Novocure Announces FDA Approval of IDE Supplement for Phase 3 Pivotal LUNAR Trial of Tumor Treating Fields in Non-Small Cell Lung Cancer

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IDE supplement incorporates recommended changes from the interim analysis of the LUNAR trial conducted by an independent data monitoring committee

ST. HELIER, Jersey–(BUSINESS WIRE)–Novocure (NASDAQ: NVCR) today announced the U.S. Food and Drug Administration (FDA) has approved the company's Investigational Device Exemption (IDE) supplement, reducing the enrollment requirement for its LUNAR trial to 276 patients with 12 months follow-up. LUNAR is a phase 3 pivotal trial testing the effectiveness of Tumor Treating Fields in combination with immune checkpoint inhibitors or docetaxel versus immune checkpoint inhibitors or docetaxel alone for patients with stage 4 NSCLC who progressed during or after platinum-based therapy.

The IDE supplement incorporates recommended changes from the interim analysis of the LUNAR trial conducted by an independent data monitoring committee (DMC). After review of the interim analysis report earlier this year, the DMC concluded that the LUNAR trial should continue with no evidence of increased systemic toxicity. The DMC also stated that it is likely unnecessary and possibly unethical for patients randomized to the control arm of the trial to continue accrual according to the original protocol. The DMC recommended a reduced sample size of approximately 276 patients with 12 months follow-up which it believes will provide sufficient overall power for both primary and secondary endpoints. The DMC recommended no other changes to the trial design. Novocure remains blinded to all data.

"We are very pleased with the FDA approval of the DMC's recommended protocol adjustments and are grateful for the FDA's prompt review," said Asaf Danziger, Novocure's CEO. "We now anticipate last patient enrollment in the LUNAR trial in the fourth quarter of 2021 with final data available in 2022 and look forward to sharing data from the LUNAR trial as quickly as possible."

About LUNAR

LUNAR is a phase 3 pivotal trial testing the effectiveness of TTFields in combination with immune checkpoint inhibitors or docetaxel versus immune checkpoint inhibitors or docetaxel alone for patients with stage 4 NSCLC who progressed during or after platinum-based therapy. It is estimated that approximately 46,000 patients receive second-line treatment for stage 4 NSCLC each year in the U.S. The primary endpoint is superior overall survival of patients treated with TTFields plus immune checkpoint inhibitors or docetaxel versus immune checkpoint inhibitors or docetaxel alone. TTFields is intended principally for use in combination with other standard-of-care treatments, and LUNAR was designed to generate data that contemplates multiple outcomes, all of which Novocure believes will be clinically meaningful.

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 is 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 broad range of clinical trials across all phases, included four phase 3 pivotal trials in a variety of tumor types. To date, more than 18,000 patients have been treated with TTFields.

Use of Tumor Treating Fields for the treatment of NSCLC is investigational only.

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 clinical trials investigating TTFields 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 www.novocure.com or follow us at www.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 LUNAR progress and timelines, interpretation of the LUNAR interim analysis, 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 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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