



Zai Lab and Novocure Announce Positive Topline Results from Phase 3 PANOVA-3 Clinical Trial of Tumor Treating Fields (TTFields) Therapy for Pancreatic Cancer

December 2, 2024

PANOVA-3 met its primary endpoint with a statistically significant improvement in overall survival for patients with unresectable, locally advanced pancreatic adenocarcinoma treated in the first-line with TTFields concomitant with gemcitabine and nab-paclitaxel

Novocure plans to file for regulatory approval in the U.S., EU, Japan and other key markets; Zai Lab plans to file for regulatory approval in China

Full results from the PANOVA-3 trial will be presented at an upcoming medical congress

SHANGHAI & CAMBRIDGE, Mass. & ROOT, Switzerland--(BUSINESS WIRE)--Dec. 2, 2024-- Zai Lab Limited (Nasdaq: ZLAB; HKEX: 9688) and Novocure (NASDAQ: NVCR) announced today that the pivotal, Phase 3 PANOVA-3 trial met its primary endpoint, demonstrating a statistically significant improvement in median overall survival (mOS) versus control. PANOVA-3 evaluated the use of Tumor Treating Fields (TTFields) therapy concomitantly with gemcitabine and nab-paclitaxel as a first-line treatment for unresectable, locally advanced pancreatic adenocarcinoma.

"As a researcher and clinician, I have experienced the challenges of developing treatments in pancreatic cancer. It is exciting to see the PANOVA-3 trial achieve the positive primary endpoint of overall survival, a landmark outcome for this field," said Vincent Picozzi, M.D., medical oncologist and investigator in the PANOVA-3 trial. "These data for Tumor Treating Fields are very promising, especially in this difficult to treat patient population."

In the intent-to-treat population, patients treated with TTFields therapy concomitant with gemcitabine and nab-paclitaxel had an mOS of 16.20 months compared to 14.16 months in patients treated with gemcitabine and nab-paclitaxel alone, a statistically significant 2.0-month improvement (hazard ratio=0.819; $P=0.039$) ($N=571$). The survival rate benefit for patients treated with TTFields therapy increased over time with a 13% improvement in the overall survival rate at 12 months and a 33% improvement in survival rate at 24 months. TTFields therapy was well-tolerated, and safety was consistent with prior clinical studies.

"PANOVA-3 is the first and only Phase 3 trial to demonstrate a statistically significant benefit in overall survival specifically in unresectable, locally advanced pancreatic cancer, and is Novocure's third positive Phase 3 clinical trial in the last two years," said Nicolas Leupin, M.D., PhD, Chief Medical Officer, Novocure. "We are grateful to the patients and investigators for their participation in the trial, and we look forward to sharing the full data at an upcoming medical conference."

"There are approximately 134,000 new cases of pancreatic cancer diagnosed annually in China, and this cancer is one of the most challenging to treat globally, with limited effective treatment options and poor survival outcomes," said Dr. Rafael Amado, M.D., President, Head of Global Research and Development at Zai Lab. "Demonstrating a statistically significant and clinically meaningful improvement in overall survival for patients with unresectable, locally advanced pancreatic cancer is an important achievement. We are pleased to have been able to contribute to the PANOVA-3 study, and we look forward to working with Novocure to bring this therapy to patients as soon as possible."

Novocure plans to file for regulatory approval of TTFields in unresectable, locally advanced pancreatic adenocarcinoma based on PANOVA-3 and plans to submit the PANOVA-3 results for presentation at an upcoming medical congress. Zai Lab plans to file for regulatory approval in China.

About PANOVA-3

PANOVA-3 is a prospective, randomized open-label, controlled Phase 3 clinical trial designed to test the efficacy and safety of Tumor Treating Fields (TTFields) therapy used concomitantly with gemcitabine and nab-paclitaxel, as a first-line treatment of locally advanced pancreatic adenocarcinoma. Patients were randomized to receive either TTFields therapy concomitant with gemcitabine and nab-paclitaxel or gemcitabine and nab-paclitaxel alone.

The primary endpoint is overall survival. Secondary endpoints include progression free survival, local progression free survival, objective response rate, one-year survival rate, quality of life, pain-free survival, puncture-free survival, resectability rate, and toxicity.

A total of 571 patients were enrolled in the study, randomized 1:1 and followed for a minimum of 18 months.

About Pancreatic Cancer in China

Pancreatic cancer is one of the most common and deadliest cancers globally. In China, there were an estimated 134,374 new cases in 2022, and it is now the eighth most common cancer type¹. The current median survival of patients with locally advanced, unresectable pancreatic cancer is nine to twelve months, and the five-year survival rate was 7.2%², making it the malignancy with the lowest survival rate in China.

¹ Xia C, Dong X, Li H et al. Cancer statistics in China and United States, 2022: profiles, trends, and determinants. Chin Med J (Engl) 2022; 135: 584-590.

² Hu JX, Zhao CF, Chen WB et al. Pancreatic cancer: A review of epidemiology, trend, and risk factors. World J Gastroenterol 2021; 27: 4298-4321.

About Tumor Treating Fields

Tumor Treating Fields (TTFields) are electric fields that exert physical forces to kill cancer cells via a variety of mechanisms. TTFields do not significantly affect healthy cells because they have different properties (including division rate, morphology, and electrical properties) than cancer cells. These multiple, distinct mechanisms work together to target and kill cancer cells. Due to these multimechanistic actions, TTFields therapy can be added to cancer treatment modalities in approved indications and demonstrates enhanced effects across solid tumor types when used with chemotherapy, radiotherapy, immune checkpoint inhibition, or targeted therapies in preclinical models. TTFields therapy provides clinical versatility that has the potential to help address treatment challenges across a range of solid tumors.

To learn more about TTFields therapy and its multifaceted effect on cancer cells, visit tumortreatingfields.com.

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. We are focused on discovering, developing, and commercializing innovative products that address medical conditions with significant unmet needs in the areas of oncology, immunology, neuroscience, and infectious disease. Our goal is to leverage our competencies and resources to positively impact human health in China and worldwide.

For additional information about Zai Lab, 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, non-small cell lung cancer, malignant pleural mesothelioma and pleural mesothelioma. Novocure has several additional ongoing or completed clinical trials exploring the use of Tumor Treating Fields therapy in the treatment of glioblastoma, non-small cell lung cancer and pancreatic cancer.

Novocure's global headquarters is located in Root Switzerland, with U.S. headquarters located in Portsmouth, New Hampshire and research and development facilities located in Haifa, Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on [LinkedIn](#) and [X \(Twitter\)](#).

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements about future expectations, plans, and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for developing and commercializing TTFields therapy, the potential benefits of TTFields therapy, and the potential treatment of pancreatic cancer. 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 or 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 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) risks related to doing business in China, and (6) 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 the SEC's website at www.sec.gov.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20241202363277/en/>

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