

# Interim Analysis of Novocure's Phase III Trial in Newly Diagnosed Glioblastoma to be Presented at Japan Society For Neuro-Oncology 2014

Planned interim analysis demonstrates the EF-14 Phase III trial met its endpoints of progression-free survival and overall survival

**St. Helier, Jersey** – December 1, 2014 – Novocure<sup>™</sup>, a commercial stage oncology company, announced today that the interim analysis of the EF-14 Phase III trial of Tumor Treating Fields (TTFields) therapy in patients with newly diagnosed glioblastoma will be presented on Tuesday, December 2 at the Japan Society for Neuro-Oncology (JSNO) 2014 Annual Meeting in Maihama, Chiba, Japan. The interim data will be presented by Roger Stupp, MD, Professor and Chairman, Department of Oncology and Director, University Hospital Cancer Center, University of Zurich, Zurich, Switzerland. A second presentation at JSNO by Maciej Mrugala, MD, PhD, MPh, University of Washington and Fred Hutchinson Cancer Research Center, Seattle, Washington will provide an overview of the theory and practice of TTFields therapy.

The pre-specified, EF-14 interim analysis encompassed the first 315 patients, representing 50 percent of the targeted study population. The data show that:

- Patients treated with TTFields together with temozolomide demonstrated a significant increase in progression-free survival (PFS) compared to temozolomide alone (median PFS of 7.1 months compared to 4.0 months, respectively, hazard ratio=0.63, p=0.001).
- Patients treated with TTFields together with temozolomide demonstrated a significant increase in overall survival (OS) compared to temozolomide alone (median OS of 19.6 months compared to 16.6 months, respectively, hazard ratio=0.75, p=0.034).
- The percentage of patients alive at 2 years in the TTFields together with temozolomide arm was 43% compared to 29% in the temozolomide alone arm, a 48% increase in the 2-year survival compared to temozolomide alone.

"The EF-14 study is a well-executed and robust study. The data are very clear as to the survival benefit and low toxicity," said Takamitsu Fujimaki, MD, PhD, President of the 32nd Annual Meeting of the Japanese Society For Neuro-Oncology and Professor and Chair, Department of Neurosurgery, Saitama Medical University, and Professor, Department of Neuro-oncology, Comprehensive Cancer Center, International Medical Center, SMU "I hope this will become the new standard of care."

"The ability to extend survival without an increase in toxicity is incredible. This is the first time in over a decade that we have something new to offer patients with this deadly disease," said Masao Matsutani, MD, PhD, Honorary Member of the Japanese Society for Neuro-Oncology, and Professor Emeritus, Department of Neuro-Oncology, Saitama Medical University. "Our patients need to have access to TTFields therapy as soon as possible."

"We are very pleased with the EF-14 results and are working closely with the Japanese regulatory authorities to obtain approval for TTFields therapy in Japan," said Asaf Danziger, Novocure's Chief Executive Officer. "Novocure remains committed to

supporting glioblastoma patients worldwide in their battle against cancer."

#### **About Glioblastoma**

Glioblastoma (GBM) is the most common form of primary brain cancer with approximately 10,000 patients diagnosed each year in the U.S. and about 1,600 patients diagnosed each year in Japan.

## **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. TTFields therapy is not approved for commercial use in Japan.

## **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 <a href="https://www.optune.com/safety">www.optune.com/safety</a> or by calling toll free 1-855-281-9301. TTFields therapy is not approved for commercial use in Japan.

# **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 <a href="https://www.novocure.com">www.novocure.com</a>.

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