

## **Novocure Announces FDA Approval of an IDE Supplement Allowing All Control Patients in its Phase III Trial in Newly Diagnosed GBM to Cross Over to Receive Tumor Treating Fields**

*Based on the results of the trial's pre-specified interim analysis all control patients in the EF-14 phase III trial will be offered the opportunity to cross over to receive Tumor Treating Fields*

**New York, NY** – December 2, 2014 – Novocure announced today that the United States Food and Drug Administration (FDA) has approved an investigational device exemption (IDE) supplement allowing all control patients in the EF-14 Phase III trial in newly diagnosed glioblastoma (GBM) to receive tumor treating fields (TTFields) delivered by the NovoTTF-100A System. The IDE supplement approval is based on the results of the trial's pre-specified interim analysis of overall survival and progression free survival and the subsequent recommendations of the trial's independent data monitoring committee (DMC) that the trial be terminated early for success and that all control patients be offered tumor treating fields therapy even prior to progression.

"We are pleased the FDA has granted this approval so quickly," said Dr. Roger Stupp, M.D., Director of the University Hospital Cancer Center the University of Zurich, Switzerland and EF-14 Principal Investigator. "Allowing the control patients to receive TTFields immediately is an ethical obligation considering the results of the interim analysis of the trial."

"We are working closely with the trial sites, institutional review boards and local health authorities to implement patient cross over to the TTFields arm of the study," said Uri Weinberg, M.D, Ph.D., Vice President for Research and Development at Novocure. "It is a rare and exciting event to be able to offer the active investigational treatment to patients who were randomized to the control arm of a trial."

"The FDA was extremely responsive in working with Novocure towards this IDE approval, given the exceptional circumstances presented. We are looking forward to continuing to work closely with the FDA to obtain marketing approval for TTFields therapy in patients with newly diagnosed GBM as expeditiously as possible," said Asaf Danziger, Novocure's Chief Executive Officer.

### **About Glioblastoma**

Glioblastoma (GBM) is the most common form of primary brain cancer with approximately 10,000 patients diagnosed each year in the United States. Overall survival with standard of care temozolomide chemotherapy alone is approximately 15 months.

### **About Tumor Treating Fields Therapy**

Tumor Treating Fields (TTFields) therapy is delivered by a portable, non-invasive medical device designed for continuous use by patients. *In vitro* and *in vivo* studies have shown that TTFields therapy slows and reverses tumor growth by inhibiting mitosis, the process by which cells divide and replicate. TTFields therapy creates a low intensity, alternating electric field within a tumor that exerts physical forces on electrically charged cellular components, preventing the normal mitotic process and causing cancer cell death. TTFields therapy is experimental for the treatment of newly diagnosed glioblastoma in the U.S. and is limited by law to investigational use only.

**Approved Indication**

The U.S. FDA has approved the TTFields therapy delivery system, Optune, previously known as the NovoTTF-100A System, for use as a treatment for adult patients (22 years of age or older) with histologically-confirmed GBM, following histologically or radiologically-confirmed recurrence in the supra-tentorial 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 Optune under the supervision of a physician properly trained in use of the device. Full prescribing information is available at [www.optune.com/safety](http://www.optune.com/safety) or by calling toll free 1-855-281-9301.

**About Novocure**

Novocure is a private Jersey Isle oncology company pioneering a novel therapy for solid tumors called TTFields. Novocure US operations are based in Portsmouth, NH and New York, NY. Additionally, the company has offices in Switzerland and Japan and a research center in Haifa, Israel. For additional information about the company, please visit [www.novocure.com](http://www.novocure.com).

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