

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

June 6, 2023
Date of Report (date of earliest event reported)

NovoCure Limited
(Exact name of registrant as specified in its charter)

Jersey	001-37565	98-1057807
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)
No. 4 The Forum, Grenville Street St. Helier Jersey	JE2 4UF	
(Address of Principal Executive Offices)	(Zip Code)	

+44 (0) 15 3475 6700
Registrant's telephone number, including area code
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, no par value	NVCR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

On June 6, 2023, NovoCure Limited (the "Company" or "Novocure"), presented positive results from the phase 3 LUNAR clinical trial evaluating the use of Tumor Treating Fields (TTFields) therapy together with standard therapies for the treatment of non-small cell lung cancer (NSCLC) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. Exhibit 99.1 attached hereto and incorporated by reference are the data provided at the presentation. This data will be available on the investor relations page of www.novocure.com.

The information contained in this Current Report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation Data from 2023 ASCO Meeting June 6, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NovoCure Limited
(Registrant)

Date: June 6, 2023

By: /s/ Ashley Cordova
Name: Ashley Cordova
Title: Chief Financial Officer

Tumor Treating Fields (TTFields) Therapy With Standard of Care (SOC) in Metastatic Non-Small Cell Lung Cancer (mNSCLC) After Platinum-Based Therapies: Randomized, Phase 3 LUNAR Study

Ticiana Leal¹, Rupesh Kotecha², Rodryg Ramlau³, Li Zhang⁴, Janusz Milanowski⁵, Manuel Cobo⁶, Jaromir Roubec⁷, Lubos Petruzela⁸, Libor Havel⁹, Sujith Kalmadi¹⁰, Jeffrey Ward¹¹, Zoran Andric¹², Thierry Berghmans¹³, David E. Gerber¹⁴, Goetz Kloecker¹⁵, Rajiv Panikkar¹⁶, Joachim Aerts¹⁷, Angelo Delmonte¹⁸, Miklos Pless¹⁹, Richard Greil²⁰, Christian Rolfo²¹, Wallace Akerley²², Michael Eaton²³, Mussawar Iqbal²⁴, and Corey Langer²⁵; on behalf of the LUNAR study investigators

¹Winship Cancer Institute at Emory University, Atlanta, GA, USA; ²Miami Cancer Institute, Baptist Health South Florida, Miami, FL, USA; ³Rodryg Ramlau, Poznan University of Medical Sciences, Poznan, Poland; ⁴Sun Yat-sen University Cancer Center (SYSUCC), Guangzhou, China; ⁵Medical University of Lublin, Lublin, Poland; ⁶Medical Oncology Intercenter Unit, Regional and Virgen de la Victoria University Hospitals, IBIMA, Málaga, Spain. ⁷Nemocnice AGEL Ostrava-Vitkovice, Ostrava, Czech Republic; ⁸General University Hospital in Prague, Prague, Czech Republic; ⁹Thomayer Hospital, Prague, Czech Republic; ¹⁰Ironwood Cancer & Research Centers, Chandler, AZ, USA; ¹¹Washington University School of Medicine, St. Louis, MO, USA; ¹²Clinical Hospital Centre Bežanijska Kosa, Belgrade, Serbia; ¹³Jules Bordet Institute, Hôpitaux Universitaires de Bruxelles, Université Libre de Bruxelles, Brussels, Belgium; ¹⁴Harold C. Simmons Comprehensive Cancer Center, UT Texas Southwestern Medical Center, Dallas, TX, USA; ¹⁵University of Louisville, Louisville, KY, USA; ¹⁶Geisinger Cancer Institute, Danville, PA, USA; ¹⁷Erasmus University Medical Center, Erasmus MC Cancer Institute, Rotterdam, The Netherlands; ¹⁸IRCCS Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori" (IRST), Meldola, Italy, Meldola, Italy; ¹⁹Kantonsspital Winterthur, Winterthur, Switzerland; ²⁰Salzburg Cancer Research Institute-Center for Clinical Cancer and Immunology Trials (SCRI-CCCIT); Paracelsus Medical University Salzburg; Cancer Cluster, Salzburg, Austria; ²¹Center for Thoracic Oncology, Tisch Cancer Institute at Icahn School of Medicine, Mount Sinai, New York, NY; ²²Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA; ²³St Francis Hospital, Indianapolis, IN; ²⁴College of Medicine, University of Saskatchewan, Saskatoon, Canada; ²⁵Abramson Cancer Center, Perelman School of Medicine, University of Pennsylvania, PA, USA

As presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, IL; June 2–6, 2023 (Abstract LBA9005).

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1

Background

- Metastatic NSCLC remains largely incurable
- Platinum-based chemotherapy with immune checkpoint inhibitors (ICIs) are standard first line therapy for metastatic NSCLC lacking actionable driver mutations^{1–3}
- Unfortunately, most patients develop disease progression^{4–7} and 5-year survival is only 9%⁸
- Treatment options that extend survival beyond progression are limited
- Current approaches in the second line include chemotherapy regimens, mainly docetaxel (DTX) with or without ramucirumab, or ICI (if eligible)²
- Phase 3 studies demonstrated that ICIs (OS of 10–14 months) are superior to DTX (OS of 8–9 months) for NSCLC progressing on platinum therapy^{9–11}
- Unmet need remains high for new, well-tolerated and effective options for second-line treatment and beyond

DTX, docetaxel; ICI, immune checkpoint inhibitor; NSCLC, non-small cell lung cancer; OS, overall survival.

