Novocure Announces Clinical Trial Collaboration with Roche to Evaluate Tumor Treating Fields as Part of a Novel Combination for the First-line Treatment of Metastatic Pancreatic Cancer

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ST. HELIER, Jersey–(BUSINESS WIRE)–Novocure (NASDAQ: NVCR) today announced it has entered into a clinical trial collaboration agreement with Roche (SIX: RO. ROG; OTCQX: RHHBY), to develop Tumor Treating Fields (TTFields) together with Roche's anti-PD-L1 therapy, atezolizumab, in metastatic pancreatic ductal adenocarcinoma (mPDAC).

Pancreatic ductal adenocarcinoma (PDAC) is the most common type of pancreatic cancer and accounts for 85%–95% of all solid pancreatic tumors. As a highly lethal malignancy, it is the seventh leading cause of cancer death worldwide and is responsible for more than 300,000 deaths per year. PDAC is highly resistant to current therapies, affording patients a 5-year overall survival rate of only 7.2%.

"We are pleased to collaborate with Roche, a global leader in oncology, to explore the efficacy of TTFields together with atezolizumab immunotherapy in pancreatic cancer," said William Doyle, Novocure's Executive Chairman. "The immune-shielded environment of the pancreas has proved challenging for immunotherapies alone to provide benefit. Our phase 2 pilot trial with Roche will study the ability of TTFields together with atezolizumab to improve clinical outcomes for patients with this deadly disease."

The phase 2 study was designed to test the safety and efficacy of TTFields together with atezolizumab, gemcitabine and nab-paclitaxel as a first-line treatment for mPDAC. The study is designed to enroll approximately 75 patients in the EU and United States. The primary endpoint of the study is disease control rate by RECIST 1.1. The secondary endpoints include overall survival, progression free survival, one year survival, objective response rate, PFS at six months, duration of response, and toxicity profile. Novocure is the study sponsor and Roche is providing atezolizumab for the trial.

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, TTFields. TTFields are electric fields that disrupt cancer cell division. Novocure's commercialized products are approved for the treatment of adult patients with glioblastoma and 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 us, visit 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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