FDA Approves the NovoTTF-100A System for the Treatment of Patients with Recurrent Glioblastoma Multiforme (GBM) Brain Tumors

First ever medical device therapy indicated as an alternative to chemotherapy for cancer

WASHINGTON, D.C. – April 15, 2011 – Novocure today announced that the U.S. Food and Drug Administration (FDA) approved the NovoTTF-100A System (NovoTTF) for the treatment of adult patients with glioblastoma multiforme (GBM) brain tumors, following tumor recurrence after receiving chemotherapy. The portable, wearable device delivers an anti-mitotic, anti-cancer therapy as patients maintain their normal daily activities. The NovoTTF is a novel, first-in-class treatment option for patients and physicians battling glioblastoma.

“Our device provides patients and physicians with a novel, non-invasive alternative to chemotherapy that is safe and effective,” said Eilon Kirson, M.D., Ph.D., Novocure’s Chief Medical Officer. “The device allows for continuous treatment without the usual, debilitating side effects that chemotherapies inflict on recurrent GBM patients and indirectly on their families.”

Results from a 237 patient randomized pivotal trial demonstrated that compared to patients treated with chemotherapy, NovoTTF treated patients achieved comparable median overall survival times, had fewer side effects, and reported improved quality of life scores.

Glioblastoma is the most aggressive and most common form of primary brain tumor in the United States. The disease affects approximately 10,000 Americans each year. The median overall survival time from initial diagnosis is 15 months with optimal therapy, and median survival from the time of tumor recurrence is only three to four months without additional effective treatment. The disease is widely recognized as one of the most aggressive and deadly forms of cancer.

“We move forward from today proud of the efforts and accomplishments of our team, thankful to our investors for their support and guidance, and humbled by the trust of our patients and physicians.” said Asaf Danziger, CEO of Novocure. “Our next task is to make NovoTTF therapy available as a treatment option for all recurrent GBM patients in the US.”

“The FDA approval of the NovoTTF device is the culmination of ten years of research, development and clinical trials conducted by an exceptional team of scientists, engineers, and clinicians and built on the original insights of our founder and CTO Yoram Palti, M.D., Ph.D.” said William F. Doyle, Novocure’s executive chairman. “We look forward to bringing this device to recurrent GBM patients and their families, and we look forward to developing NovoTTF therapy for a range of additional solid tumor cancers.”

Pivotal Trial Results
The FDA approval was based on data from a randomized pivotal trial of 237 patients with glioblastoma tumors that had recurred or progressed despite previous surgical, radiation and chemotherapy treatments. Patients treated with the NovoTTF alone achieved a comparable overall survival time to patients treated with the physician’s choice of the best chemotherapy. The rate of progression free survival at six months (PFS6) was 21% in the NovoTTF group compared to 15% in chemotherapy patients. Also, patients treated with the NovoTTF had a 14% tumor response rate (RR) compared to 10% in chemotherapy treated patients in the trial, and 3 complete radiographic responses were observed in the NovoTTF group compared to none in chemotherapy patients. NovoTTF treated patients reported better quality of life scores and fewer side effects during the trial compared to patients treated with
chemotherapy. Specifically, quality of life using the device was better than that of chemotherapy patients in the following subscale domains: vomiting, nausea, pain, diarrhea, constipation, cognitive functioning and emotional functioning, all of which are hallmarks of patient suffering while receiving chemotherapy. The most commonly reported side effect from NovoTTF treatment was a mild-to-moderate rash beneath the electrodes.

The NovoTTF-100A
NovoTTF-100A is a portable, non-invasive medical device designed for continuous use throughout the day by the patient. The device has been shown in \textit{in vitro} 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. Novocure currently has US and European marketing approvals for the NovoTTF-100A.

Ongoing Clinical Studies
Novocure is sponsoring an ongoing pivotal trial of the NovoTTF for patients with newly diagnosed glioblastoma tumors under an approved investigational device exemption (IDE) application. For additional information about this trial, please visit \url{www.novocuretrial.com}.

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 \url{www.novocure.com}.

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Pictures

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![Image 2](image2.png)