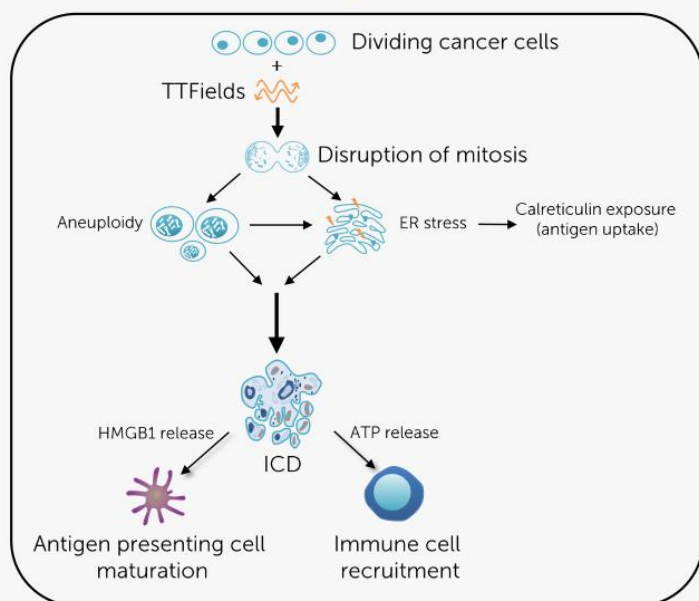
References: 1. Hendriks LE et al. *Ann Oncol.* 2023;34(4):358–376. 2. National Comprehensive Cancer Network. Version 3. 2022. 3. Owen DH et al. *J Clin Oncol.* 2023;41(5):e1–e9.

4. de Castro G et al. *J Clin Oncol.* 2023;41(11):1986–1991. 5. Reck M et al. *J Clin Oncol.* 2021;39(21):2339–2349. 6. Brahmer JR et al. *J Clin Oncol.* 2023;41(6):1200–1212.

7. Herbst RS et al. *N Engl J Med.* 2020;383(14):1328–1339. 8. www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics. 9. Herbst RS et al. *J Thorac Oncol.* 2021;16(10):1718–1732.

10. Borghaei H et al. *J Clin Oncol.* 2015;33(7):723–733. 11. Rittmeyer A et al. *Lancet.* 2017;389(10066):255–265.

Tumor Treating Fields (TTFields) Mechanism of Action



- TTFields are electric fields that exert physical forces on electrically charged components in dividing cancer cells, leading to an antimitotic effect^{1,2}

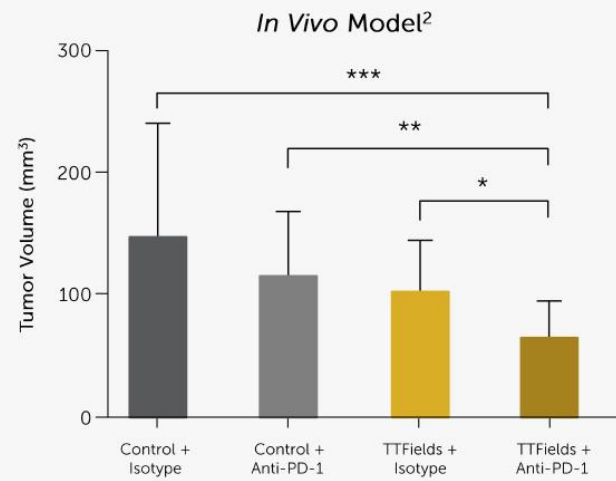
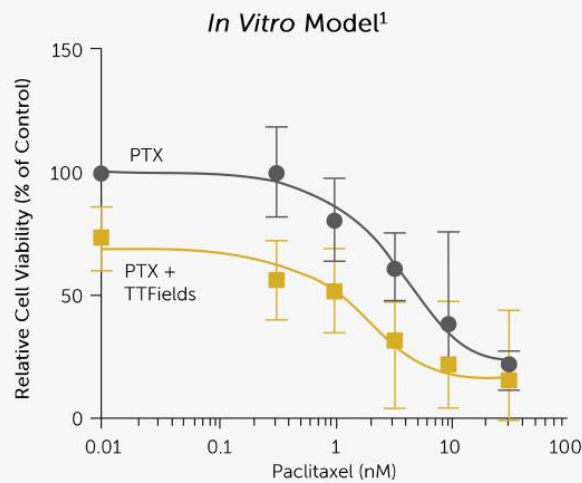
- Downstream effects include cell stress-induced immunogenic cell death (ICD), triggering a systemic anti-tumor immune response^{3,4}

ATP, adenosine triphosphate; ER, endoplasmic reticulum; HMGB1, high mobility group box 1 protein; ICD, immunogenic cell death; TTFields, Tumor Treating Fields.

References: 1. Mun EJ et al. *Clin Cancer Res*. 2018;24(2):266–275. 2. Giladi M et al. *Sci Rep*. 2015;5:18046. 3. Voloshin T et al. *Cancer Immunol Immunother*. 2020;69(7):1191–1204. 4. Barsheshet Y et al. *Int J Mol Sci*. 2022;23(22):14073. Figure adapted from: Shteingauz A et al. *Cell Death Dis*. 2018;9(11):1074.

Preclinical Evidence

TTFields application together with ICIs or taxanes demonstrated efficacy in preclinical NSCLC models¹⁻³



* **, *** indicate $P < 0.05$, 0.01 , 0.001 , respectively.

ICI, immune checkpoint inhibitor; NSCLC, non-small cell lung cancer; PD-1, programmed cell death protein 1; PTX, paclitaxel; TTFields, Tumor Treating Fields.

References: 1. Giladi M et al. *Semin Oncol*. 2014;41(suppl 6):S35-S41. 2. Voloshin T et al. *Cancer Immunol Immunother*. 2020;69(7):1191-1204.

