



## Updated 2-THE-TOP Data Suggest Improvements in Progression-Free Survival, Overall Survival Compared to Matched-Control Patients from EF-14 Trial

March 25, 2022

*Patients in phase 2 pilot trial 2-THE-TOP had median progression-free survival of 12.1 months compared with 7.9 months for matched-control patients from EF-14*

ST. HELIER, Jersey--([BUSINESS WIRE](#))--Novocure (NASDAQ: NVCR) today announced that Dr. David Tran, Chief of the Division of Neuro-Oncology at the McKnight Brain Institute at the University of Florida, will present updated results from his investigator-initiated phase 2 pilot 2-THE-TOP clinical trial testing the safety and preliminary efficacy of [Tumor Treating Fields \(TTFields\)](#) together with pembrolizumab and temozolomide for the treatment of adult patients with newly diagnosed glioblastoma (GBM).

These preliminary results, which are based on a median follow-up time of 16.8 months, compare outcomes for 26 patients in the ongoing 2-THE-TOP trial versus a historical, matched-control group of 26 patients from the TTFields plus temozolomide arm of the phase 3 pivotal EF-14 clinical trial. For patients in the 2-THE-TOP trial, median progression-free survival was 12.1 months, compared with 7.9 months for the matched-control patients in EF-14 (hazard ratio=0.46, p=0.033). Patients in 2-THE-TOP had a median overall survival of 25.2 months, compared with 15.9 months for the matched-control patients in EF-14 (hazard ratio=0.38, p=0.020).

Of the 15 patients in 2-THE-TOP with measurable target lesions, six (40%) achieved partial to complete response and eight (53%) had stable disease.

"These data from 2-THE-TOP are exciting and point to the potential benefit of [Tumor Treating Fields](#) together with pembrolizumab and temozolomide," said [Uri Weinberg](#), Novocure's Chief Science Officer. "TTFields' ability to activate a downstream immune response, effectively turning a cold tumor hot, is a unique element of TTFields therapy."

Dr. Tran will present his data from 2-THE-TOP at the 6<sup>th</sup> Quadrennial Meeting of the World Federation of Neuro-oncology Societies (*WFNOS 2022*) in Seoul, South Korea on March 26, 2022. His oral presentation, which has been selected for a Best Abstract Award, will be delivered during the conference's Top 10 Session 2 at 10:15 a.m. KST, followed by a live question-and-answer session.

In a preclinical [study published in the \*Journal of Clinical Investigation\* \(JCI\)](#) on Feb. 24, 2022, Dr. Tran's research group reported that TTFields-mediated cell disruption activates the immune system, triggering an anti-tumor cell response that may be effectively used together with existing immunotherapy approaches in the treatment of solid tumors with limited systemic toxicity. These preclinical findings provided the mechanistic rationale for the 2-THE-TOP study.

"We are very encouraged by the data from Dr. Tran's 2-THE-TOP study, and by the mechanistic insights published by his research group in *JCI*," said William Doyle, Novocure's Executive Chairman. "We plan to continue exploring the potential of using Tumor Treating Fields with immunotherapies, which could shift the treatment paradigm for patients with this aggressive disease."

Dr. Tran's oral presentation at WFNOS 2022 is one of three oral presentations at the conference highlighting research on TTFields.

Dr. Carsten Hagemann of the Department of Neurosurgery at University Hospital Würzburg will present preclinical data on TTFields as a novel chemotherapeutic delivery strategy on March 25, 2022 at 17:30 KST.

Dr. Wenyin Shi, Co-Director of the Brain Tumor Center of the Sidney Kimmel Cancer Center, will present data from the SPARE trial: Scalp sparing radiation with concurrent temozolomide and TT Fields (200 kHz) for patients with newly diagnosed glioblastoma on March 26, 2022 at 18:00 KST.

In addition, 28 posters at WFNOS 2022 will feature research on TTFields.

TTFields is investigational for the treatment of newly diagnosed GBM when used together with pembrolizumab.

### About 2-THE-TOP

The 2-THE-TOP trial is an investigator-initiated, phase 2 pilot trial designed to assess the safety and preliminary efficacy of Tumor Treating Fields (TTFields) together with pembrolizumab and temozolomide for the treatment of adult patients with newly diagnosed GBM. Patients enrolled in the trial underwent maximal tumor resection followed by standard chemoradiation. Following the completion of chemoradiation, patients began a course of monthly cycles of adjuvant temozolomide. Treatment with TTFields started at approximately the same time as the first cycle of adjuvant temozolomide. Pembrolizumab was introduced in the second cycle of treatment and subsequent cycles of pembrolizumab were administered every three weeks until first disease progression or unacceptable toxicities or 2 years, whichever comes first.

### About EF-14

The EF-14 trial was a randomized, phase 3 pivotal trial which compared, post radiation, TTFields plus temozolomide versus temozolomide alone for the treatment of newly diagnosed GBM. Median progression-free survival, the primary endpoint, was 6.7 months for TTFields plus temozolomide versus 4 months for temozolomide alone. Median overall survival was 20.9 months for TTFields plus temozolomide versus 16 months for temozolomide alone.

## **About Tumor Treating Fields**

Tumor Treating Fields, or TTFields, are electric fields that disrupt cancer cell division. Fundamental scientific research extends across more than two decades and, in all preclinical research to date, TTFields have demonstrated a consistent anti-mitotic effect. TTFields therapy is intended principally for use together with other standard-of-care cancer treatments. There is a growing body of evidence that supports TTFields' broad applicability with certain other cancer therapies, including radiation therapy, certain chemotherapies and certain immunotherapies. In clinical research and commercial experience to date, TTFields therapy has exhibited no systemic toxicity, with mild to moderate skin irritation being the most common side effect. The TTFields global development program includes a network of preclinical collaborators and a broad range of clinical trials across all phases, including four phase 3 pivotal trials in a variety of tumor types. To date, more than 22,000 patients have been treated with TTFields therapy.

## **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 and in the U.S. for the treatment of adult patients with malignant 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 Jersey, and with a growing global footprint, Novocure has regional operating centers in Root, Switzerland, Portsmouth, New Hampshire and Tokyo, as well as a research center in Haifa, Israel. For additional information about the company, please visit [Novocure.com](http://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 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 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 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.

## **Contacts**

### **Investors:**

Ingrid Goldberg  
[investorinfo@novocure.com](mailto:investorinfo@novocure.com)  
610-723-7427

### **Media:**

Leigh Labrie  
[media@novocure.com](mailto:media@novocure.com)  
610-723-7428

Source: Novocure