Combination of Optune™ with Standard of Care Chemotherapy, Temozolomide, Provides Landmark Five-Year Survival Rates for Newly Diagnosed Glioblastoma Patients

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Final analyses provide unprecedented five-year survival advantage reinforcing Optune plus temozolomide as a combination treatment for glioblastoma patients

Survival benefit was maintained in all patient subgroups, including those with the worst prognostic features

ST. HELIER, Jersey–(BUSINESS WIRE)– Novocure (NASDAQ:NVCR) announced today final results from its phase 3 pivotal EF-14 trial adding Optune to standard temozolomide chemotherapy for the treatment of newly diagnosed glioblastoma (GBM). Landmark analyses show a consistent and maintained improvement in overall survival at two, three, four and five years. The final results include data from all 695 patients included in the EF-14 trial with a median follow-up of 40 months.

The two-year survival rate increased from 30 percent to 43 percent for patients treated with Optune together with temozolomide versus patients treated with temozolomide alone. The five-year survival rate increased from five percent to 13 percent for patients treated with Optune together with temozolomide versus patients treated with temozolomide alone. These are the best results reported for newly diagnosed GBM patients in a phase 3 trial to date and represent clinically meaningful increases in landmark survival rates (hazard ratio, 0.63; p<0. 00006).

EF-14 Principal Investigator Roger Stupp, M.D., Associate Director for Strategic Initiatives at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, presented these late breaking results today, April 2, during a press briefing and oral presentation (Abstract CT007) at the American Association for Cancer Research Annual Meeting 2017 in Washington D.C.

“When I started treating patients with GBM 20 years ago, the majority of patients died within less than one year and long-term survival was nearly absent. Now, we see a meaningful improvement in survival at two years and beyond,” Dr. Stupp said. “With the combination of Optune and temozolomide, one out of seven patients is living longer than five years.”

“This is the first positive phase 3 trial in newly diagnosed GBM since we demonstrated the efficacy of temozolomide in 2005, establishing it as a standard first-line therapy,” continued Dr. Stupp. “Beyond GBM, I believe this trial establishes an entirely different approach to cancer treatment with minimal toxicity which may be well suited for combination with conventional treatments for many other cancer types.”

GBM is the most common form of primary brain cancer. An estimated 12,500 people are diagnosed with GBM in the United States each year. Prior to the approval of Optune, the median overall survival for patients with newly diagnosed GBM was approximately 15 months with standard therapies. Combining Optune with temozolomide resulted in a statistically significant extension of median overall survival to 21 months in Novocure’s phase 3 pivotal EF-14 trial.

“We are excited that combination therapy with Optune plus temozolomide continues to show a meaningful extension of long-term survival for newly diagnosed GBM patients,” said Elizabeth M. Wilson, President and CEO of the American Brain Tumor Association. “Before temozolomide was approved, newly diagnosed GBM patients only had a

1.9 percent five-year survival rate, so to see numbers that are over six times that rate shows the significant progress that has been made in treating this disease."

The data presented confirmed that the overall survival benefit of Optune together with temozolomide compared to temozolomide alone was seen across all patient subgroups including young versus elderly patients, patients with methylated versus unmethylated MGMT promoter and patients who underwent any extent of tumor resection. The data showed a safety profile consistent with previous reports of data from the study.

"These data further support our belief that Optune plus temozolomide is an essential combination treatment for patients with newly diagnosed GBM," said Asaf Danziger, Novocure's CEO. "The efficacy shown in EF-14 for GBM gives us hope that TTFields used in combination other cancer treatments may increase survival without significantly increasing side effects for a variety of solid tumors."

About Novocure

Novocure is an oncology company developing a profoundly different cancer treatment centered on a proprietary therapy called TTFields, the use of electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division. Novocure's commercialized product, Optune, is approved for the treatment of adult patients with glioblastoma. Novocure has ongoing or completed clinical trials investigating TTFields in brain metastases, non-small cell lung cancer, pancreatic cancer, ovarian cancer and mesothelioma.

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 and Japan, and a research center in Israel. For additional information about the company, please visit www.novocure.com or follow us at www.twitter.com/novocure.

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 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.

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 (NovoTTF-100A) is approved in the treatment of adult patients with supra-tentorial glioblastoma (GBM) and is used following maximal safe surgical resection and radiation therapy.

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.

Important Safety Information

Contraindications: Do not use Optune if you have an active implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. 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.

Do not use Optune if you are known to be sensitive to conductive hydrogels. In this case, skin contact with the gel used with Optune may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions: Use Optune only after receiving training from qualified personnel, such as your doctor, a nurse, or other medical personnel who have completed a training course given by Novocure (the device manufacturer).

Do not use Optune if you are pregnant, you think you might be pregnant or are trying to get pregnant. It is not known if Optune is safe or effective in these populations.

The most common (≥10%) adverse events involving Optune in combination with temozolomide were low blood platelet count, nausea, constipation, vomiting, fatigue, scalp irritation from device use, headache, convulsions, and depression.

The most common (≥10%) adverse events seen when using Optune alone were scalp irritation from device use and headache.

The following adverse reactions were considered related to Optune when using the device alone: scalp irritation from device use, headache, malaise, muscle twitching, fall and skin ulcer.

All servicing procedures must be performed by qualified and trained personnel.

Do not use any parts that do not come with the Optune Treatment Kit, or that were not sent to you by the device manufacturer or given to you by your doctor.

Do not wet the device or transducer arrays.

If you have an underlying serious skin condition on the scalp, discuss with your doctor whether this may prevent or temporarily interfere with Optune treatment.

Please see http://www.optune.com/safety to see the Optune Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.

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, development of potential products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, 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 more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 23, 2017, 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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