3. Barshesht Y et al. *Int J Mol Sci*. 2022;23(22):14073.

TTFields Therapy

- Non-invasive anticancer treatment modality
- Delivered locoregionally to the chest by a wearable medical device and two pairs of arrays (adhesive bandages with biocompatible insulated ceramic discs covered by hydrogel)¹
- Delivered to the patient's home with 24/7 phone support by a device technician; continuous use (~ 18 h/day)
- FDA-approved* for glioblastoma and malignant pleural mesothelioma²⁻⁴
- Pilot study demonstrated safety and feasibility of TTFields therapy with pemetrexed in advanced NSCLC⁵

TTFields device



Array Placement



*TTFields for glioblastoma was approved via the Premarket Approval (PMA) pathway. TTFields for malignant pleural mesothelioma was approved via the Humanitarian Device Exemption (HDE) pathway.

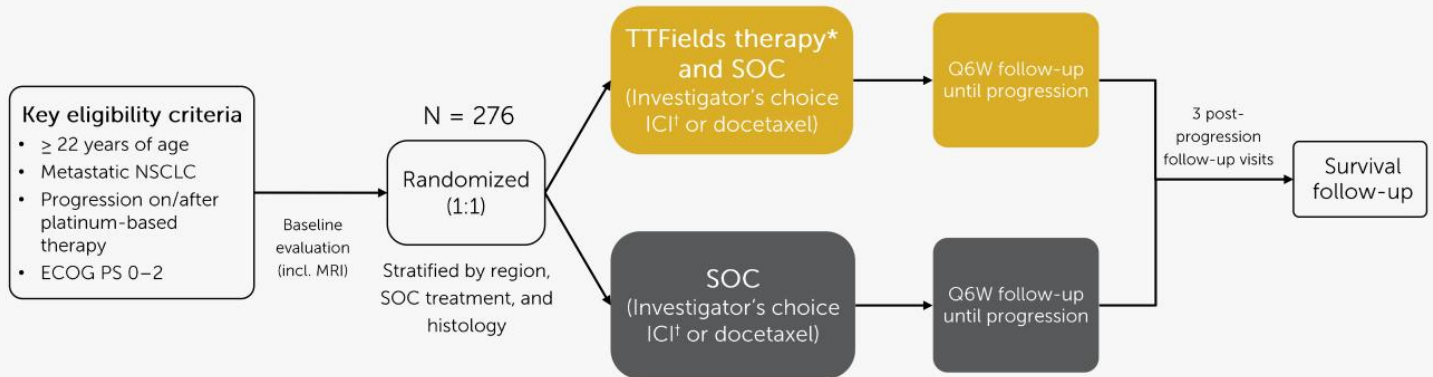
NSCLC, non-small cell lung cancer; TTFields, Tumor Treating Fields. Image shows an actor. Used with permission from Novocure GmbH.

References: 1. Optune Lua. Instructions for Use for Unresectable Malignant Pleural Mesothelioma. Novocure; 2021. 2. Stupp R et al. *Eur J Cancer*. 2012;48(14):2192-2202.

3. Stupp R et al. *JAMA*. 2017;318(23):2306-2316. 4. Ceresoli GL et al. *Lancet Oncol*. 2019;20(12):1702-1709. 5. Pless M et al. *Lung Cancer*. 2013;81(3):445-450.

LUNAR Phase 3 Study Design

Objective: To evaluate safety and efficacy of TTFields therapy with standard of care (SOC) compared to SOC alone in metastatic NSCLC progressing on or after platinum-based therapy



Data cut-off: November 26, 2022

Study sites: 124 in 17 countries (North America, Europe, Asia)

*150 kHz, ≥18 h/day; †pembrolizumab, nivolumab, or atezolizumab.
ECOG PS, Eastern Cooperative Oncology Group performance status; ICI, immune checkpoint inhibitor; MRI, magnetic resonance imaging; NSCLC, non-small cell lung cancer;
Q6W, every 6 weeks; SOC, standard of care; TTFields, Tumor Treating Fields.

LUNAR Study Endpoints and Statistical Analysis

Primary	Key Secondary	Other Secondary
<ul style="list-style-type: none">• OS with TTFIELDS + SOC vs SOC alone	<ul style="list-style-type: none">• OS in ICI-treated subgroup• OS in docetaxel-treated subgroup	<ul style="list-style-type: none">• PFS• ORR• PFS/OS by histology• QoL (EORTC QLQ C30/LC13)• Safety

Statistical Analysis

- Targeted hazard ratio < 0.75 using two-sided proportional hazards testing ($\alpha = 0.05$) with 80% power, stratified by SOC treatment and histology
- Key secondary endpoints were tested hierarchically if the primary endpoint was met
- March 2021 planned interim analysis: DMC recommended a reduced patient accrual (534 to 276 patients) and follow-up (18 to 12 months) would be sufficient to evaluate endpoints while retaining statistical power

DMC, Data Monitoring Committee; ICI, immune checkpoint inhibitor; ORR, overall response rate; OS, overall survival; PFS, progression free survival; QoL, Quality of Life; SOC, standard of care; TTFIELDS, Tumor Treating Fields.

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7

Baseline Demographics and Characteristics

	TTFields + SOC (n = 137)	SOC (n = 139)	Overall (N = 276)
Age, yr — median (range)	63 (36–85)	65 (22–86)	64 (22–86)
Sex, male	66%	63%	65%
Race			
White	81%	80%	80%
Asian	12%	9%	10%
Black or African American	2%	2%	2%
Other/unknown	5%	8%	6%
Region			
North America	30%	31%	30%
W. Europe and Israel	31%	30%	30%
Eastern Europe	30%	31%	30%
East Asia	10%	9%	9%
ECOG PS			
0	28%	29%	28%
1	68%	68%	68%
2	4%	3%	4%
Smoking history*			
Current or former	85%	83%	84%
Never	15%	17%	16%

Baseline demographics were similar across both arms of the study

Percentages rounded to nearest integer; totals may not equal 100%

*Missing data from 1 patient in the TTFields + DTX group.
DTX, docetaxel; ECOG PS, Eastern Cooperative Oncology Group performance status; ICI, immune checkpoint inhibitor; SOC, standard of care; TTFields, Tumor Treating Fields.

