novocure

# FDA Approves Optune in Combination with Temozolomide for the Treatment of Newly Diagnosed Glioblastoma

*Optune is the first FDA-approved therapy in more than a decade to demonstrate statistically significant extension of survival in newly diagnosed glioblastoma patients*

*The EF-14 trial achieved statistically significant extension of both progression-free survival and overall survival in newly diagnosed glioblastoma with a 50% increase in the number of patients alive two-years after starting treatment when treated with TTFields in combination with temozolomide as compared to temozolomide alone*

**St. Helier, Jersey** – October 5, 2015 – Novocure (NASDAQ: NVCR) announced today that the U.S. Food and Drug Administration (FDA) has approved Optune in combination with temozolomide for the treatment of adult patients with newly diagnosed glioblastoma (GBM). Optune is a portable, non-invasive device that delivers low-intensity, intermediate frequency, alternating electric fields – referred to as Tumor Treating Fields (TTFields) – that inhibit cancer cell replication and cause cancer cell death.

Optune is the first FDA-approved therapy in more than a decade to demonstrate statistically significant extension of overall survival in newly diagnosed GBM. The two-year survival rate among patients treated with Optune in combination with temozolomide was 50% higher than in patients treated with temozolomide alone. No significant additive systemic toxicity was observed in the trial, and patients maintained stable quality-of-life, cognitive function and activities of daily living while using Optune.

“Novocure is committed to helping patients with glioblastoma, and we are proud that Optune has been shown to offer patients such a significant improvement in both progression-free and overall survival,” said Asaf Danziger, Novocure’s Chief Executive Officer. “Glioblastoma is the most common form of primary brain cancer which, until now, has not seen any significant therapeutic improvements in over a decade. We’re thankful to the many patients, their caregivers and healthcare providers who partnered with us to develop a treatment that has finally led to a significant improvement in the outcomes for patients with glioblastoma.”

The FDA approval follows a priority review of the Optune Premarket Approval (PMA) supplement application. The FDA grants priority review status to medical devices that are intended to treat life-threatening diseases and that offer clinically meaningful advantages over existing approved alternatives. Optune was previously approved in April 2011 for the treatment of adult patients with GBM following tumor recurrence after receiving chemotherapy.

GBM is the most common and aggressive form of primary brain cancer. An estimated 12,500 people are diagnosed with GBM or tumors that typically progress to GBM in the United States each year. Median overall survival in newly diagnosed patients is approximately 15 months with existing standard therapies.

**Proven Superiority vs. Standard of Care in a Phase 3 Clinical Trial**
The expanded indication for Optune is based on the results of EF-14, a large, multinational, open-label, randomized Phase 3 trial comparing Optune in combination with temozolomide to temozolomide alone in 700 patients with newly diagnosed GBM. The trial was powered to test both progression-free survival and overall survival.

In November 2014, the trial was stopped due to success based on an assessment by the independent data monitoring committee which concluded that the study met its endpoints at its pre-specified interim analysis, demonstrating superior progression-free and overall survivals in patients receiving Optune in combination with temozolomide compared to temozolomide alone.

The EF-14 interim analysis of the pre-specified trial endpoints demonstrated that:

- the two-year survival rate among patients treated with TTFields, in combination with temozolomide, in the as-treated population, was 48% compared to 32% among patients treated with temozolomide alone ($p=0.0058$);

- patients treated with TTFields, in combination with temozolomide, in the intent-to-treat population, demonstrated a statistically significant increase in progression-free survival compared to temozolomide alone (median progression-free survival of 7.2 months compared to 4.0 months, hazard ratio=0.62, p=0.001); and

- patients treated with TTFields, in combination with temozolomide, in the as-treated population, demonstrated a statistically significant increase in overall survival compared to temozolomide alone (median overall survival of 20.5 months compared to 15.6 months, hazard ratio=0.66, p=0.004).

In addition, the study demonstrated Optune could be safely combined with temozolomide. There was no significant increase in serious adverse events from Optune in combination with temozolomide versus temozolomide alone. The most common adverse reaction from Optune treatment was mild to moderate skin irritation, which was easily managed, reversible, and did not result in treatment discontinuation.

“Today marks a significant milestone in glioblastoma treatment,” said Elizabeth Wilson, President and CEO of the American Brain Tumor Association, Chicago. “For a disease for which there are few treatment options, Optune offers new hope for extending survival from the start of treatment.”

**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 low intensity, alternating electric fields within a tumor that exert physical forces on electrically charged cellular components, preventing the normal mitotic process and causing cancer cell death.

**Approved Indications**
In the United States, Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

In the United States, Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

In the United States, for the treatment of recurrent GBM, Optune is indicated 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 a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

In the European Union, Optune is intended for the treatment of patients with newly diagnosed GBM, after surgery and radiotherapy with adjuvant temozolomide, concomitant to maintenance temozolomide. The treatment is intended for adult patients, 18 years of age or older, and should be started more than 4 weeks after surgery and radiation therapy with adjuvant temozolomide. Treatment may be given together with maintenance temozolomide and after maintenance temozolomide is stopped.

In the European Union, Optune is also intended for the treatment of patients with recurrent GBM who have progressed after surgery, radiotherapy and temozolomide treatment for their primary disease. The treatment is intended for adult patients, 18 years of age or older, and should be started more than 4 weeks after the latest surgery, radiation therapy or chemotherapy.

In Japan, Optune (the NovoTTF-100A System) is approved for the treatment of adult patients with recurrent supra-tentorial glioblastoma after all possible surgical and radiation therapy 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 or by calling toll free 1-855-281-9301 in the US or by email at supportEMEA@novocure.com in the European Union.

**About Novocure**
Novocure is a Jersey Isle oncology company pioneering a novel therapy for solid tumors called TTFields. Novocure's US operations are based in Portsmouth, NH and New York, NY. Additionally, the company has offices in Germany, Switzerland, and Japan and a research center in Haifa, Israel. For additional information about the company, please visit www.novocure.com or follow us at www.twitter.com/novocure.

###

**Media and Investor Contact:**
Ashley Cordova, Novocure
acordova@novocure.com
212 767 7558