METIS Phase 3 Clinical Trial Met Primary Endpoint Significantly Delaying Time to Intracranial Progression with Improved Quality of Life Deterioration-Free Survival

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

Patients treated with TTFields therapy experienced prolonged quality of life deterioration-free survival and TTFields therapy was well-tolerated

Data from the METIS trial to be presented today during the 2024 ASCO Annual Meeting

ROOT, Switzerland–(BUSINESS WIRE)– Novocure (NASDAQ: NVCR) today announced the presentation of clinical data from the phase 3 METIS trial, which investigated the use of Tumor Treating Fields (TTFields) therapy in the treatment of brain metastases from non-small cell lung cancer (NSCLC). These data will be presented at the ongoing 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

The METIS trial enrolled 298 adult patients with 1-10 brain metastases from NSCLC, who were randomized following stereotactic radiosurgery (SRS) to receive either TTFields therapy and best supportive care (BSC) (n=149) or BSC alone (n=149). METIS met its primary endpoint, demonstrating a statistically significant improvement in time to intracranial progression. Patients treated with TTFields therapy and BSC exhibited a median time to intracranial progression of 21.9 months compared to 11.3 months in patients treated with BSC alone (hazard ratio=0.67; *P*=0.016). Median TTFields therapy duration was 16 weeks and median usage was 67%. Baseline patient demographics and characteristics were well balanced between arms.

Patients treated with TTFields therapy demonstrated improved quality of life deterioration-free survival, with median time to quality of life deterioration-free survival not reached in the TTFields therapy cohort compared to 7.7 months in control arm (*P*=0.038). A positive trend was observed in patients treated with TTFields therapy in the majority of scales and items assessed by the EORTC QLQ C30 and BN20 patient questionnaire. There was no evidence of worsening cognitive functioning in the TTFields therapy arm compared to the control arm. Consistent with prior clinical trials, TTFields therapy was well-tolerated with no additive systemic toxicity.

Preliminary analyses of key secondary endpoints did not demonstrate statistical significance. Median overall survival for patients randomized to receive TTFields therapy and BSC was 11.3 months compared to 10.6 months in patients treated with BSC alone. Full analysis of secondary endpoints is ongoing.

“One of the key challenges in combatting the spread of brain metastases is maintaining patients’ quality of life and cognitive function,” said lead investigator Minesh Mehta, MD, Chief of Radiation Oncology and Deputy Director at Miami Cancer Institute, part of Baptist Health South Florida. “The ability of TTFields therapy to prolong the time to intracranial progression without negatively impacting either quality of life or cognitive function has the potential to change the way brain metastases from non-small cell lung cancer are treated.”

“Despite the high incidence level of brain metastases from NSCLC, the treatment options available for patients are very limited,” said Nicolas Leupin, MD, Novocure’s Chief Medical Officer. “The observations from the METIS trial are an important first step in potentially adding a new treatment option for these patients and we are eager to pursue the necessary steps to ensure TTFields therapy is available to those in need.”

These data will be featured by Dr. Mehta in an oral presentation (abstract #2008) at 10:24 a.m. CDT on Monday, June 3, 2024 during ASCO’s Central Nervous System Tumors session. Novocure intends to publish these findings in a peer-reviewed scientific journal and submit these data to regulatory authorities.

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. Full analysis of secondary endpoints is ongoing. 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 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 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 Tumor Treating Fields therapy and its multifaceted effect on cancer cells, visit tumortreatingfields.com.

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 and malignant pleural mesothelioma. Novocure has ongoing or completed clinical studies investigating Tumor Treating Fields in brain metastases, gastric cancer, glioblastoma, liver cancer, non-small cell lung cancer, pancreatic cancer and ovarian cancer.

Headquartered in Root, Switzerland and with a growing global footprint, Novocure has regional operating centers in Portsmouth, New Hampshire and Tokyo, as well as a research center in Haifa, Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on LinkedIn and Twitter.

Forward-Looking Statements

In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Novocure's current expectations or forecasts of future events. These may include statements regarding anticipated scientific progress on its research programs, clinical study progress, development of potential products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, coverage, collections from third-party payers and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Novocure's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, environmental, regulatory and political conditions and other more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 22, 2024, and subsequent filings with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Novocure does not intend to update publicly any forward-looking statement, except as required by law. Any forward-looking statements herein speak only as of the date hereof. The Private Securities Litigation Reform Act of 1995 permits this discussion.

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