Baseline Disease Characteristics

	TTFields + SOC (n = 137)	SOC (n = 139)	Overall (N = 276)
Histology			
Non-squamous/squamous	58%/42%	55%/45%	56%/44%
PD-L1			
< 1%	17%	17%	17%
1–49%	27%	29%	28%
≥ 50%	7%	13%	10%
Unknown*	49%	42%	45%
Prior lines of systemic therapy**			
1	89%	89%	89%
2+	11%	10%	11%
Prior ICI	31%	31%	31%
Best response to any prior therapy			
Complete response	6%	4%	5%
Partial response	23%	26%	25%
Stable disease	34%	32%	33%
Progressive disease	21%	26%	24%
Unknown	15%	13%	14%
Liver metastasis[†]	15%	16%	16%
CNS metastasis[‡]	0	1%	1%

Percentages rounded to nearest integer; totals may not equal 100%

*PD-L1 status reporting was optional and was available for 83% of patients in the United States; **Missing data for 1 patient in the ICI group. †One patient had liver and CNS metastasis.

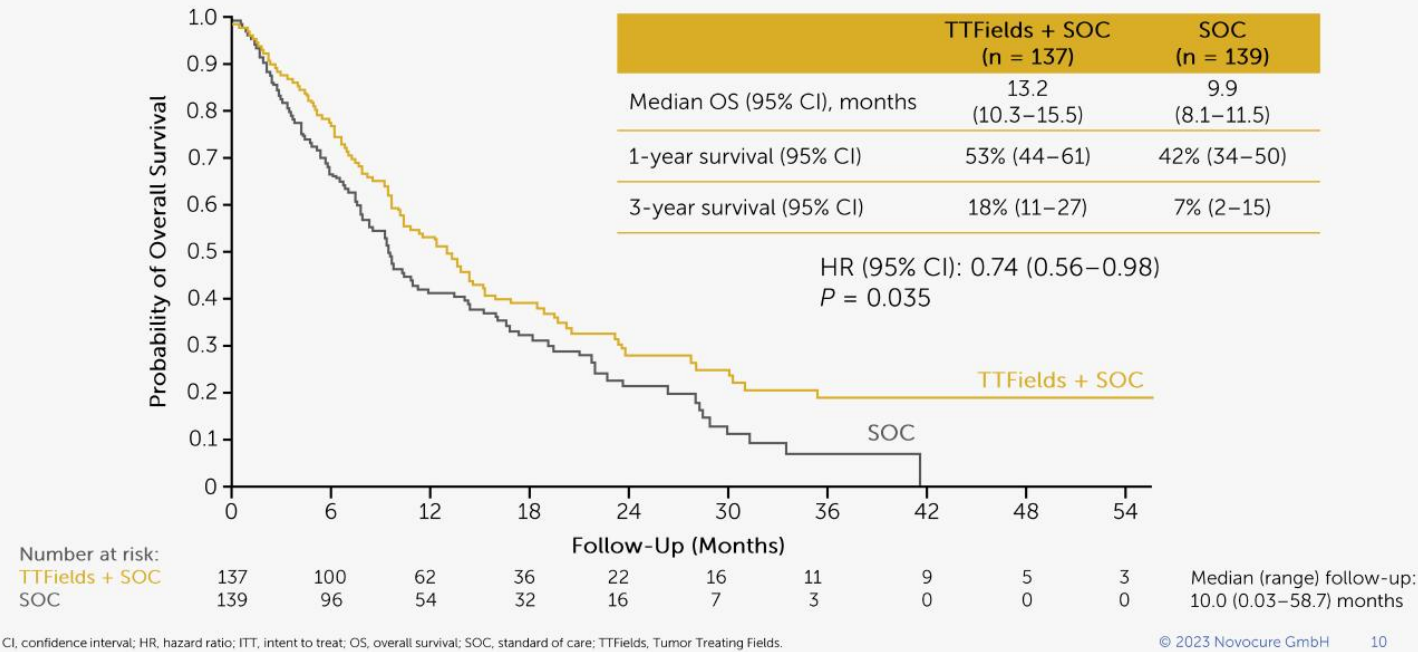
‡Patients with CNS metastases were excluded under the original study design; later amended to allow stable CNS metastases.

CNS, central nervous system; ICI, immune checkpoint inhibitor; PD-L1, Programmed Cell Death Ligand 1; SOC, standard of care; TTFields, Tumor Treating Fields.

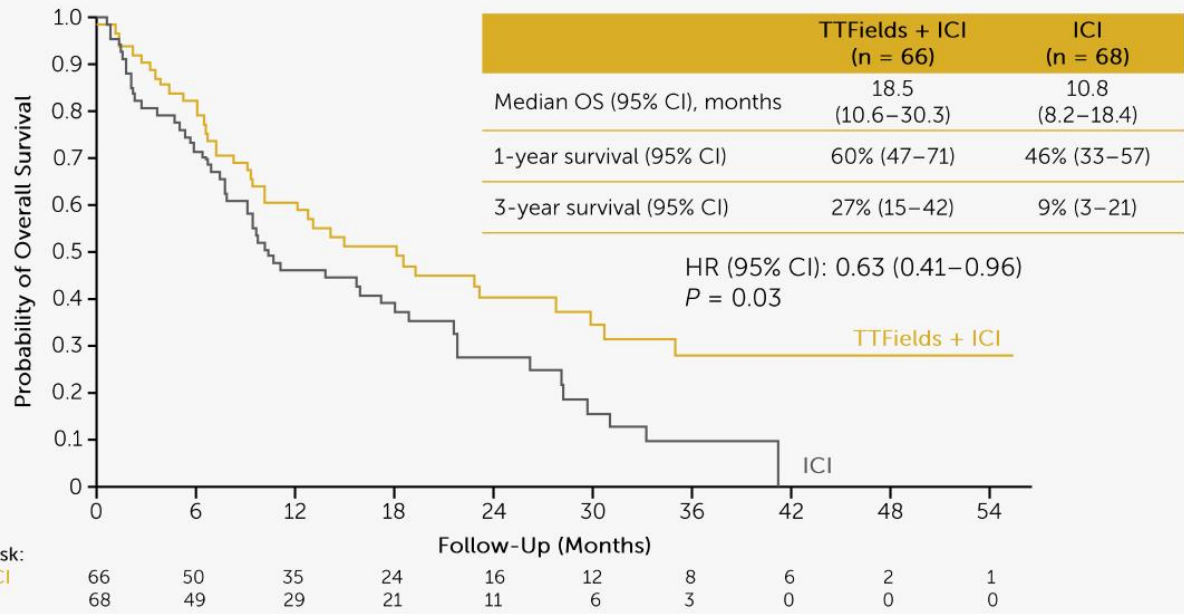
- Available PD-L1 data showed no differences between arms

