



Novocure Announces Last Patient Enrolled in Phase 3 Pivotal INNOVATE-3 Trial of Tumor Treating Fields in Ovarian Cancer

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Final data from INNOVATE-3 trial anticipated in 2023

ST. HELIER, Jersey—(BUSINESS WIRE)—Novocure (NASDAQ: NVCR) today announced that the final patient has been enrolled in phase 3 pivotal INNOVATE-3 trial evaluating the efficacy of Tumor Treating Fields (TTFields) together with paclitaxel for treatment of patients with platinum-resistant ovarian cancer.

“This is a major step forward for our clinical trial program and an important achievement for patients, trial investigators and our company,” said William Doyle, Novocure’s Executive Chairman. “Ovarian cancer is the fifth leading cause of cancer death in women, impacting nearly 100,000 patients annually in the U.S., Europe and Japan, alone. INNOVATE-3 is the largest abdominal trial to complete enrollment in Novocure history, and we are excited to be enhancing the clinical field in support of people with this deadly disease.”

Following the completion of enrollment, an independent Data Monitoring Committee (DMC) will conduct the pre-specified interim analysis pursuant to the trial protocol. Final data from the INNOVATE-3 trial is anticipated in 2023.

INNOVATE-3 is a randomized, open-label study which was designed to enroll 540 adult patients with recurrent, platinum-resist ovarian cancer. Patients have been randomized to receive either weekly paclitaxel alone or weekly paclitaxel concomitant with TTFields tuned to 200 kHz until progression. The primary endpoint is overall survival. Secondary endpoints include progression free survival, objective response rate, severity and frequency of adverse events, time to undisputable deterioration in health-related quality of life or death, and quality of life. The European Network for Gynecological Oncological Trials (ENGOT) and The GOG Foundation, Inc. collaborated with Novocure on the design and facilitation of this trial.

About Ovarian Cancer

In the U.S., ovarian cancer ranks fifth in cancer deaths among women, with approximately 24,000 women diagnosed each year. Ovarian cancer incidence increases with age, and the median age at time of diagnosis is 63 years old. Physicians use different combinations of surgery and pharmacological therapies to treat ovarian cancer, depending on the stage of the disease. Surgery is usually used in early stages of the disease and is usually combined with chemotherapy, including paclitaxel and platinum-based chemotherapy. Unfortunately, the majority of patients are diagnosed at an advanced stage when the cancer has spread outside of the ovaries to include regional tissue involvement and/or metastases. Platinum-based chemotherapy remains part of the standard of care in advanced ovarian cancer, but most patients with advanced ovarian cancer will have tumor progression or, more commonly, recurrence. Almost all patients with recurrent disease ultimately develop platinum resistance, and the prognosis for this population remains poor.

About Tumor Treating Fields

Tumor Treating Fields, or TTFields, are electric fields that disrupt cancer cell division.

When cancer develops, rapid and uncontrolled division of unhealthy cells occurs. Electrically charged proteins within the cell are critical for cell division, making the rapidly dividing cancer cells vulnerable to electrical interference. All cells are surrounded by a bilipid membrane, which separates the interior of the cell, or cytoplasm, from the space around it. This membrane prevents low frequency electric fields from entering the cell. TTFields, however, have a unique frequency range, between 100 to 500 kHz, enabling the electric fields to penetrate the cancer cell membrane. As healthy cells differ from cancer cells in their division rate, geometry and electric properties, the frequency of TTFields can be tuned to specifically affect the cancer cells while leaving healthy cells mostly unaffected.

Whether cells are healthy or cancerous, cell division, or mitosis, is the same. When mitosis starts, charged proteins within the cell, or microtubules, form the mitotic spindle. The spindle is built on electric interaction between its building blocks. During division, the mitotic spindle segregates the chromosomes, pulling them in opposite directions. As the daughter cells begin to form, electrically polarized molecules migrate towards the midline to make up the mitotic cleavage furrow. The furrow contracts and the two daughter cells separate. TTFields can interfere with these conditions. When TTFields are present in a dividing cancer cell, they cause the electrically charged proteins to align with the directional forces applied by the field, thus preventing the mitotic spindle from forming. Electrical forces also interrupt the migration of key proteins to the cell midline, disrupting the formation of the mitotic cleavage furrow. Interfering with these key processes disrupts mitosis and can lead to cell death.

TTFields are intended principally for use together with other standard-of-care cancer treatments. There is a growing body of evidence that supports TTFields’ broad applicability with certain other cancer therapies, including radiation therapy, certain chemotherapies and certain immunotherapies. In clinical research and commercial experience to date, TTFields has exhibited no systemic toxicity, with mild to moderate skin irritation being the most common side effect.

Fundamental scientific research extends across two decades and, in all preclinical research to date, TTFields has demonstrated a consistent anti-mitotic effect. The TTFields global development program includes a network of preclinical collaborators and a broad range of clinical trials across all phases, including four phase 3 pivotal trials in a variety of tumor types. To date, more than 20,000 patients have been treated with TTFields.

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, gastric cancer, glioblastoma, liver cancer, non-small cell lung cancer, pancreatic cancer and ovarian 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 [Novocure.com](https://www.novocure.com) and follow @Novocure on LinkedIn and Twitter.

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, environmental, 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 Annual Report on Form 10-K filed on February 25, 2021 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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