



Novocure Announces Presentation of EF-19 Post-approval Registry Trial Data Studying Optune as a Monotherapy for the Treatment of Recurrent GBM at the American Association for Cancer Research 2020 Virtual Annual Meeting I

April 29, 2020

EF-19 data confirm the effectiveness and safety of Optune as monotherapy and further strengthen Optune's clinical profile in recurrent GBM

ST. HELIER, Jersey--([BUSINESS WIRE](#))-- [NovoCure Ltd.](#) (NASDAQ: NVCR) today announced that an abstract highlighting results from the EF-19 post-approval registry trial studying Optune for the treatment of recurrent GBM will be presented as a virtual poster at the American Association for Cancer Research (AACR) 2020 Virtual Annual Meeting I, taking place April 27-28, 2020.

The FDA-mandated EF-19 post-approval registry trial studied Optune as a monotherapy for the treatment of recurrent GBM in 192 patients compared to the 117 recurrent GBM patients who received best standard of care chemotherapy in Novocure's EF-11 registration trial. Optune as monotherapy reduced the risk of death with fewer adverse events compared to best standard of care chemotherapy. For patients who received at least one course of therapy, Optune prolonged survival by a median 1.7 months. No new safety signals were noted. The EF-19 data confirm the effectiveness and safety of Optune as monotherapy and further strengthen Optune's clinical profile in recurrent GBM.

The AACR Virtual Annual Meeting I will feature a selection of high-impact proffered paper presentations in several clinical trial plenary sessions and clinical trial poster sessions, along with minisymposia featuring basic and translational science. The virtual meeting will be available free to everyone, although attendees will be asked to register to participate.

Details for the AACR 2020 Virtual Meeting I presentations are as follows:

Title: EF-19 - A post-approval registry study of TTFIELDS for the treatment of recurrent glioblastoma (GBM)

Lead author: Jay-Jiguang Zhu, University of Texas Health Science Center, Houston, TX

Poster #: CT211

Session: VPO.CT03. Phase III Clinical Trials

Date and Time: April 27, 2020 9:00 AM – 6:00 PM

URL: <https://www.abstractsonline.com/pp8/#!/9045/presentation/10714>

Title: HEPANOVA: Interim safety analysis from a phase 2 study of Tumor Treating Fields (TTFIELDS, 150 kHz) concomitant with sorafenib in advanced hepatocellular carcinoma (HCC)

Lead author: Eleni Gkika, University of Freiburg, Freiburg, Germany

Poster #: CT186

Session: VPO.CT02. Phase II Clinical Trials

Date and Time: April 27, 2020 9:00 AM – 6:00 PM

URL: <https://www.abstractsonline.com/pp8/#!/9045/presentation/10686>

Title: Optimizing Tumor Treating Fields therapy for recurrent glioblastoma with targeted and individualized skull remodeling surgery. A multi-center randomized phase 2 trial

Lead author: Nikola Mikic, Aarhus University Hospital, Aarhus, Denmark

Poster #: CT184

Session: VPO.CT02. Phase II Clinical Trials

Date and Time: April 27, 2020 9:00 AM – 6:00 PM

URL: <https://www.abstractsonline.com/pp8/#!/9045/presentation/10684>

Title: PriCoTTF trial: A phase I/II trial of TTFIELDS prior and concomitant to radiotherapy in newly diagnosed glioblastoma

Lead author: Sied Kebir, University Hospital Essen, Essen, Germany

Poster #: CT106

Session: VPO.CT01. Phase I Clinical Trials

Date and Time: April 27, 2020 9:00 AM – 6:00 PM

URL: <https://www.abstractsonline.com/pp8/#!/9045/presentation/10605>

Title: Final results for OptimalTTF-1: Optimizing Tumor Treating Fields with targeted skull remodeling surgery for first recurrence glioblastoma: Phase 1 trial

Lead author: Nikola Mikic, Aarhus University Hospital, Aarhus, Denmark

Poster #: CR103

Session: VPO.CT01. Phase I Clinical Trials

Date and Time: April 27, 2020 9:00 AM – 6:00 PM

URL: <https://www.abstractsonline.com/pp8/#!/9045/presentation/10602>

About Optune

Optune is a noninvasive, antimitotic cancer treatment for GBM. Optune delivers Tumor Treating Fields to the region of the tumor.

Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing affected cancer cells to die. Tumor Treating Fields does not stimulate or heat tissue and targets dividing cancer cells of a specific size. Tumor Treating Fields causes minimal damage to healthy cells. Mild to moderate skin irritation is the most common side effect reported. Tumor Treating Fields is approved in certain countries for the treatment of adults with GBM and in the U.S. for MPM, two of the most difficult cancer types to treat. The therapy shows promise in multiple solid tumor types – including some of the most aggressive forms of cancer.

Approved Indications

Optune is intended as a treatment for adult patients with histologically-confirmed GBM.

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

For the treatment of recurrent GBM, Optune is indicated following histologically- or radiologically-confirmed recurrence in the supratentorial 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.

Important Safety Information

Contraindications

Do not use Optune in patients with GBM with an implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective.

Use of Optune for GBM together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune for GBM in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions

Optune can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common (≥10%) adverse events involving Optune in combination with chemotherapy in patients with GBM were thrombocytopenia, nausea, constipation, vomiting, fatigue, convulsions, and depression.

The most common (≥10%) adverse events related to Optune treatment alone in patients with GBM were medical device site reaction and headache. Other less common adverse reactions were malaise, muscle twitching, and falls related to carrying the device.

If the patient has an underlying serious skin condition on the treated area, evaluate whether this may prevent or temporarily interfere with Optune treatment.

Do not prescribe Optune for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune in these populations have not been established.

About Novocure

Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer through the development and commercialization of its innovative therapy, Tumor Treating Fields. Novocure's commercialized products are approved in certain countries for the treatment of adult patients with glioblastoma and in the U.S. for the treatment of adult patients with malignant pleural mesothelioma. Novocure has ongoing or completed clinical trials investigating Tumor Treating Fields in brain metastases, non-small cell lung cancer, pancreatic cancer, ovarian cancer, liver cancer and gastric cancer.

Headquartered in Jersey, Novocure has U.S. operations in Portsmouth, New Hampshire, Malvern, Pennsylvania and New York City. Additionally, the company has offices in Germany, Switzerland, Japan and Israel. For additional information about the company, please visit www.novocure.com or follow us at [www.twitter.com/novocure](https://twitter.com/novocure).

Forward-Looking Statements

In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Novocure's current expectations or forecasts of future events. These may include statements regarding anticipated scientific progress on its research programs, clinical trial progress, development of potential products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, coverage, collections from third-party payers and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Novocure's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, regulatory and political conditions as well as issues arising from the COVID-19 pandemic and other more specific risks and uncertainties facing Novocure such as those set forth in its Report on Form 10-K filed on February 27, 2020, with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Novocure does not intend to update publicly any forward-looking statement, except as required by law. Any forward-looking statements herein speak only as of the date hereof. The Private Securities Litigation Reform Act of 1995 permits this discussion.

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