U.S. FDA Approves Novocure’s Optune Pax® for the Treatment of Locally Advanced Pancreatic Cancer

February 12, 2026

Optune Pax concomitant with gemcitabine and nab-paclitaxel is the first treatment to be FDA approved in nearly 30 years for locally advanced pancreatic cancer

Phase 3 PANOVA-3 trial showed a statistically significant improvement in overall survival (OS) and significantly extended time to pain progression in patients treated with Optune Pax

Optune Pax is a wearable medical device that delivers Tumor Treating Fields (TTFields), alternating electric fields that disrupt cancer cell replication to cause cell death, providing a new treatment approach for pancreatic tumors

BAAR, Switzerland--(BUSINESS WIRE)-- Novocure (NASDAQ: NVCR) announced today that the U.S. Food and Drug Administration (FDA) approved Optune Pax® for the treatment of adult patients with locally advanced pancreatic cancer concomitant with gemcitabine and nab-paclitaxel.

“In the Phase 3 PANOVA-3 trial, treatment with Optune Pax resulted in a statistically significant improvement in overall survival without adding to the systemic side effects commonly associated with existing therapies. It also significantly extended time to pain progression, helping to preserve overall quality of life, which is a priority when I am treating patients living with pancreatic cancer,” said Vincent Picozzi, M.D., MMM, medical oncologist and investigator in the PANOVA-3 trial. “With FDA approval, Optune Pax has the potential to be practice changing for the treatment of patients with locally advanced pancreatic cancer.”

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

“The FDA approval of Optune Pax marks the first new treatment in decades for people living with locally advanced pancreatic cancer. Systemic therapies have shown poor bioavailability in pancreatic tumors, limiting their effectiveness. Optune Pax is a fundamentally different treatment, utilizing a biophysical approach that targets the unique electrical properties of cancer cells,” said Frank Leonard, CEO, Novocure. “This is a proud moment for Novocure and we look forward to bringing Optune Pax to patients and the healthcare providers who care for them.”

“The approval of Optune Pax is an important milestone for the pancreatic cancer community. Survival rates for pancreatic cancer have seen only modest improvements over time and treatment advances have remained limited, underscoring how challenging this disease is to treat,” said PanCAN’s Chief Scientific and Medical Officer Anna Berkenblit, MD, MMSc. “This approval for locally advanced disease highlights the importance of continued innovation and investment in new approaches for difficult-to-treat cancers and represents meaningful progress for patients who urgently need more options.”

Data Supporting the Optune Pax FDA Approval

PANOVA-3 was an international, prospective, randomized, open-label, controlled Phase 3 clinical trial designed to evaluate the use of Optune Pax concomitantly with gemcitabine and nab-paclitaxel (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 median overall survival (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 per protocol (mPP) population, defined as patients who received at least 28 days of Optune Pax therapy concomitant with gem/nab-pac arm 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 mPP 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 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.

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 adverse events 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 course of 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.

About Pancreatic Cancer

Pancreatic cancer is one of the most lethal cancers and is the third most frequent cause of death from cancer in the U.S. While overall cancer incidence and death rates are remaining stable or declining, the incidence and death rates for pancreatic cancer are increasing. It is estimated that approximately 67,000 patients are diagnosed with pancreatic cancer each year in the U.S. Pancreatic cancer has a five-year relative survival rate of just 13%.[1]

Physicians use different combinations of surgery, radiation, and pharmacological therapies to treat pancreatic cancer, depending on the stage of the disease. For patients with locally advanced pancreatic cancer involving encasement of arteries but no extra-pancreatic disease, the standard of care is surgery followed by chemotherapy with or without radiation. Unfortunately, most locally advanced cases are diagnosed when the cancer is no longer operable, generally leaving chemotherapy with or without radiation as the only treatment option.

Indication and Important Safety Information for Optune Pax®

What is Optune Pax® approved to treat?

Optune Pax is an FDA-approved wearable therapeutic device, used together with gemcitabine and nab-paclitaxel (a chemotherapy combination). It is indicated for the treatment of adult patients with locally advanced pancreatic cancer.

Who should not use Optune Pax?

Optune Pax for locally advanced pancreatic cancer is not for everyone. Talk to your doctor if you have:

- **An electrical implant.** Use of Optune Pax 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 Pax may commonly cause increased redness and itching. In rare cases, it may lead to severe allergic reactions that can cause a drop in blood pressure and difficulty breathing

Do not use Optune Pax if you are pregnant or are planning to become pregnant. If you are a woman who is able to get pregnant, you must use birth control when using the device. It is not known if Optune Pax is safe or effective during pregnancy.

What should I know before using Optune Pax?

Optune Pax 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 Pax.

- Do not use any parts that did not come with the Optune Pax 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 Pax has a cord that plugs into an electrical socket. Be careful of tripping when it's connected
- If you have an underlying skin condition where the transducer arrays are placed, discuss with your doctor whether this may prevent or temporarily interfere with Optune Pax treatment

What are the possible side effects of Optune Pax?

The most common side effects of Optune Pax used together with chemotherapy drugs were low neutrophils, low red blood cell count, low platelet count, low white blood cell count, diarrhea, nausea, vomiting, abdominal pain, constipation, fatigue, swelling, fever, pain, COVID-19, infection, respiratory tract infection, urinary tract infection, pneumonia, liver enzyme increased, weight loss, low potassium level, low albumin level, high blood sugar, muscle pain, neuropathy peripheral (damage to the nerves outside the brain and spinal cord), taste disorder, dizziness, difficulty sleeping, shortness of breath, hair loss, skin-related disorders, and low blood pressure.

Device-related skin adverse effects associated with the use of Optune Pax include skin inflammation, rash, itching, skin redness, skin irritation, skin infection, heavy sweating, and open sores. Other device-related adverse effects associated with the use of Optune Pax include overheating of the array, leading to pain and/or local skin burns, allergic reaction to the adhesive or gel from the transducer arrays, and local warmth and tingling sensation beneath the arrays. Talk to your doctor if you have any of these side effects or have any 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 multi-mechanistic 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 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, 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 27, 2025, 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] American Cancer Society. Cancer Facts & Figures 2026. Atlanta: American Cancer Society; 2026

Investors:

Adam Daney
investorinfo@novocure.com

Media:
Catherine Falcetti
media@novocure.com

Source: Novocure