- 58% of patients in the TTFields + docetaxel subgroup received a prior ICI vs 2% in the TTFields + ICI subgroup

Overall Survival in the ITT Population

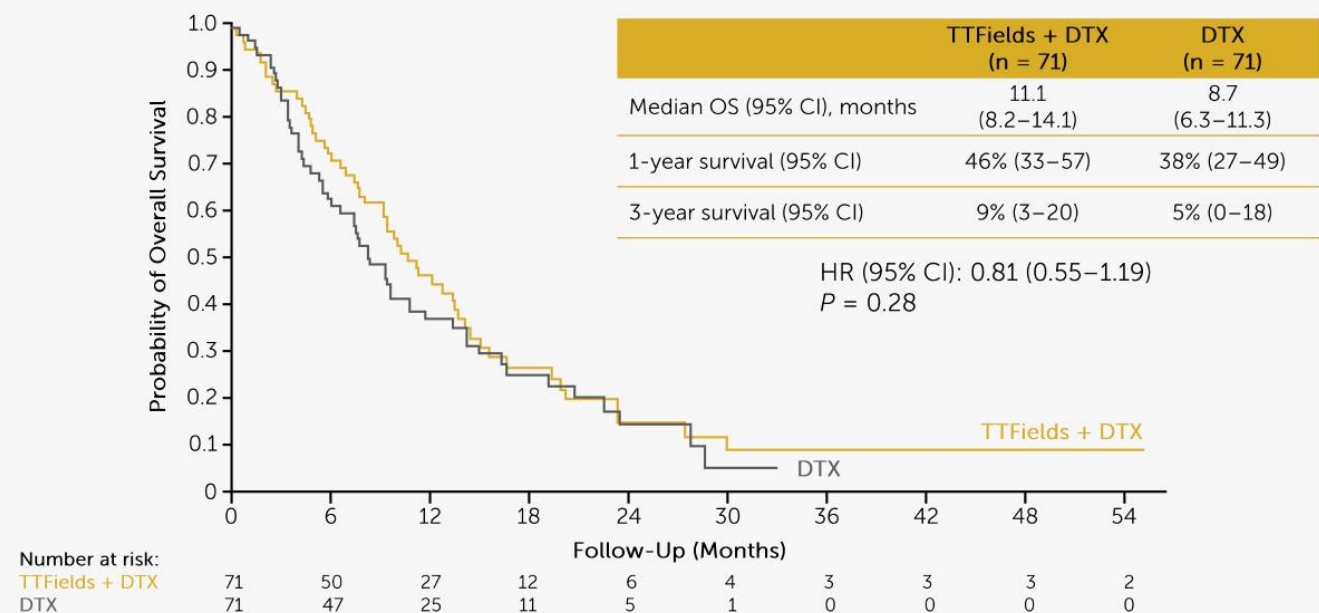


Overall Survival in ICI-Treated Patients



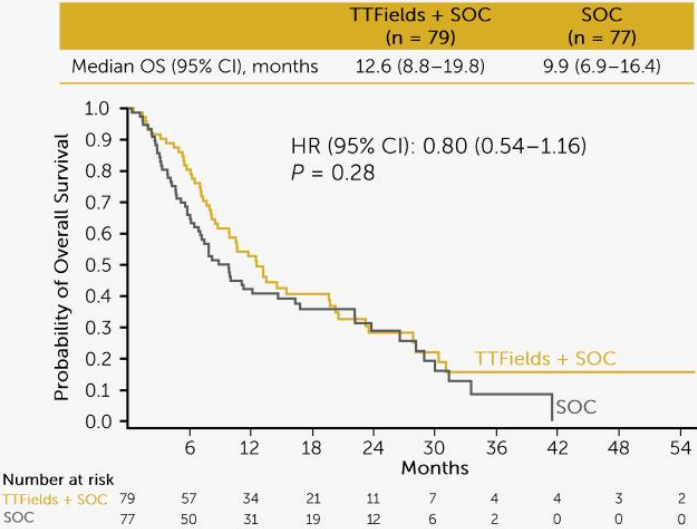
CI, confidence interval; HR, hazard ratio; ICI, immune checkpoint inhibitor; OS, overall survival; TTFIELDS, Tumor Treating Fields.

