FDA Approves Novocure's Optune Lua® for the Treatment of Metastatic Non-Small Cell Lung Cancer

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The first treatment of its kind for metastatic NSCLC, Optune Lua is approved for use concurrently with PD-1/PD-L1 inhibitors or docetaxel in adult patients with metastatic NSCLC who progressed on or after a platinum-based regimen

Results of the pivotal Phase 3 LUNAR trial represent the first substantial improvement in median overall survival in more than 8 years for this patient population

Optune Lua is a wearable treatment that delivers Tumor Treating Fields (TTFields), which exert physical forces on the electrically charged components of dividing cancer cells, resulting in cell death

Root, Switzerland – Novocure (NASDAQ: NVCR) announced today that the U.S. Food and Drug Administration (FDA) has approved Optune Lua® for concurrent use with PD-1/PD-L1 inhibitors or docetaxel, for the treatment of adult patients with metastatic non-small cell lung cancer (mNSCLC) who have progressed on or after a platinum-based regimen.

"Novocure is committed to extending survival in some of the most aggressive and difficult to treat cancers. The approval of Optune Lua brings a new and urgently needed option for people with metastatic NSCLC who have progressed while on or after platinum-based chemotherapy," said Asaf Danziger, CEO, Novocure. "We are grateful to the patients, caregivers, investigators and healthcare providers who supported the clinical trials that led to this approval."

Optune Lua is a portable device that produces alternating electric fields known as tumor treating fields (TTFields), which are delivered through non-invasive, wearable arrays. TTFields exert physical forces on the electrically charged components of dividing cancer cells, resulting in cell death.

"There have been a number of important advances in first-line treatment for NSCLC, but this is an aggressive disease, and most patients will develop progression, with limited effective treatment options in second line and beyond," said Ticiana Leal, MD, Associate Professor and Director of the Thoracic Oncology Program at the Winship Cancer Institute of Emory University School of Medicine and primary investigator of the LUNAR study. "The overall survival results we observed with Optune Lua in the LUNAR study mark the first substantial improvement in more than 8 years in this patient population which, when combined with Optune Lua's lack of systemic toxicity, make this a compelling

development for many patients and their physicians who need better treatment options for this advanced disease."

"We are excited patients with metastatic NSCLC have more options, which they urgently need," said GO2 for Lung Cancer Chief Patient Officer Danielle Hicks. "The fight against lung cancer is always evolving, and the number of people affected by this disease is underappreciated. That is why Novocure's commitment to advancing treatment is exciting for the whole lung cancer community."

DATA SUPPORTING THE OPTUNE LUA APPROVAL

The Phase 3 LUNAR study was a prospective, randomized, open-label, multicenter study that compared the use of Optune Lua concurrent with PD-1/PD-L1 inhibitors or docetaxel (experimental arm) to PD-1/PD-L1 inhibitors or docetaxel alone (control arm) for patients with metastatic NSCLC who progressed during or after platinum-based therapy.

The primary endpoint of the study was achieved demonstrating a statistically significant and clinically meaningful 3.3-month (P=0.04) extension in median overall survival (OS) for patients treated with Optune Lua concurrently with a PD-1/PD-L1 inhibitor or docetaxel (n=145). The group treated with Optune Lua concurrently with a PD-1/PD-L1 inhibitor or docetaxel had a median OS of 13.2 months (95% CI, 10.3 to 15.5 months) compared to a median OS of 9.9 months (95% CI, 8.2 to 12.2 months) in the PD-1/PD-L1 inhibitor or docetaxel treated group (n=146).

The LUNAR study included two pre-specified powered secondary endpoints. The first secondary endpoint, which met statistical significance, assessed median OS in patients treated with Optune Lua concurrently with a PD-1/PD-L1 inhibitor versus a PD-1/PD-L1 inhibitor alone. The second secondary endpoint, which showed a positive trend but did not meet statistical significance, assessed Optune Lua concurrently with docetaxel versus docetaxel alone.

Patients randomized to Optune Lua and a PD-1/PD-L1 inhibitor (n=70) demonstrated a median OS of 19.0 months (95% CI, 10.6 to 28.2 months) compared to a median OS of 10.8 months (95% CI, 8.3 to 17.6 months) in patients treated a with PD-1/PD-L1 inhibitor alone (n=71), which was a statistically significant extension in median OS of more than 8.0 months (P=0.02).

Patients randomized to receive Optune Lua and docetaxel (n=75) had a median OS of 11.1 months (95% CI, 8.2 to 13.9 months) compared to a median OS of 8.9 months (95% CI, 6.5 to 11.3 months) in patients treated with docetaxel alone (n=75). This 2.2 month extension in median OS did not provide a statistically significant demonstrated benefit, but did show a positive trend.

Device-related adverse events (AEs) occurred in 63.1% of patients (n=89), these were skin-related disorders under the transducer arrays. The majority of these events were low grade (Grade 1 – 2), with only 4% (n=6) experiencing Grade 3 skin toxicity that required a break from treatment. There were no Grade 4 or Grade 5 toxicities related to Optune Lua, and no device-related AEs that caused death.

