Novocure's Optune Pax® Receives CE Mark for the Treatment of Locally Advanced Pancreatic Cancer

June 30, 2026

The CE Mark is supported by results from the Phase 3 PANOVA-3 trial demonstrating a statistically significant improvement in overall survival (OS) for patients treated with Optune Pax concomitant with gemcitabine and nab-paclitaxel

Treatment with Optune Pax was also shown to significantly delay patients' pain progression, helping to preserve quality of life

Optune Pax is a first-of-its-kind wearable medical device for the treatment of pancreatic cancer that delivers Tumor Treating Fields, alternating electric fields that cause cancer cell death

BAAR, Switzerland--(BUSINESS WIRE)--Jun. 30, 2026-- Novocure (NASDAQ: NVCR) announced today that Optune Pax® has received CE (Conformité Européenne) Mark for the treatment of adult patients with locally advanced pancreatic cancer of exocrine origin, concomitant with gemcitabine and nab-paclitaxel (gem/nab-pac) in accordance with guideline recommendations.

"Pancreatic cancer is often diagnosed in late stages when tumors are more difficult to treat. As a result, treatment options have limited effect and survival rates have remained low for decades. However, in the Phase 3 PANOVA-3 trial for Optune Pax, a statistically significant improvement in overall survival was observed in patients who were at an advanced stage of disease," said Teresa Macarulla, MD, PhD, Head of the Department of Medical Oncology at Hospital Clínic Barcelona. "In addition, Optune Pax was also shown to delay pain progression, a debilitating symptom of pancreatic cancer. This is a promising treatment for patients who have an urgent need for new options."

Optune Pax is a portable medical device that delivers Tumor Treating Fields (TTFields) non-invasively through wearable arrays. TTFields are alternating electric fields that disrupt processes critical for cancer cell division and survival, resulting in cancer cell death without significantly affecting healthy cells.

The CE Mark for Optune Pax for locally advanced pancreatic cancer is supported by data from the Phase 3 PANOVA-3 clinical trial, which met its primary endpoint by demonstrating a statistically significant improvement in median overall survival (mOS) for patients treated with Optune Pax and gem/nab-pac, compared to those patients who received gem/nab-pac alone, while also significantly extending time to pain progression, a key secondary endpoint. Because the use of gemcitabine and nab-paclitaxel may vary by market, the approved CE Mark intended purpose for Optune Pax includes a reference to guideline recommendations to account for these local differences.

"The CE Mark designation is a critical milestone in our efforts to bring Optune Pax to people living with locally advanced pancreatic cancer, a disease in need of new treatment options," said Anne Calixte de Lembeye, Senior Vice President, EMEA and Canada, Novocure. "We are proud of this achievement and are committed to working with national agencies to secure access to Optune Pax for patients with pancreatic cancer who may benefit from treatment."

Data Supporting the CE Mark of Optune Pax in Locally Advanced Pancreatic Cancer

PANOVA-3 was an international, prospective, randomized, open-label, controlled Phase 3 clinical trial designed to evaluate the use of Optune Pax concomitant with gem/nab-pac as a first-line treatment for locally advanced pancreatic cancer compared to gem/nab-pac alone.

The trial enrolled 571 patients who were randomized 1:1 and followed for a minimum of 18 months. The trial met its primary endpoint, demonstrating a statistically significant improvement in mOS for patients treated with Optune Pax.

- In the intent-to-treat population (ITT), patients treated with Optune Pax concomitantly with gem/nab-pac (n=285) had an mOS of 16.2 months [95% confidence interval (CI) 15.0–18.0] compared to 14.2 months (95% CI 12.8–15.4) for patients treated with gem/nab-pac alone (n=286), a statistically significant 2.0-month improvement [hazard ratio (HR) 0.82; (95% CI 0.68–0.99) p=0.039].
- In the modified intent-to-treat (mITT) population, defined as patients who received at least 28 days of Optune Pax therapy concomitant with gem/nab-pac or at least one complete cycle of gem/nab-pac, patients treated with Optune Pax concomitantly with gem/nab-pac (n=198) had an mOS of 18.3 months (95% CI 16.1–20.0) compared to 15.1 months (95% CI 13.4–17.0) in those treated with gem/nab-pac alone (n=207), a statistically significant 3.2-month improvement [HR 0.77; (95% CI 0.62–0.97) p=0.023].

Optune Pax concomitant with gem/nab-pac demonstrated improvement in several secondary endpoints, including the one-year survival rate.

- The one-year survival rate in the ITT population showed a significant improvement in the Optune Pax concomitant with gem/nab-pac treated group with 68.1% [95% CI 62.0–73.5] compared to those who received gem/nab-pac alone, 60.2%

[95% CI 54.2–65.7].
- In the mITT population, the one-year survival rate showed a significant improvement in the Optune Pax concomitant with gem/nab-pac treated group with 75.2% (95% CI 68.5–80.7) compared to 65.9% (95% CI 59.0–72.0) in patients who received gem/nab-pac alone.

