Zai Lab and Novocure Announce Last Patient Enrolled in Phase 2 Pilot Trial of Tumor Treating Fields Plus Chemotherapy as First-Line Treatment in Gastric Cancer in China

October 4, 2021

Final data collection is expected in the first half of 2022

SHANGHAI and St. Helier, JERSEY, Oct. 04, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (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 final patient has been enrolled in a Novocure-sponsored phase 2 pilot trial conducted by Zai Lab evaluating the safety and efficacy of Tumor Treating Fields (TTFields) in combination with chemotherapy as a first-line treatment in patients with gastric adenocarcinoma. Final data collection is expected in the first half of 2022.

“The execution of this phase 2 pilot trial in gastric cancer reflects our commitment to bringing Tumor Treating Fields to as many patients as possible in Greater China,” said Alan Sandler, M.D., President and Head of Global Development, Oncology at Zai Lab. “Gastric cancer is the third most common cancer in China in incidence and mortality and a significant unmet medical need. Late diagnosis contributes to poor prognosis in advanced gastric cancer patients. This trial, conducted entirely in China, showcases Zai’s capabilities as we partner with Novocure to expand treatment options for gastric cancer patients in China.”

The phase 2 pilot gastric cancer trial of TTFields has enrolled approximately 30 patients in Greater China. The single-arm, open-label, multi-center study is investigating the safety and efficacy of TTFields in combination with chemotherapy as the first-line treatment of unresectable gastric adenocarcinoma, or gastroesophageal junction adenocarcinoma. In the study, patients receive TTFields and XELOX (capecitabine / oxaliplatin) chemotherapy until disease progression. The primary endpoint is investigator-assessed objective response rate. The protocol is designed to include 25 evaluable patients who receive at least one tumor assessment.

“We believe that Tumor Treating Fields’ mechanism of action is broadly applicable to treat solid tumor cancers,” said Asaf Danziger, Novocure’s Chief Executive Officer. “We look forward to seeing results from this phase 2 pilot trial with our partner, Zai Lab, and to further exploring the potential of Tumor Treating Fields as a treatment for gastric cancer.”

About Gastric Cancer
Gastric cancer is the third most-frequent cancer in China. According to Globocan 2020 estimates, more than one million new gastric cancer cases are diagnosed worldwide annually, and approximately half of all gastric cancer cases occur in China. Currently, the five-year survival rate of locally advanced or metastatic gastric cancer ranges from 5 percent to 20 percent, and the median overall survival is approximately one year.

About Tumor Treating Fields
Tumor Treating Fields, or TTFields, are electric fields that disrupt cancer cell division.

When cancer develops, rapid and uncontrolled division of unhealthy cells occurs. Electrically charged proteins within the cell are critical for cell division, making the rapidly dividing cancer cells vulnerable to electrical interference. All cells are surrounded by a bilipid membrane, which separates the interior of the cell, or cytoplasm, from the space around it. This membrane prevents low frequency electric fields from entering the cell. TTFields, however, have a unique frequency range, between 100 to 500 kHz, enabling the electric fields to penetrate the cancer cell membrane. As healthy cells differ from cancer cells in their division rate, geometry and electric properties, the frequency of TTFields can be tuned to specifically affect the cancer cells while leaving healthy cells mostly unaffected.

Whether cells are healthy or cancerous, cell division, or mitosis, is the same. When mitosis starts, charged proteins within the cell, or microtubules, form the mitotic spindle. The spindle is built on electric interaction between its building blocks. During division, the mitotic spindle segregates the chromosomes, pulling them in opposite directions. As the daughter cells begin to form, electrically polarized molecules migrate towards the midline to make up the mitotic cleavage furrow. The furrow contracts and the two daughter cells separate. TTFields can interfere with these conditions. When TTFields are present in a dividing cancer cell, they cause the electrically charged proteins to align with the directional forces applied by the field, thus preventing the mitotic spindle from forming. Electrical forces also interrupt the migration of key proteins to the cell midline, disrupting the formation of the mitotic cleavage furrow. Interfering with these key processes disrupts mitosis and can lead to cell death.

TTFields are 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 has exhibited no systemic toxicity, with mild to moderate skin irritation being the most common side effect.

Fundamental scientific research extends across two decades and, in all preclinical research to date, TTFields has demonstrated a consistent anti-mitotic 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 20,000 patients have been treated with TTFields.

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.

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, Novocure has U.S. operations in Portsmouth, New Hampshire, Malvern, Pennsylvania and New York City. Additionally, the company has offices in Germany, Switzerland, Japan and Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on LinkedIn and Twitter.

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. All of our filings with the U.S. Securities and Exchange Commission are available for free on the EDGAR system at www.SEC.gov

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 25, 2021 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:
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

Novocure Contacts:

Investors:
Ingrid Goldberg
investorinfo@novocure.com

610-723-7427

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

Zai Lab Limited

Source: Zai Lab Limited