease: A *post-hoc* subgroup analysis of the PRIME study
Abstract #:	5562 (Poster #257)
Presenter:	Beihua Kong, MD, Qilu Hospital of Shandong University
Date/Time:	Monday, June 5, 1:15 p.m. CT
Location:	McCormick Place, Hall A
Abstract link:	https://meetings.asco.org/abstracts-presentations/223034

About the PRIME Study

The fully powered Phase 3 PRIME study was evaluated in 384 advanced ovarian cancer patients who were in a complete or partial response to platinum-based chemotherapy and who were randomized 2:1 to receive ZEJULA or placebo as maintenance therapy. The study evaluated the efficacy of ZEJULA as a maintenance treatment, with the primary endpoint of PFS as assessed by blinded independent central review. The starting dose was individualized at 200 mg except for those patients with a baseline body weight ≥77kg and a platelet count ≥150K/μL, in which case the starting dose was 300 mg.

About ZEJULA (niraparib)

ZEJULA (niraparib) is an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the maintenance treatment of adult patients with advanced and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to first- and second-line platinum-based chemotherapy.
In addition to the PRIME study, Zai Lab has completed several studies in Chinese patients with ovarian cancer:

- In September 2020, Zai Lab announced that ZEJULA demonstrated a significant PFS benefit with an improved safety profile in the company's Phase 3 NORA study of ZEJULA as maintenance therapy for Chinese patients with platinum-sensitive, recurrent ovarian cancer, regardless of biomarker status.
- A Phase 1 pharmacokinetic study of ZEJULA was conducted in Chinese patients with ovarian cancer.

Zai Lab has a collaboration and license agreement with GSK for the development and commercialization of ZEJULA (independently manufactured by Zai Lab) in mainland China, Hong Kong, and Macau.

About the INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomized, double-blind, placebo-controlled, international, multicenter clinical study evaluating the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of QINLOCK or placebo once daily. The primary efficacy endpoint is progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). The median PFS in the study was 6.3 months compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, $p<0.0001$). Secondary endpoints include objective response rate (ORR) as determined by independent radiologic review using modified RECIST and overall survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo ($p =0.0504$). QINLOCK also demonstrated a median OS of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36).

About QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRα mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. QINLOCK inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18 involved in GIST, as well as the primary exon 17 D816V mutation. QINLOCK also inhibits primary PDGFRα mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

QINLOCK is currently approved in 13 territories around the world, including major markets of the United States, Europe, and China for the treatment of fourth-line GIST. Zai Lab has an exclusive license agreement with Deciphera for the development and commercialization of ripretinib in Greater China (mainland China, Hong Kong, Macau and Taiwan).

About Zai Lab

Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial-stage biopharmaceutical company based in China and the United States focused on bringing transformative medicines for oncology, autoimmune disorders, infectious diseases, and neurological disorders to patients in China and around the world. Our goal is to leverage our competencies and resources to positively impact human health worldwide.

For additional information about Zai Lab, including our products, business activities and partnerships, research, and other events or developments, 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 relating to our future expectations, plans, and prospects, including, without limitation, statements about ZL-1211, niraparib, and ripretinib; related clinical trials, data readouts and presentations, and potential treatments for patients with unresectable solid tumors, ovarian cancer, and gastrointestinal tumors. 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 obtain funding for our operations and business initiatives, (3) the results of our 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 results of operations, (6) risks related to doing business in China, and (7) other factors identified in our most recent annual and quarterly reports and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). 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.

Our SEC filings can be found on our website at www.zailaboratory.com and on the SEC's website at www.sec.gov.

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