Novocure Presents Final Safety and Efficacy Results from its Phase 2 Pilot HEPANOVA Trial in Liver Cancer

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In patients who completed at least 12 weeks of Tumor Treating Fields treatment, disease control rate was 91% with 18% objective response

Novocure plans to proceed with phase 3 pivotal trial in liver cancer incorporating Tumor Treating Fields together with standard treatments, including immunotherapy

ST. HELIER, Jersey–(BUSINESS WIRE)–Novocure (NASDAQ: NVCR) today announced final results from its phase 2 pilot HEPANOVA trial in liver cancer testing the safety and efficacy of Tumor Treating Fields (TTFields) together with sorafenib for the treatment of advanced hepatocellular cancer. In 21 evaluable patients, the disease control rate was 76% in a patient population with poor prognosis and limited exposure to study treatments. The objective response rate for the intent-to-treat population was 9.5%. In patients who completed at least 12 weeks of TTFields treatment, the disease control rate was 91% with an objective response rate of 18%. The final HEPANOVA results will be presented at the virtual ESMO World Congress on Gastrointestinal Cancer on July 1.

The HEPANOVA trial enrolled 27 patients with unresectable hepatocellular cancer. Fourteen of the 27 patients, or 52%, had a Child-Turcotte-Pugh (CTP) score of 7 or 8, representing significant liver dysfunction. Six patients, or 22% of the study population, survived less than 12 weeks. The median sorafenib treatment duration was only nine weeks, a much shorter treatment duration than the referenced historical controls[1]. The median treatment duration of TTFields was 10 weeks.

“We are very encouraged by the HEPANOVA results, especially in light of the poor prognosis of the study population and low treatment exposure,” said Dr. Uri Weinberg, Novocure’s Chief Science Officer. “We intend to initiate a randomized controlled trial as soon as possible and are working with key opinion leaders to finalize a protocol incorporating the evolving treatment landscape in advanced liver cancer. We are particularly interested in the potential to use TTFields together with immunotherapy in this aggressive disease given *in vivo* data which suggest that using TTFields together with anti-PD-1 therapy results in increased tumor response versus either therapy alone.”

The objective response rate reached 9.5% in the 21 evaluable patients, more than double the historical controls. The disease control rate was 76%, a much higher rate than the historical controls of 43% to 52%. For the 11 patients who completed at least 12 weeks of TTFields therapy, the objective response rate was 18%. The disease control rate for patients who completed at least 12 weeks of TTFields therapy was 91%. The objective response rate is defined as the percentage of patients who achieved complete or partial response. The disease control rate includes the percentage of responders plus the patients who achieved stable disease. In the intent-to-treat population, median progression free survival was 5.8 months and median time-to-progression was 8.9 months, higher than the historical, sorafenib alone control for both endpoints. No increase in the toxicity of sorafenib and no device-related serious adverse events were reported.

“Hepatocellular cancer is a particularly aggressive disease,” said Professor Anca-Ligia Grosu, Medical Director at the University of Freiburg, and the principal investigator of the HEPANOVA trial. “A clear unmet need remains for safe and effective combination treatments. These data show that Tumor Treating Fields have the potential to extend survival in advanced liver cancer without increasing side effects. I look forward to further exploration of efficacy in a randomized, controlled trial.”

About Liver Cancer
Liver cancer is a leading cause of cancer deaths worldwide and is the sixth leading cause of cancer deaths annually in the U.S. The incidence of liver cancer is approximately 42,000 new cases annually in the U.S. The five-year survival rate with existing standards of care is less than 20%.

Hepatocellular carcinoma is the most widespread type of cancer that originates from the liver. Advanced liver cancer has spread either to the lymph nodes or to other organs and because these cancers are widespread, they cannot be treated with surgery. The current common standard treatment for patients with advanced disease and those who progressed on loco-regional therapy is systemic therapy with sorafenib, lenvatinib, or atezolizumab plus bevacizumab.

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

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, including four phase 3 pivotal trials in a variety of tumor types. To date, more than 18,000 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, non-small cell lung cancer, pancreatic cancer, ovarian cancer, liver cancer, gastric cancer and glioblastoma.

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 www.novocure.com or follow us @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.

[1] Llovet JM, et al. N Engl J Med. 2008;359:378–390. Abou-Alfa GK, et al. J Clin Oncol. 2006;24(26):4293-4300. Zhu AX, et al. J Clin Oncol. 2015;33(6):559-566. Cainap C, et al. J Clin Oncol. 2015;33(2):172-179.

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