Zai Lab and Novocure Announce EF-31 Phase 2 Pilot Study Evaluating Tumor Treating Fields Together with Standard-of-Care Chemotherapy Meets Primary Endpoint for First-Line Treatment of Gastric Cancer

June 3, 2022

Confirmed objective response rate was 50% for patients treated with TTFields together with standard-of-care chemotherapy

Duration of response was 10.3 months

One-year survival was 72%

SHANGHAI and SAN FRANCISCO and CAMBRIDGE, Mass. and ST. HELIER, Jersey, June 03, 2022 (GLOBE NEWSWIRE) -- Zai Lab (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, and Novocure (NASDAQ: NVCR), a global oncology company working to extend survival in some of the most aggressive forms of cancer, today announced that the EF-31 phase 2 pilot study, testing the safety and efficacy of Tumor Treating Fields (TTFields) together with standard-of-care (chemotherapy alone or in combination with trastuzumab for HER2-positive patients) as a first-line treatment in patients with gastric adenocarcinoma, met its primary endpoint of objective response rate with supportive signals across secondary endpoints. TTFields therapy was well tolerated, with no increase in the systemic toxicity of the XELOX chemotherapy regimen or the combination regimen, and no high-grade skin toxicities were reported.

Initial analysis was conducted with a median follow-up period of 8.6 months. The primary endpoint, confirmed objective response rate, was 50%. Median progression-free survival was 7.8 months. Duration of response was 10.3 months. Median overall survival has not yet been reached with a one-year survival rate of 72%.

“The EF-31 outcomes are encouraging in a historically difficult to treat cancer,” said Dr. Jin Li, Head of Department of Oncology, Shanghai East Hospital, Tongji University School of Medicine. “The addition of Tumor Treating Fields to standard-of-care chemotherapy could lead to impactful changes in the treatment of gastric cancer patients and I look forward to confirming these data in additional clinical studies.”

The EF-31 clinical study, which is a prospective, single arm, phase 2 pilot study conducted in China, included 26 patients with unresectable, locally advanced or metastatic gastroesophageal junction or gastric adenocarcinoma who were previously untreated with systemic therapy. Patients received continuous treatment with TTFields together with the XELOX chemotherapy regimen (combination of oxaliplatin and capecitabine). Trastuzumab was allowed for HER2-positive patients.

“Each year, more than one million new gastric cancer cases are diagnosed worldwide, with approximately half of all gastric cancer cases occurring in China. There is an urgent need to improve therapeutic options,” said Alan Sandler, M.D., President and Head of Global Development, Oncology at Zai Lab. “EF-31, conducted in China, represents an important milestone as Novocure and Zai work together to expand TTFields into new disease areas. We look forward to working with Novocure in future global clinical studies across multiple solid tumor indications.”

“TTFields therapy is a highly versatile modality with potential for broad applicability across solid tumor types and lines of therapy,” said Asaf Danziger, Novocure’s Chief Executive Officer. “We would like to thank our patients, study investigators, and our partners at Zai Lab. The EF-31 results suggest that the addition of TTFields to standard therapies may offer better patient outcomes in gastric cancer and we are eager to continue exploring these potential benefits as we look ahead to a randomized phase 3 clinical study.”

About Gastric Cancer
Gastric cancer is the third leading cause of cancer deaths worldwide and the third leading cause of cancer deaths in China. The incidence of gastric cancer is approximately 478,500 new cases annually in China, and approximately 26,000 new cases annually in the U.S.

Current therapies include surgery, chemotherapy, radiotherapy, targeted therapy and recently, immunotherapy. One of the most commonly used chemotherapy regimens for treating gastric cancer is XELOX, a combination of oxaliplatin and capecitabine. In the recent phase 3 trial (CheckMate 649, NCT-02872116, *Lancet* 2021) studying gastric cancer, the standard-of-care chemotherapy regimens showed an objective response rate range of 41% - 45%, median progression-free survival of 6.9 months, duration of response of 6.9 months, and overall survival of 11.6 months. One-year survival was 48%.

Gastric cancer is the third most-frequent cancer in China. Currently, the five-year survival rate of locally advanced or metastatic gastric cancer ranges from 5% to 20%, and the median overall survival is approximately one year.

About Tumor Treating Fields
Tumor Treating Fields NovoTTF-100L(P) is an investigational device for the treatment of gastric cancer. Safety and efficacy have not been established. Tumor Treating Fields, or TTFields, are electric fields that disrupt cancer cell division. Fundamental scientific research extends across more than two decades and, in all preclinical research to date, TTFields have demonstrated a consistent anti-mitotic effect. TTFields therapy is

intended principally for use together with other standard-of-care cancer treatments. There is a growing body of evidence that supports TTFields' broad applicability with certain other cancer therapies, including radiation therapy, certain chemotherapies and certain immunotherapies. In clinical research and commercial experience to date, TTFields therapy has exhibited no systemic toxicity, with mild to moderate skin irritation being the most common side effect. The TTFields global development program includes a network of preclinical collaborators and a broad range of clinical trials across all phases, including four phase 3 pivotal trials in a variety of tumor types. To date, more than 24,000 patients have been treated with TTFields therapy.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative, research-based, commercial stage biopharmaceutical company based in China and the U.S. 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 information on our products, business activities and partnerships, research, or 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 about clinical trials, data readouts and presentations, our clinical development programs, including our research and development program for the treatment of gastric cancer in China, the potential of our commercial business and pipeline programs, and the risk and uncertainties associated with drug development and commercialization. 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 general economic, regulatory and political conditions, (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. 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.

More information about our SEC filings can be found on the SEC's website at www.sec.gov.

About Novocure

Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer through the development and commercialization of its innovative therapy, Tumor Treating Fields. Novocure's commercialized products are approved in certain countries for the treatment of adult patients with glioblastoma and in the U.S. for the treatment of adult patients with malignant pleural mesothelioma. Novocure has ongoing or completed clinical trials investigating Tumor Treating Fields in brain metastases, gastric cancer, glioblastoma, liver cancer, non-small cell lung cancer, pancreatic cancer and ovarian cancer.

Headquartered in Jersey, and with a growing global footprint, Novocure has regional operating centers in Root, Switzerland, Portsmouth, New Hampshire and Tokyo, as well as a research center in Haifa, Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on LinkedIn and Twitter.

Novocure Forward-Looking Statements

In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Novocure's current expectations or forecasts of future events. These may include statements regarding anticipated scientific progress on its research programs, clinical trial progress, development of potential products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, coverage, collections from third-party payers and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Novocure's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, environmental, regulatory and political conditions as well as issues arising from the COVID-19 pandemic and other more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 24, 2022 with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Novocure does not intend to update publicly any forward-looking statement, except as required by law. Any forward-looking statements herein speak only as of the date hereof. The Private Securities Litigation Reform Act of 1995 permits this discussion.

Zai Lab Contacts:

Investors:
Lina Zhang
+86 136-8257-6943
lina.zhang@zailaboratory.com

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

Novocure Contacts:

Investors:
Ingrid Goldberg
investorinfo@novocure.com
610-723-7427

Media:
Leigh Labrie
media@novocure.com
610-723-7428

Source: Zai Lab Limited