Novocure’s Optune® Approved in Canada for the Treatment of Newly Diagnosed and Recurrent Glioblastoma

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Optune is the first treatment for glioblastoma approved in Canada in over 12 years

Novocure is actively working to secure reimbursement of Optune to make the therapy accessible for glioblastoma patients

ROOT, Switzerland—(BUSINESS WIRE)—Novocure (NASDAQ: NVCR) today announced that Health Canada has approved Optune® for the treatment of newly diagnosed and recurrent glioblastoma (GBM). GBM is the most common and one of the most aggressive forms of primary brain cancer. Optune is the first treatment for glioblastoma approved in Canada in over 12 years.

Optune is a medical device that works by creating Tumor Treating Fields (TTFields), which are electric fields that disrupt cancer cell division. Optune delivers TTFields therapy to the region of the tumor. Optune is small and light, weighing 2.7 pounds. This makes Optune wearable and portable, so continuous treatment can be received almost anywhere. Globally, more than 25,000 patients have been treated with Optune, to date.

“We’re very happy that Health Canada has approved Optune for the treatment of GBM,” said Jovan Antunovic, Country Manager of Novocure Canada. “We are grateful for the rapid and diligent review of our submission and for Health Canada’s approval of Optune. This is an important achievement in order to bring our therapy to more patients.”

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Each year in Canada, 1,600 people are diagnosed with GBM. Novocure’s phase 3 pivotal EF-14 trial compared Optune plus temozolomide to temozolomide alone in 695 patients with newly diagnosed GBM. Patients treated with Optune plus temozolomide experienced overall survival of 20.9 months versus 16 months for patients treated with temozolomide alone (HR, 0.63; 95 percent CI, 0.53-0.76; P<.001). Optune was safely used together with temozolomide with no significant increase in serious adverse events compared with temozolomide alone. The most common side effect related to Optune was mild to moderate skin irritation. Optune is commercially available as a treatment for GBM in multiple countries in North America, Europe and Asia.

“With Health Canada’s approval of Optune, the Brain Tumour Foundation of Canada (BTFC) is excited that another treatment option will soon be available for patients with GBM,” said Shannon LaHay, CEO of BTFC. “There are many GBM patients and their caregivers looking forward to the availability of Optune in Canada.”

The next critical milestone will be securing reimbursement. Novocure is actively working on this important step in order to ensure that patients have access to Optune for GBM across Canada.

“We are working to ensure that both public and private payers provide access and full reimbursement for Optune as soon as possible,” said Pritesh Shah, Novocure’s Chief Commercial Officer. “We are proud to have reached this milestone as a company and are committed to making our therapy available to all the patients who may benefit throughout the world.”

ABOUT OPTUNE
Optune is a noninvasive, antimitotic cancer treatment for glioblastoma (GBM). Optune delivers Tumor Treating Fields (TTFields) therapy to the region of the tumor.

Tumor Treating Fields therapy uses electric fields to disrupt cell division. Tumor Treating Fields does not stimulate or heat tissue and targets dividing cancer cells of a specific size. Tumor Treating Fields causes minimal damage to healthy cells. Mild to moderate skin irritation is the most common side effect reported. Tumor Treating Fields is approved in...
approved in certain countries for the treatment of adult patients with glioblastoma and malignant 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Do not use Optune in patients with an active implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective.

Do not use Optune in patients that are known to be sensitive to conductive hydrogels. In this case, skin contact with the gel used with Optune may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

WARNINGS AND PRECAUTIONS

Do not prescribe Optune for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune in these populations have not been established.

The most common (≥10%) adverse events involving Optune in combination with
Use of Optune in patients with an inactive implanted medical device in the brain has not been studied for safety and effectiveness, and use of Optune in these patients could lead to tissue damage or lower the chance of Optune being effective.

If the patient has an underlying serious skin condition on the scalp, evaluate whether this may prevent or temporarily interfere with Optune treatment.

**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 24, 2022, 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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On this site, videos and images identified as Optune users, caregivers or healthcare professionals depict actual patients, caregivers and healthcare professionals. Patient images reflect the health status of the patients at the time each photo or video was taken.