Baseline patient characteristics were well balanced between cohorts: median age was 65 years (range, 22-86); 66% male, 34% female; 96% of patients had an ECOG performance status of 0-1. PD-L1

expression data were collected from 83% of patients (69 of 83 patients) enrolled at U.S. sites and were well balanced across the four cohorts.

NON-SMALL CELL LUNG CANCER (NSCLC)

Lung cancer is the most common cause of cancer-related death worldwide[1], and non-small cell lung cancer (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, including both PD-1 and PD-L1 inhibitors, have been approved for the first-line treatment of NSCLC and the standard of care in this setting continues to evolve rapidly.

It is estimated that approximately 30,000 patients actively seek treatment for stage 4 NSCLC after progressing during or after platinum-based therapy each year in the U.S. 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, pemetrexed, docetaxel or immune checkpoint inhibitors.

WHAT IS OPTUNE LUA® APPROVED TO TREAT?

Optune Lua is a wearable, portable, FDA-approved device used together with PD-1/PD-L1 inhibitors (immunotherapy) or docetaxel. It is indicated for adult patients with metastatic non-small cell lung cancer (mNSCLC) who have progressed on or after a platinum-based regimen.

IMPORTANT SAFETY INFORMATION

WHO SHOULD NOT USE OPTUNE LUA?

Optune Lua for mNSCLC is not for everyone. Talk to your doctor if you have:

- An electrical implant. Use of Optune Lua together with electrical implants has not been tested and may cause the implanted device not to work properly
- A known sensitivity to gels like the gel used on electrocardiogram (ECG) stickers or transcutaneous electrical nerve stimulation (TENS) electrodes. In this case, skin contact with the gel used with Optune Lua may commonly cause increased redness and itching, and rarely may even lead to severe allergies such as a fall in blood pressure and difficulty breathing

DO NOT USE OPTUNE LUA IF YOU ARE PREGNANT OR ARE PLANNING TO BECOME PREGNANT. It is not known if Optune Lua is safe or effective during pregnancy.

WHAT SHOULD I KNOW BEFORE USING OPTUNE LUA?

Optune Lua should only be used after receiving training from qualified personnel, such as your doctor, a nurse, or other medical staff who have completed a training course given by Novocure®, the maker of Optune Lua.

- Do not use any parts that did not come with Optune Lua Treatment Kit sent to you by Novocure or given to you by your doctor
- Do not get the device or transducer arrays wet
- Please be aware that Optune Lua has a cord that plugs into an electrical socket. Be careful of tripping when it's connected
- If you have an underlying serious skin condition where the transducer arrays are placed, discuss with your doctor whether this may prevent or temporarily interfere with Optune Lua treatment

WHAT ARE THE POSSIBLE SIDE EFFECTS OF OPTUNE LUA?

The most common side effects of Optune Lua when used together with certain immunotherapy and chemotherapy drugs were dermatitis, pain in the muscles, bones, or joints, fatigue, anemia, alopecia (hair loss), dyspnea, nausea, cough, diarrhea, anorexia, pruritus (itching), leukopenia, pneumonia, respiratory tract infection, localized edema (swelling), rash, pain, constipation, skin ulcers, hypokalemia (low potassium levels), hypoalbuminemia (low albumin levels), hyponatremia (low sodium levels), and dysphagia (difficulty swallowing).

Other potential adverse effects associated with the use of Optune Lua include treatment related skin irritation, allergic reaction to the adhesive or to the gel, overheating of the array leading to pain and/or local skin burns, infections at site where the arrays make contact with the skin, local warmth and tingling sensation beneath the arrays, medical device site reaction, muscle twitching, and skin breakdown/skin ulcer. Talk to your doctor if you have any of these side effects or questions.

ABOUT TUMOR TREATING FIELDS

Tumor Treating Fields (TTFields) are electric fields that exert physical forces to kill cancer cells via a variety of mechanisms. TTFields do not significantly affect healthy cells because they have different properties (including division rate, morphology, and electrical properties) than cancer cells. These multiple, distinct mechanisms work together to target and kill cancer cells. Due to these multimechanistic actions, TTFields therapy can be added to cancer treatment modalities in approved indications and demonstrates enhanced effects across solid tumor types when used with chemotherapy, radiotherapy, immune checkpoint inhibition, or targeted therapies in preclinical models. TTFields therapy provides clinical versatility that has the potential to help address treatment challenges across a range of solid tumors.

To learn more about TTFields therapy and its multifaceted effect on cancer cells, visit tumortreatingfields.com.

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 studies 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 "could," "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 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 22, 2024, 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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[1] World Health Organization Lung Cancer Fact Sheet. Accessed October 3, 2024. https://www.who.int/news-room/fact-sheets/detail/lung-cancer#:~:text=Lung%20cancer%20is%20the%20leading%20cause%20of%20cancer-related%20deaths%20worldwide

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