Overall Survival in DTX-Treated Patients

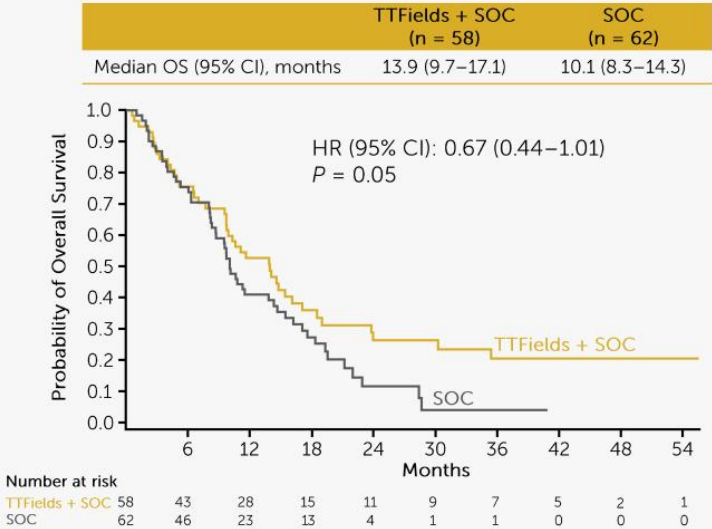


Overall Survival by Histology Subgroups

Non-Squamous

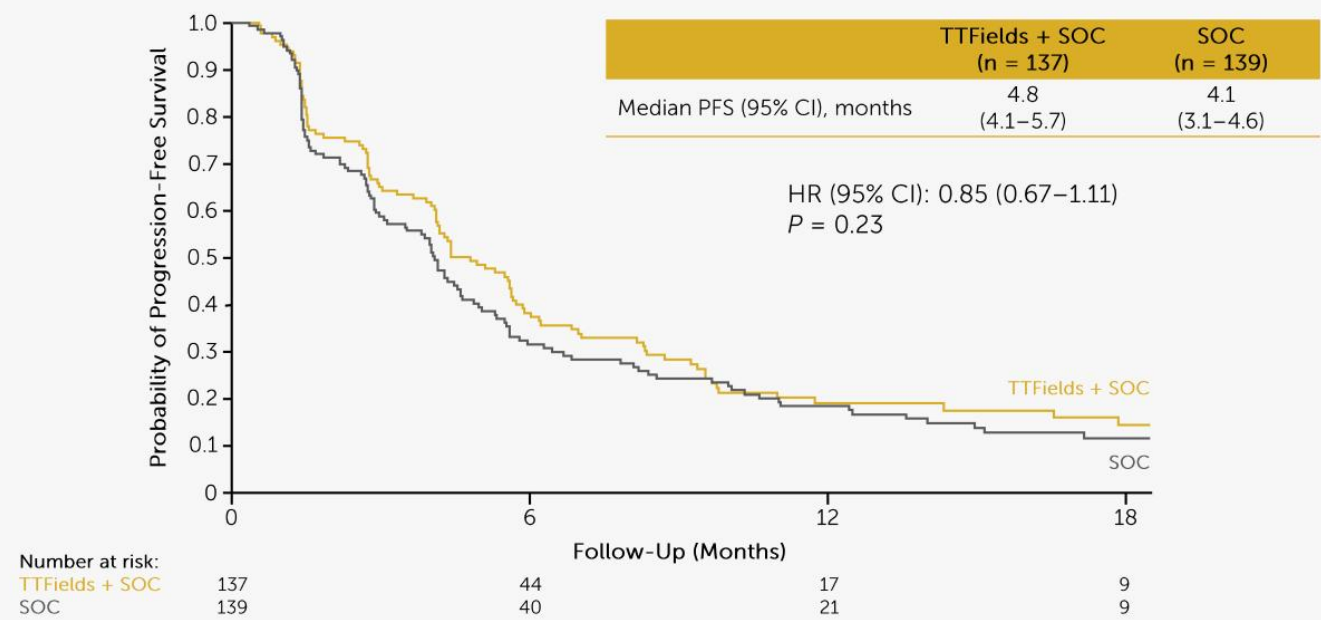


Squamous



CI, confidence interval; HR, hazard ratio; OS, overall survival; SOC, standard of care; TTFields, Tumor Treating Fields.

Progression-Free Survival in the ITT Population



PFS was defined as the time from date of randomization until date of disease progression, or death by any cause.
CI, confidence interval; HR, hazard ratio; ITT, intent to treat; PFS, progression-free survival; SOC, standard of care; TTFIELDS, Tumor Treating Fields.

Response Rates in the ITT Population

	TTFields + SOC (n = 137)	SOC (n = 139)
Patients with a follow-up scan	n = 122	n = 127
ORR, % (95% CI)	20% (14–28)	17% (11–25)
Difference in ORR, % (95% CI)	3% (-8.5–15.0) <i>P</i> = 0.5	
Best overall response, %		
Complete response	3%	1%
Partial response	18%	17%
Stable disease	49%	47%
Progressive disease	18%	26%
Not evaluable	2%	1%

- All 5 complete responses occurred in patients receiving an ICI
 - 4 with TTFields therapy
 - 1 with ICI alone
- Analysis of patterns of progression (infield* vs outfield) is ongoing

*Infield=thorax and upper abdomen.
CI, confidence interval; ICI, immune checkpoint inhibitor; ITT, intent to treat; ORR, overall response rate; SOC, standard of care; TTFields, Tumor Treating Fields.

Safety and Tolerability

	TTFields + SOC (n = 133)		SOC (n = 134)	
	All grades	Grade ≥ 3	All grades	Grade ≥ 3
Any AE*	97%	59%	91%	56%
Most frequent AEs				
Dermatitis	43%	2%	2%	0%
Fatigue	28%	4%	37%	8%
Musculoskeletal pain	36%	3%	27%	4%
Dyspnea	20%	7%	25%	3%
Anemia	23%	8%	22%	8%
Diarrhea	19%	2%	19%	0%
Cough	18%	0%	19%	1%
Nausea	19%	0%	16%	1%
Leukopenia	17%	14%	18%	14%
Pneumonia	15%	11%	17%	11%
Alopecia	10%	0%	17%	1%
Respiratory tract infection	15%	3%	16%	0%
Localized edema	15%	1%	16%	2%
Any Serious AE	53%		38%	
Any AE leading to discontinuation	36%		20%	
Any AE leading to death	10%		8%	

*Any adverse event; not necessarily related to treatment.

