Zai Lab Partner Novocure Announces METIS Phase 3 Clinical Trial Met Primary Endpoint, Demonstrating a Statistically Significant Extension in Time to Intracranial Progression for Patients with Brain Metastases from Non-Small Cell Lung Cancer

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The METIS trial demonstrated 21.9 months median time to intracranial progression for patients treated with Tumor Treating Fields and supportive care compared to 11.3 months for patients treated with supportive care alone

SHANGHAI & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 27, 2024-- Zai Lab Limited (Nasdaq: ZLAB; HKEX: 9688) partner Novocure (NASDAQ: NVCR) today announced the phase 3 METIS clinical trial met its primary endpoint, demonstrating a statistically significant improvement in time to intracranial progression for adult patients treated with Tumor Treating Fields (TTFields) therapy and supportive care compared to supportive care alone in the treatment of patients with 1-10 brain metastases from non-small cell lung cancer (NSCLC) following stereotactic radiosurgery (SRS). Patients treated with TTFields therapy and supportive care exhibited a median time to intracranial progression of 21.9 months compared to 11.3 months in patients treated with supportive care alone for brain metastasis (n=298; hazard ratio=0.67; P=0.016). Median TTFields therapy treatment duration was 16 weeks and median usage was 67%. Consistent with previous studies, TTFields therapy was well-tolerated with sustained quality of life and neurocognitive function. Baseline characteristics were well balanced between arms.

Preliminary analyses of key secondary endpoints (time to neurocognitive failure, overall survival, and radiological response rate) did not demonstrate statistical significance. Certain secondary endpoints showed positive trends in favor of treatment with TTFields therapy, including time to distant progression and quality of life. Full analysis of secondary endpoints is ongoing.

Novocure intends to submit these data to regulatory authorities. Novocure also intends to publish these findings in a peer-reviewed scientific journal and share them at an upcoming scientific congress.

Zai Lab contributed to the METIS trial and achieved treatment of the first patient in Greater China in May 2021.

About METIS

METIS [NCT02831959] is a phase 3 trial of stereotactic radiosurgery with or without TTFields therapy for patients with 1-10 brain metastases from NSCLC. 298 adult patients were enrolled in the trial and randomized to receive either TTFields therapy with supportive care or supportive care alone following SRS. Supportive care consisted of, but was not limited to, treatment with steroids, anti-epileptic drugs, anticoagulants, pain control or nausea control medications. Patients in both arms of the study were eligible to receive systemic therapy for their NSCLC at the discretion of their treating physician. Patients with known tumor mutations for which targeted agents are available were excluded from the trial.

The primary endpoint of the METIS trial is time to first intracranial progression, as measured from the date of first SRS treatment to intracranial progression or neurological death (per RANO-BM criteria), whichever occurs first. Time to intracranial progression was calculated according to the cumulative incident function. Patient scans were evaluated by a blinded, independent radiologic review committee. Secondary endpoints include, but are not limited to, time to distant progression, time to neurocognitive failure, overall survival, time to second intracranial progression, quality of life and adverse events. Key secondary endpoints (time to neurocognitive failure, overall survival, and radiological response rate) were planned to be used in labeling claims, if successful. Patients were stratified by the number of brain metastases (1-4 or 5-10 metastases), prior systemic therapy, and tumor histology. Patients were allowed to crossover to the experimental TTFields therapy arm following confirmation of second intracranial progression.

About Brain Metastases from NSCLC in China

Brain metastases are secondary tumors formed when cancer cells break away from the primary tumor and travel through the blood or lymph system to form new tumors (or metastases) in the brain. Brain metastases are a negative prognostic factor in NSCLC and adversely impact neurocognitive function and quality of life.

Each year in China, approximately 740,000 patients are newly diagnosed with NSCLC. Approximately 20%–65% of lung cancer patients develop brain metastases at some point during their illness.[1] Among patients who received chemotherapy, the survival of patients with brain metastases at diagnosis was still poor, which is about six months.[2]

Treatment options for patients with brain metastases from NSCLC are limited to neurosurgery, SRS, whole brain radiation therapy, or combinations of these options. However, given the neurotoxicity and significant decline in cognitive functioning, whole brain radiation therapy (WBRT) is an unfavorable treatment option. New therapeutic options are needed for greater intracranial control while minimizing the risk of neurocognitive adverse events.

[1] *China guidelines for the treatment of brain metastases from lung cancer (2021 edition). Chinese Journal of Oncology, 2021, 43(3): 269-281. DOI: 10.3760/cma.j.cn112152-20210104-00009.*

[2] *Ali, A., Goffin, J. R., Arnold, A., & Ellis, P. M. (2013). Survival of patients with non-small-cell lung cancer after a diagnosis of brain metastases. Current oncology (Toronto, Ont.), 20(4), e300–e306. https://doi.org/10.3747/co.20.1481.*

About Tumor Treating Fields Therapy

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. The multiple, distinct mechanisms of TTFields therapy work together to selectively target and kill cancer cells. Due to its 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 PARP inhibition 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 Tumor Treating Fields therapy and its multifaceted effect on cancer cells, visit tumortreatingfields.com.

About Zai Lab

Zai Lab (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, autoimmune disorders, infectious diseases, and neuroscience. 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.

Zai Lab Forward-Looking Statements

This press release contains forward-looking statements relating to the future expectations, plans, and prospects, for Zai Lab, including, without limitation, statements relating to Zai Lab's prospects and plans for developing and commercializing TTFields, the potential benefits of TTFields, and the potential treatment for patients with brain metastases from NSCLC. 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 Zai Lab's 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) Zai Lab's ability to successfully commercialize and generate revenue from the approved products, (2) Zai Lab's ability to obtain funding for the operations and business initiatives, (3) the results of Zai Lab's clinical and pre-clinical development of the product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of the product candidates, (5) risks related to doing business in China, and (6) other factors identified in Zai Lab's most recent annual and quarterly reports and in other reports Zai Lab has filed with the U.S. Securities and Exchange Commission (SEC). Zai Lab anticipates that subsequent events and developments will cause the expectations and assumptions to change, and Zai Lab undertakes 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 Zai Lab's views as of any date subsequent to the date of this press release.

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

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