Zai Lab Announces China National Medical Products Administration Grants Innovative Medical Device Designation for Tumor Treating Fields for Patients with Pancreatic Cancer

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SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 19, 2025-- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced that the China National Medical Products Administration (NMPA) has granted Innovative Medical Device Designation for Tumor Treating Fields (TTFields) for patients with pancreatic cancer based on the positive results from the Phase 3 PANOVA-3 trial. The Innovative Medical Device Designation allows Zai Lab to take advantage of an expedited approval procedure for TTFields that offers opportunities for the NMPA to prioritize the allocation of review resources to expedite the regulatory review and approval process.

“We are excited that TTFields has been granted the Innovative Medical Device Designation, a status that offers expedited registration and priority review by the NMPA. This designation also allows us to submit the application in China before approval in the country of origin,” said Rafael Amado, M.D., President, Head of Global Research and Development at Zai Lab. “Pancreatic cancer remains one of the most challenging cancers to treat globally, with approximately 134,000 new cases diagnosed annually in China alone. We are on track to submit for regulatory approval in China in the second half of 2025 and look forward to collaborating closely with the NMPA throughout the review process.”

The Phase 3 PANOVA-3 trial evaluated the use of TTFields therapy concomitantly with gemcitabine and nab-paclitaxel as a first-line treatment for unresectable, locally advanced pancreatic adenocarcinoma compared to gemcitabine and nab-paclitaxel alone. The trial met its primary endpoint, demonstrating a statistically significant improvement in median overall survival for patients treated with TTFields. Zai Lab participated in the study in Greater China (mainland China, Hong Kong, Macau and Taiwan, collectively).

In August 2019, the NMPA granted Innovative Medical Device Designation for Optune® in China for the treatment of newly diagnosed and recurrent glioblastoma (GBM). Zai Lab subsequently submitted the regulatory application in September 2019 and received approval in May 2020. Optune is a registered trademark of Novocure GmbH, and Zai Lab markets Optune under license from Novocure GmbH.

About PANOVA-3

PANOVA-3 is an international prospective, randomized, open-label, controlled Phase 3 clinical trial designed to test the efficacy and safety of TTFields therapy used concomitantly with gemcitabine and nab-paclitaxel, as a first-line treatment for 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.

The PANOVA-3 trial enrolled 571 patients who were 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 and 131,203 cancer deaths in 2022, and it is the sixth leading cause of cancer mortality in China[1]. Pancreatic cancer has a 5-year survival rate of less than 10%, making it the malignancy with the lowest survival rate in China [2].

The patients with locally advanced, unresectable pancreatic cancer are no longer operable, so chemotherapy with or without radiation is the only treatment option, with a median overall survival only nine to twelve months.

[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) is a cancer therapy that uses 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 multi mechanistic 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 inhibitors, 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 effects 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.

For additional information about Zai Lab, please visit www.zailaboratory.com or follow us at https://x.com/ZaiLab_Global.

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.

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For more information, please contact:

Investor Relations:
Christine Chiou / Lina Zhang
+1 (917) 886-6929 / +86 136 8257 6943
christine.chiou1@zailaboratory.com / lina.zhang@zailaboratory.com

Media:
Shaun Maccoun / Xiaoyu Chen
+1 (857) 270-8854 / +86 185 0015 5011
shaun.maccoun@zailaboratory.com / xiaoyu.chen@zailaboratory.com

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