AE, adverse event; SOC, standard of care; HRQoL, Health-related quality of life; TTFields, Tumor Treating Fields.

- Majority of patients (94%) had ≥ 1 AE
- Comparable incidence of grade ≥ 3 AEs between arms
- No difference in rate of pneumonitis or other immune-related AEs
- No notable differences in HRQoL when TTFields therapy was added to SOC (detailed analysis ongoing)

TTFields Adverse Device Effects (ADEs)

Preferred term	TTFields + ICI (n = 67)	TTFields + DTX (n = 66)
Any ADE*	73.1%	69.7%
ADEs Grade ≥ 3	4.5%	7.6%
Dermatitis	1.5%	3.0%
Pruritus	0	1.5%
Skin ulcer	0	1.5%
Pain	1.5%	0%
Skin infection	0	1.5%
Bronchopleural fistula	1.5%	0%
Serious ADEs	1.5%	4.5%
Dermatitis	0	3.0%
Skin ulcer	0	1.5%
Skin infection	0	1.5%
Bronchopleural fistula	1.5%	0
ADEs leading to device discontinuation	11.9%	16.7%
Dermatitis	6.0%	7.6%
Skin ulcer	3.0%	3.0%
Rash	0	3.0%
Pain	1.5%	1.5%
Maculopapular rash	0	1.5%
Skin infection	0	1.5%
Bronchopleural fistula	1.5%	0
ADEs leading to death	0	0

*Adverse event deemed related to device use.
DTX, docetaxel; ICI, immune checkpoint inhibitor; ADE, adverse device effect; TTFields, Tumor Treating Fields.

- Median device usage was 15 weeks with ICI; 13 weeks with DTX
- Most device-related effects were grade 1–2 dermatitis
- Dermatitis resolved in 87% of cases; median duration was 3 weeks
- No grade 4 toxicities and no deaths were attributable to TTFields therapy

Conclusions

- Pivotal, phase 3 LUNAR study met its primary endpoint
- TTFields therapy with SOC provided a statistically significant and clinically meaningful 3-month improvement in median OS vs SOC (HR: 0.74, $P = 0.035$) with no added systemic toxicities
 - Statistically significant ~8-month increase in median OS (from 10.8 to 18.5 months) was demonstrated with TTFields therapy and an ICI (HR: 0.63, $P = 0.030$)
 - There was a 2.4-month difference in median OS (from 8.7 to 11.1) for TTFields therapy and docetaxel vs docetaxel alone (HR: 0.81, $P = 0.28$)
- TTFields therapy should be considered part of SOC for metastatic NSCLC following progression on or after platinum-based therapy
- Additional studies evaluating TTFields therapy with current SOC for first-line metastatic and locally advanced NSCLC are underway
- TTFields therapy is a potentially paradigm shifting new treatment modality

Acknowledgements

Special thank you to all participating patients, their families, and clinical research teams for your commitment and contributions

Thank you to all participating sites around the world:

Austria: Medical University Salzburg; **Belgium:** Institut Jules Bordet, Hospital AZ Sint Maarten; **Canada:** McGill University Health Centre, Universitaire de Sherbrooke (CIUSSS de l'Estrie - CHUS), Allan Blair Cancer Centre; **Czech Republic:** Thomayer Hospital, General University Hospital in Prague, Vitkovice Hospital; **China:** Beijing Cancer Hospital, Sun Yat-sen University Cancer Center (SYSUCC), Affiliated Cancer Hospital and Institute of Guangzhou Medical University, Henan Provincial People's Hospital, Henan Cancer Hospital, PKUCare Luzhong Hospital, Zhejiang Cancer Hospital, Sir Run Run Shaw Hospital, Zhejiang University School of Medicine; **France:** Institut Bergonié, Institut de Cancérologie du Gard, Hôpital Saint-Louis; **Hong Kong:** Queen Mary Hospital; **Hungary:** Tolna County Hospital, Jász-Nagykun-Szolnok County Hospital; **Italy:** IRCCS - Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST), Ospedale S.Maria delle Croci; **Netherlands:** St Jansdal Ziekenhuis, Erasmus MC; **Poland:** Non-Invasive Medicine Center, Center of Modern Therapy, Medical University of Lublin, University Hospital in Poznań; **Serbia:** Clinical Hospital Center, Bežanijska Kosa, Clinical Center Kragujevac; **Spain:** Hospital Quirón Teknon, Hospital Universitario Arnau de Vilanova, Hospital Universitario Gregorio Marañón, Hospital Universitario 12 de Octubre, Hospital Regional Universitario Carlos Haya, Hospital Universitari i Politècnic La Fe; **Switzerland:** KS Winterthur; **United States:** Central Alabama Research, Ironwood Cancer & Research Centers, St. Joseph Hospital and Medical Center, Beverly Hills Cancer Center, Compassionate Cancer Care, California Cancer Associates for Research and Excellence, Inc (cCARE), St. Joseph Heritage Healthcare, Long Beach Memorial Medical Center, Sutter Medical Group, Mercy Cancer Center, Emad Ibrahim, MD, Inc, The Oncology Institute of Hope & Innovation, McKee Medical Center, Associated Neurologists of Southern Connecticut, MedStar Washington Hospital Center, GenesisCare, Miami Cancer Institute, Mount Sinai Comprehensive Cancer Center, AdventHealth Neuro Oncology, UF Health Cancer Center at Orlando Health, South Florida Oncology & Hematology Consultants LLC, The University of Kansas Cancer Center, University of Louisville, Norton Cancer Institute, University of Illinois Hospital, Illinois CancerCare PC, Southern Illinois University School of Medicine, Franciscan Health Indianapolis, University Medical Center, Tulane Cancer Center, CHRISTUS Highland Cancer Treatment Center, Tufts Medical Center, Beth Israel Deaconess Medical Center, Central Maine Medical Center, University of Maryland, St. Joseph Mercy Hospital, Karmanos Cancer Institute, Clinical Oncology Associates, Memorial Healthcare, Regions Cancer Care Center, Saint Luke's Hospital, Washington University School of Medicine, Oncology Specialists of Charlotte, WG "Bill" Hefner VA Medical Center, Piedmont Radiation Oncology PA, Nebraska Medical Center, Oncology Hematology West, PC dba Nebraska Cancer Specialists, CHI Health Creighton University Medical Center - Bergan Mercy, New Jersey Hematology Oncology Associates, Presbyterian Cancer Care at Kaseman, OptumCare Cancer Center, Renown Regional Medical Center, Northern Westchester Hospital, New York Presbyterian/Queens Center for Research and Education, Stony Brook Cancer Center, Summa Health System, Toledo Clinic Cancer Center, Vita Medical Associates, PC, Geisinger Medical Center, University of Tennessee/Erlanger Oncology and Hematology, Texas Oncology - Amarillo, Texas Oncology - Arlington North, Christus Spohn Cancer Center, VA North Texas Health Care System, Texas Oncology - Baylor Charles A Sammons Cancer Center, UT Southwestern Medical Center, Oncology Consultants, PA, Texas Oncology - McKinney, Texas Oncology - Paris, Texas Oncology - Plano West, Texas Oncology - Waco, McClinton Cancer Center, University of Utah, Overlake Hospital Medical Center, University of Wisconsin.

