



Zai Lab Announces First Patient Treated in Greater China in METIS Phase 3 Pivotal Trial of Tumor Treating Fields in Brain Metastases from Non-Small Cell Lung Cancer

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SHANGHAI and SAN FRANCISCO, May 24, 2021 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, today announced treatment of the first patient in Greater China in the METIS trial, a Phase 3 pivotal trial being conducted by Zai's partner NovoCure Limited (NASDAQ: NVCR) to study radiosurgery plus Tumor Treating Fields (TTFields) compared to radiosurgery alone for the treatment of brain metastases from non-small cell lung cancer (NSCLC).

"I am excited that Zai Lab is participating in this important clinical trial that aims to address a significant unmet medical need," said Alan Sandler, M.D., President, Head of Global Development, Oncology of Zai Lab. "Patients with brain metastasis resulting from non-small cell lung cancer generally have few treatment options and poor outcomes. We look forward to generating data from use of Tumor Treating Fields in this and several other major cancer types as soon as possible."

The METIS trial (also known as the EF-25 trial) is a pivotal, randomized, controlled Phase 3 trial designed to test the efficacy and safety of TTFields, generated by a medical device, the NovoTTF-100M System, in patients with 1-10 newly diagnosed brain metastasis from NSCLC. TTFields are administered to patients concomitantly with the best standard of care treatments that would normally be used to treat lung cancer. The trial is expected to enroll 270 patients randomized 1:1 to receive, following radiosurgery, either TTFields at a frequency of 150kHz plus supportive care or supportive care alone. The primary endpoint is time to first cerebral progression. Secondary endpoints include, among others, time to neurocognitive failure, overall survival, and radiological response rate.

About Brain Metastasis from NSCLC in China

Lung cancer consists of NSCLC in approximately 85% of cases and small cell lung cancer (SCLC) in approximately 15% of cases. Lung cancer has the highest total incidence of any cancer in China. According to the World Health Organization, the incidence of lung cancer in China in 2020 was 815,563 cases, with 714,699 deaths. About 7%–10% of NSCLC patients evidence brain metastases at the time of initial diagnosis, and approximately 20%–40% of patients develop brain metastases at some point during their illness.ⁱ ⁱⁱ The average survival for these patients is about six months from diagnosis.ⁱ

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

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer and infectious and autoimmune diseases to patients in China and around the world. We aim to address significant unmet medical needs in large, fast-growing segments of the pharmaceutical market. 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 drug candidates. We have also built an in-house team with strong drug discovery and translational research capabilities and are establishing a pipeline of proprietary drug 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/Zai_lab_Global.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects and plans for developing and commercializing Tumor Treating Fields in Greater China and other 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 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 its approved products; (2) Zai Lab’s ability to finance its operations and business initiatives and obtain funding for such activities, (3) Zai Lab’s results of clinical and pre-clinical development of its product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab’s 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 Zai Lab anticipates that subsequent events and developments will cause Zai Lab’s expectations and assumptions to change and 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.

For more information, please contact:

ZAI LAB CONTACTS:

Zai Lab

Billy Cho, CFO

+86 137 6151 2501

billy.cho@zailaboratory.com

Media: Ryo Imai / Robert Flamm, Ph.D.

Burns McClellan, on behalf of Zai Lab

212-213-0006 ext. 315 / 364

rimei@burnsmc.com / rflamm@burnsmc.com

Investors: Pete Rahmer / Mike Zanoni

Endurance Advisors, on behalf of Zai Lab

415-515-9763 / 610-442-8570

prahmer@enduranceadvisors.com / mzanoni@enduranceadvisors.com

Zai Lab Limited

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ⁱ 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>

ⁱⁱ Liu, Q., Tong, X. & Wang, J. Management of brain metastases: history and the present. *Chin Neurosurg JI* 5, 1 (2019). <https://doi.org/10.1186/s41016-018-0149-0>



Source: Zai Lab Limited