Novocure Announces FDA Acceptance of the PMA Application for TTFields Therapy in Non-Small Cell Lung Cancer

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ROOT, Switzerland--(BUSINESS WIRE)--Novocure (NASDAQ: NVCR) today announced that its Premarket Approval (PMA) application seeking approval for the use of Tumor Treating Fields (TTFields) therapy together with standard systemic therapies for the treatment of non-small cell lung cancer (NSCLC), following progression on or after platinum-based therapy, has been accepted for filing by the U.S. Food and Drug Administration (FDA).

“We are thrilled to announce the FDA has accepted our PMA application for review of the LUNAR data in NSCLC,” said Asaf Danziger, Novocure’s Chief Executive Officer. “This significant milestone brings us one step closer to treating patients seeking treatment for NSCLC, post-platinum, for which very few effective non-toxic options exist today. I would like to thank our investigators and patients, as well as our Novocure colleagues, for their dedication in pursuit of bringing our novel therapy to thousands of patients in need.”

The PMA application for LUNAR was submitted with a filing date of December 15, 2023, and is now under substantive review by the FDA. Novocure expects to receive a regulatory decision from FDA in second half 2024.

About LUNAR

LUNAR tested the safety and effectiveness of TTFields therapy when used together with either an immune checkpoint inhibitor (ICI) or docetaxel for the treatment of patients diagnosed with metastatic NSCLC following progression on or after the use of platinum-based therapy. Patients randomized to receive TTFields therapy together with standard therapies (n=137) demonstrated median overall survival (OS) of 13.2 months compared to 9.9 months in patients treated with standard therapies alone (n=139). Patients randomized to receive TTFields therapy and physician’s choice ICI (n=66) demonstrated a median OS of 18.5 months versus a median OS of 10.8 months in patients treated with an ICI alone (n=68; HR=0.63; *P*=0.03). Patients randomized to receive TTFields therapy and docetaxel (n=71) had a positive survival trend with a median OS of 11.1 months vs 8.7 months in patients treated with docetaxel alone (n=71). TTFields therapy was well-tolerated with no added systemic toxicities and few grade 3 (no grade 4 or 5) device-related adverse events.

About NSCLC

Lung cancer is the most common cause of cancer-related death worldwide, and NSCLC accounts for approximately 85% of all lung cancers. It is estimated that approximately 193,000 patients are diagnosed with NSCLC each year in the U.S. Physicians use different combinations of surgery, radiation and pharmacological therapies to treat NSCLC, depending on the stage of the disease. Surgery, which may be curative in a subset of patients, is usually used in early stages of the disease. Since 1991, radiation with a combination of platinum-based chemotherapy drugs has been the first-line standard of care for locally advanced or metastatic NSCLC. Certain immune checkpoint inhibitors have been approved for the first-line treatment of NSCLC and the standard of care in this setting appears to be evolving rapidly. The standard of care for second-line treatment is also evolving and may include platinum-based chemotherapy for patients who received immune checkpoint inhibitors as their first-line regimen, docetaxel, immune checkpoint inhibitors or pemetrexed.

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, malignant pleural mesothelioma and 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 Root, Switzerland and with a growing global footprint, Novocure has regional operating centers in Portsmouth, New Hampshire and Tokyo, as well as a research center in Haifa, Israel. For additional information about the company, please 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 study 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 23, 2023, and subsequent filings 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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