This study was sponsored by Novocure

Statistical analysis performed by Gitit Lavy-Shahaf, PhD (Novocure)

Editorial assistance from Chelsea Higgins, PhD (Novocure), Rose Goodchild, PhD and Melissa Purves, CMPP, PhD (Prime); Editorial support funded by Novocure

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Back up



Baseline Demographics and Characteristics

Baseline demographics were similar across all subgroups

	TTFields + SOC (n = 137)	SOC (n = 139)	TTFields + ICI (n = 66)	ICI (n = 68)	TTFields + DTX (n = 71)	DTX (n = 71)
Age, yr — median (range)	63 (36–85)	65 (22–86)	64 (36–85)	65 (23–86)	63 (43–81)	65 (22–81)
Sex, male	66%	63%	67%	66%	66%	59%
Race						
White	81%	80%	82%	78%	80%	82%
Asian	12%	9%	11%	7%	13%	10%
Black or African American	2%	2%	2%	3%	3%	1%
Other/unknown	5%	8%	6%	12%	4%	7%
Region						
North America	30%	31%	21%	25%	38%	37%
W. Europe and Israel	31%	30%	38%	35%	24%	24%
Eastern Europe	30%	31%	32%	32%	28%	30%
East Asia	10%	9%	9%	7%	10%	10%
ECOG PS*						
0	28%	29%	30%	32%	25%	25%
1	68%	68%	67%	68%	69%	69%
2	4%	3%	3%	0	6%	6%
Smoking history†						
Current or former	85%	83%	85%	82%	85%	84%
Never	15%	17%	15%	18%	14%	16%

Percentages rounded to nearest integer; totals may not equal 100%

*Two patients had ECOG PS defined at the first follow up visit in the TTFields + ICI group. †Missing data from 1 patient in the TTFields + DTX group.

DTX, docetaxel; ECOG PS, Eastern Cooperative Oncology Group performance status; ICI, immune checkpoint inhibitor; SOC, standard of care; TTFields, Tumor Treating Fields.

Baseline Disease Characteristics

	TTFields + SOC (n = 137)	SOC (n = 139)	TTFields + ICI (n = 66)	ICI (n = 68)	TTFields + DTX (n = 71)	DTX (n = 71)
Histology						
Non-squamous/squamous	58%/42%	55%/45%	56%/44%	54%/46%	59%/41%	56%/44%
PD-L1						
<1%	17%	17%	18%	24%	16%	10%
1–49%	27%	29%	26%	27%	28%	31%
≥50%	7%	13%	8%	12%	7%	14%
Unknown*	49%	42%	49%	38%	49%	45%
Prior lines of systemic therapy**						
1	89%	89%	97%	94%	82%	85%
2+	11%	10%	3%	4%	18%	15%
Prior ICI	31%	31%	2%	3%	58%	58%
Best response to any prior therapy						
Complete response	6%	4%	6%	4%	6%	3%
Partial response	23%	26%	29%	19%	18%	32%
Stable disease	34%	32%	38%	31%	31%	32%
Progressive disease	21%	26%	15%	29%	27%	23%
Unknown	15%	13%	12%	16%	18%	10%
Liver metastasis†	15%	16%	14%	12%	17%	20%
CNS metastasis‡	0	1%	0	0	0	3%

Percentages rounded to nearest integer; totals may not equal 100%.

*PD-L1 status reporting was optional and was available for 83% of patients in the United States; **Missing data for 1 patient in the ICI group. †One patient had liver and CNS metastasis. ‡Patients with CNS metastases were excluded under the original study design; later amended to allow stable CNS metastases.

CNS, central nervous system; DTX, docetaxel; ICI, immune checkpoint inhibitor; PD-L1, Programmed Cell Death Ligand 1; SOC, standard of care; TTFields, Tumor Treating Fields.

TTFields Therapy in the Clinic and Daily Life

- The patient is prescribed TTFields therapy by the treating oncologist
- Novocure team generates a recommended personalized array layout based on disease burden and torso size to maximize field intensity at the tumor location
- TTFields system delivered directly to patient's home by device support technician
- Training and 24/7 telephone support for system provided to patient and caregivers by device support technician
- Arrays changed at home by patient/caregiver every 3 to 4 days
- Treating oncologist continues to provide all standard medical therapy/patient care during TTFields therapy

TTFields Therapy in Daily Life



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TTFields, Tumor Treating Fields.

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23