Pancreatic cancer can cause significant pain as the disease progresses and managing pain is a key clinical challenge. In PANOVA-3, time to pain progression was defined as the time from baseline until an increase of 20 or more points was reported by patients on a visual analogue scale for pain or until death.

- Patients treated with Optune Pax concomitant with gem/nab-pac had a median time to pain progression of 15.2 months (95% CI 10.3–22.8) compared to a median 9.1 months in the group treated with gem/nab-pac alone (95% CI 7.4–12.7). This is a significant 6.1-month extension in time to pain progression [HR 0.74; (95% CI 0.56–0.97) p=0.027].

Quality of life (QoL) was a secondary endpoint measured at baseline and every 8 weeks. Analyses were performed for all patients using the European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) with the pancreatic cancer-specific PAN26 addendum. Treatment with Optune Pax concomitant with gem/nab-pac resulted in longer deterioration-free survival (DFS) in global health status, pain, pancreatic pain and most of the digestive problems. Similar trends were observed for emotional function and fatigue/lack of energy.

There was no significant difference in additional secondary outcome measures of progression-free survival, local progression-free survival, objective response rate, puncture-free survival or tumor resectability rate between the Optune Pax concomitant with gem/nab-pac and the gem/nab-pac alone arms.

Optune Pax was well-tolerated and did not exacerbate gem/nab-pac -related systemic toxicity, no new safety signals were observed, and serious adverse events (SAEs) were comparable between study arms. Most Optune Pax-treated patients experienced the expected device-related skin adverse events (AEs) under the arrays (76.3% of the Optune Pax-treated participants). The majority of these events were mild to moderate (Grade 1-2), with 21 (7.7%) experiencing a Grade ≥3 event. The most common device-related AE not related to skin AEs was fatigue, reported in 14 participants (5.1%). There was one Grade 4 AE suspected to be related to the device by the investigator, which was a non-serious event of neutrophil count decrease. There were no device-related AEs that led to death, and no unanticipated device-related safety issues during the study.

The results from the Phase 3 PANOVA-3 trial were published in the *Journal of Clinical Oncology,* available online at https://ascopubs.org/doi/10.1200/JCO-25-00746.

Optune Pax was approved by the U.S. Food and Drug Administration in February 2026.

Novocure plans to launch Optune Pax in Germany in the coming weeks.

About Pancreatic Cancer

According to the World Health Organization (WHO), pancreatic cancer is one of the most lethal cancers and is the fifth most frequent cause of death from cancer in Europe.[1] While overall cancer incidence and death rates are remaining stable or declining, the incidence and death rates for pancreatic cancer are increasing.[2] It is estimated that in Europe approximately 146,000 patients are diagnosed with pancreatic cancer each year.[3] Pancreatic cancer has a five-year relative survival rate of just 13%.[4]

Physicians use different combinations of surgery, radiation, and pharmacological therapies to treat pancreatic cancer, depending on the stage of the disease. Unfortunately, most locally advanced pancreatic cancer cases are diagnosed when the cancer is no longer operable, meaning encasement of blood vessels, but no extra-pancreatic disease, leaving few treatment options. The standard of care for locally advanced pancreatic cancer is chemotherapy with or without radiation, and surgery if it is possible.

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 multi-mechanistic actions, TTFields therapy can be added to cancer treatment modalities in approved indications and it demonstrated 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 novocure.com/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, pancreatic cancer, non-small cell lung cancer, malignant pleural mesothelioma and pleural mesothelioma. Novocure has several additional ongoing or completed clinical trials

exploring the use of Tumor Treating Fields therapy in the treatment of glioblastoma, non-small cell lung cancer and pancreatic cancer.

Novocure's global headquarters is located in Baar, Switzerland, with U.S. headquarters located in Portsmouth, New Hampshire and research and development facilities located in Haifa, Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on LinkedIn and X (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 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 26, 2026, 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] International Agency for Research on Cancer. 2024. Cancer Today (GLOBOCAN 2022). https://gco.iarc.who.int/today/en/dataviz/tables?mode=cancer&group_populations=1&populations=908&multiple_populations=1&types=1 Accessed on June 16, 2026.

[2] American Cancer Society. Cancer Facts & Figures 2025. 1930;(500825). https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acs.pdf Accessed January 16, 2026.

[3] International Agency for Research on Cancer. 2024. Cancer Today (GLOBOCAN 2022). https://gco.iarc.who.int/today/en/dataviz/tables?mode=cancer&group_populations=1&populations=908&multiple_populations=1&types=0 Accessed on June 16, 2026.

[4] American Cancer Society. Cancer Facts & Figures 2026. Atlanta: American Cancer Society; 2026

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