



## **FDA Advisory Committee Finds Data Support the Safety and Effectiveness of NovoTTF-100A System**

### *A Novel, First-in-Class Treatment for Glioblastoma Brain Tumor Patients*

**Washington, D.C. – March 17, 2011** – Novocure announced today that the U.S. Food and Drug Administration (FDA) Neurological Devices Advisory Panel of the Medical Devices Advisory Committee voted (7 yes; 3 no; 2 abstain) that for patients with supra-tentorial glioblastoma multiforme (GBM) tumors that recur after maximal surgical and radiation treatments, there is reasonable assurance that the benefits of the NovoTTF-100A System (NovoTTF) outweigh its risks when administered as a monotherapy in place of standard medical therapy.

“We are pleased with the outcome of the Advisory Committee’s vote on the safety and effectiveness of NovoTTF,” said Eilon Kirson, M.D., Ph.D., and the Chief Medical Officer of Novocure.

The committee’s recommendation followed a review of data from the EF-11 Trial, a randomized phase III trial for 237 patients with glioblastoma tumors that had recurred or progressed despite previous treatments. The committee received and considered the final data from the EF-11 Trial, which updated data previously reported at the American Society for Clinical Oncology Annual Meeting in June 2010. The trial demonstrated that patients treated with the NovoTTF alone achieved a comparable overall survival time to patients treated with the physician’s choice of the best chemotherapy. Patients treated with the NovoTTF also had higher rates of progression free survival at six months (PFS6) and higher tumor response rates (RR) compared to chemotherapy treated patients in the trial (PFS6 of 21 percent vs. 15 percent and RR of 14 percent vs. 10 percent). NovoTTF treated patients reported better quality of life scores and fewer side effects during the trial compared to patients treated with chemotherapy. The NovoTTF’s most commonly reported side effect was a mild-to-moderate rash beneath the electrodes.

“We look forward to working with the FDA to bring this novel, important therapy to patients as soon as possible,” said Asaf Danziger, CEO of Novocure. The FDA is currently reviewing a pre-market approval (PMA) application for the NovoTTF for this indication.

### **ABOUT NOVOTTF-100A**

NovoTTF-100A is a portable, non-invasive medical device designed for continuous use throughout the day by the patient. TTF therapy has been shown in vitro to slow and reverse tumor cell proliferation 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. The device is an investigational device in the US and has not been approved by the FDA for sale in the US for any use. Novocure currently has CE Mark for the NovoTTF-100A and the treatment is available to patients in Europe.

### **ABOUT THE ONGOING PHASE III TRIAL OF THE NOVOTTF-100A**

Novocure is now sponsoring a second phase III study of TTF therapy at 26 centers in the US, Europe, and Israel. This study is designed to enroll 283 patients with newly diagnosed glioblastoma tumors. Patients will be randomized (2 to 1) to receive TTF therapy and temozolomide (Temodar; Merck & Co) or temozolomide alone (the current best standard of care).

### **ABOUT NOVOCURE**

Novocure is a Jersey Isle based oncology company pioneering Tumor Treating Fields (TTF) therapy, a new modality for treating solid tumors. 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).

For additional information about the ongoing phase III trial for newly diagnosed glioblastoma patients, please visit [www.novocuretrial.com](http://www.novocuretrial.com).

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