

## **Study Results of Novocure's Pivotal Phase 3 Trial Published in *European Journal of Cancer* Show that NovoTTF™ Therapy was Comparable to Physicians' First Chemotherapy Choice in Clinical Efficacy with Better Quality of Life Outcomes in Patients with Recurrent Glioblastoma**

*TTFields therapy uses Novocure's NovoTTF™-100A portable device to deliver alternating electrical fields to disrupt cancer cell growth*

**Portsmouth, NH – May 21** – Results of the first randomized controlled trial to compare a novel cancer treatment modality delivering Tumor Treating Fields (TTFields) therapy versus chemotherapy in patients with recurrent glioblastoma (GBM) were published in the *European Journal of Cancer* (Stupp R. et al., NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomized phase III trial of a novel treatment modality, *Eur J Cancer*(2012), <http://dx.doi.org/10.1016/j.ejca.2012.04.011>). The study showed that NovoTTF™ therapy was comparable to active chemotherapy in extending overall survival, with minimal side effects and far better quality of life.

Novocure™, a commercial stage private oncology company, manufactures the device, NovoTTF™-100A, a wearable device that delivers TTFields, or alternating electrical fields, specifically tuned to disrupt the uncontrolled division of cancer cells, resulting in cell death.

This is the first publication in a peer reviewed journal of the Phase 3 trial of chemotherapy-free treatment with NovoTTF monotherapy (20-24h/day) versus active chemotherapy in the treatment of patients with recurrent GBM. The primary endpoint of the trial was overall survival. The secondary endpoints were progression-free survival at six months, 1-year survival rate, and quality of life.

Patients enrolled in the Phase 3 trial had a median age of 54 years (range 23-80) with a Karnofsky performance status of 80% (range 50-100). Patients were randomized to NovoTTF alone (n=120) or active chemotherapy control (n=117). The average number of prior non-TTField treatments was two (range 1-6). At a median follow-up of 39 months, median survival was 6.6 versus 6.0 months (hazard ratio 0.86 [95% CI 0.66-1.12]; p=0.27), one-year survival rate was 20% and 20%, and progression-free survival rate at six months was 21.4% and 15.1% (p=0.13), in NovoTTF and active control patients,

respectively. Radiological responses were comparable (14% versus 9.6%,  $p=0.19$ ), with 3% complete responses seen only in the NovoTTF arm.

The most common NovoTTF-related adverse events were principally mild (14%) to moderate (2%) skin rash beneath the device's transducer arrays. Severe adverse events occurred in 6% of patients treated with NovoTTF vs 16% for those treated with chemotherapy ( $p=0.02$ ). Quality of life analyses favored NovoTTF therapy in most domains, including vomiting, nausea, pain, diarrhea, constipation, and cognitive and emotional functioning.

"The patients treated within this trial had very, very advanced disease. Most of our patients rapidly become independent in handling the device and loved having a treatment without the need for chemotherapy," said Dr. Roger Stupp of the University of Lausanne, lead author of the study. "We are encouraged by our findings and the future groundbreaking potential of NovoTTF therapy in this tough-to-treat disease and other cancer."

The study's co-principal investigator Dr. Philip Gutin, Chair of the Department of Neurosurgery and Co-Executive Director of the Brain Tumor Center at Memorial Sloan Kettering Cancer Center in New York said, "Patients who have GBM face significant challenges, and we as physicians currently have limited treatment options. This study shows that a new, safe and effective treatment option is now available."

"The results of this important trial clearly show that a fourth treatment modality now exists for patients with recurrent GBM," said Asaf Danziger, Novocure's Chief Executive Officer. "We are working closely with many of the leading cancer centers in the world to make NovoTTF therapy available to their patients, and will continue to develop this new cancer fighting weapon to improve the lives of people suffering from this disease."

## **About Glioblastoma**

Glioblastoma (GBM) is the most aggressive and most common form of primary brain tumor in the U.S. The disease affects approximately 10,000 Americans each year. Historically, based on literature, the median overall survival time from initial diagnosis is 15 months with optimal treatment, and median survival from the time of tumor recurrence is only 3-5 months without additional effective treatment. The disease is widely recognized as one of the deadliest forms of cancer.

## **About the NovoTTF™-100A System**

NovoTTF™-100A System is a portable, non-invasive medical device designed for continuous use throughout the day by the patient. The device has been shown in both *in vitro* and *in vivo* studies to slow and reverse tumor growth by inhibiting mitosis, the process by which cells divide and replicate. The NovoTTF-100A device, which weighs about six pounds (three kilograms), creates a low intensity, alternating electric field within the tumor that exerts physical forces on electrically charged cellular components, preventing the normal mitotic process and causing cancer cell death prior to division. In patients with recurrent glioblastoma brain tumors, the device has shown clinical efficacy comparable to that of active chemotherapies with better quality of life and without many of the side effects of chemotherapy. The NovoTTF-100A has received marketing approval in the US and is a CE Marked device that is cleared for sale in Europe.

## **Approved Indication**

The US Food and Drug Administration (FDA) approved the NovoTTF-100A System in April 2011 for use as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM), following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

Patients should only use the NovoTTF-100A System under the supervision of a physician properly trained in use of the device. Full prescribing information is available at [www.novottftherapy.com](http://www.novottftherapy.com) or by calling toll free 1-855-281-9301.

## **About Novocure™**

Novocure™ Limited is a private oncology company pioneering a novel therapy for solid tumors. Novocure's worldwide headquarters is located in the Jersey Isle. Novocure's US operations are based in Portsmouth, NH and the company's research center is located in Haifa, Israel. For additional information about the company, please visit [www.novocure.com](http://www.novocure.com).

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