



Asian Sub-Group Analysis of Novocure's EF-14 Phase 3 Trial of Optune® in Newly Diagnosed Glioblastoma Presented at ASNO 2019 Demonstrating Efficacy and Safety Benefits

2019年 9月 29日

September 29, 2019

Novocure (NASDAQ: NVCR) today presented the sub-group data in Asian patients from the EF-14 phase 3 pivotal trial of Optune in combination with temozolomide for the treatment of newly diagnosed glioblastoma (GBM). This is the first data analyzing the benefits of tumor treating fields on Asian patients, which has won the first place of the JNO (Journal of Neuro-Oncology) Outstanding Paper Award at the 16th annual meeting of the Asian Society for Neuro-Oncology (ASNO) in China Taiwan. Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing certain cancer cells to die. The Asian sub-group data show that glioblastoma patients who received TTFs in combination with chemotherapy lived significantly longer than patients who received chemotherapy alone.

The EF-14 trial enrolled Asian patients in 8 sites in South Korea. A total of 39 patients were enrolled (24 in the Optune/TMZ arm and 15 in the TMZ alone arm). This analysis demonstrated that there was no difference between the clinical outcome in the general study population and 39 Korean patients randomized to the EF-14 study in newly diagnosed GBM patients. The median OS and 1- and 2- survival rates were higher than those reported for the general EF-14 study population. In addition, adding Optune to TMZ did not lead to increased toxicity and most adverse events were seen at a lower incidence in the Optune/TMZ group than in the TMZ alone group. This further emphasizes that the results of the EF-14 trial are applicable to Asian patients.

- The baseline characteristics of Korean patients were well-balanced between the two arms, and largely followed the reported baseline characteristics in the general EF-14 study.

- There were no differences in the adverse events incidence in Korea between arms in the trial. In the Optune/TMZ group, 30% of patients suffered from skin irritation while in the entire study, the incidence rate is 44%.

- The median PFS in the Optune/TMZ arm was 6.2 months versus 4.2 in the TMZ alone arm ($p=0.67$). Median overall survival was 27.2 months in the Optune/TMZ arm of the study, significantly higher than the median OS in the entire Optune/TMZ population of the EF-14 trial and higher than the median OS of the TMZ alone arm of the trial (15.2 months, 95% CI 7.5-24.1). The Hazard Ratio was 0.27 ($p=0.01$).

- The 1-year survival rates were 95.6% versus 73% and the 2-year survival rates were 60% versus 30% in the Optune/TMZ and TMZ only arms, respectively. While the 1- and 2-year survival rates in the Korean TMZ alone arm were very similar to those reported for the entire EF-14 control arm population, the difference in rates was higher in Optune-treated Korean patients compared to the entire Optune-treated EF-14 population (95.6% Vs. 73% and 59.9% Vs. 43%, respectively).

“The data shows that Asian GBM patients are also benefited from Tumor Treating Fields therapy with improved overall survival and good safety profile.” said Chae-Yong Kim, MD, PhD, a trial investigator and Professor of Department of Neurosurgery, Seoul National University Bundang Hospital, Seoul National

University College of Medicine in Korea. “We are encouraged by the results and we believe that TTFIELDS will likely join surgery, systemic therapy, and radiation therapy as a component of multimodality management of patients with solid malignancies.”

“The results of EF-14 and Asian sub-group analysis demonstrated that TTFIELDS can improve progression-free survival, overall survival and quality of life, without compromising any cognitive function. It has the potential to fundamentally transform the treatment paradigm for GBM patients in China based on its compelling efficacy and safety data.” said Jiang Tao, M.D., Ph.D., Head of Beijing Neurosurgical Institute, Founder of Chinese Glioma Genome Atlas, and Professor of Beijing Tiantan Hospital. “GBM is one of the highest unmet medical need diseases in oncology and we need to bring this novel therapy to Chinese patients as soon as possible.”

In mainland China, the Marketing Authorization Application (MAA) for Optune for the treatment of patients with GBM has been accepted by the China National Medical Products Administration (NMPA) and was granted with Innovative Medical Device Designation.

About Tumor Treating Fields

Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing affected cancer cells to die. Tumor Treating Fields does not stimulate or heat tissue and targets dividing cancer cells of a specific size. Tumor Treating Fields causes minimal damage to healthy cells. Mild to moderate skin irritation is the most common side effect reported. Tumor Treating Fields is approved in certain countries for the treatment of adults with glioblastoma and mesothelioma, two of the most difficult cancer types to treat. The therapy shows promise in multiple solid tumor types – including some of the most aggressive forms of cancer.

Approved Indications

Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, Optune is indicated following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

The NovoTTF-100L System is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

About Novocure

Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer by developing and commercializing its innovative therapy, Tumor Treating Fields. Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division. Novocure’s commercialized product is approved for the treatment of adult patients with glioblastoma and malignant pleural mesothelioma. Novocure has ongoing or completed clinical trials investigating Tumor Treating Fields in brain metastases, non-small cell lung cancer, pancreatic cancer, ovarian cancer and liver 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.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a China and U.S.-based innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.