Novocure Q3 2023 Earnings

Thursday, October 26, 2023

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forward-looking statements

In addition to historical facts or statements of current condition, this presentation 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 23, 2023 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.

The statements contained in this presentation are made as at the date of this presentation, unless some other time is specified in relation to them, and service of this presentation shall not give rise to any implication that there has been no change in the facts set out in this presentation since such date. Nothing contained in this presentation shall be deemed to be a forecast, projection or estimate of the future financial performance of Novocure, except where expressly stated.

As of the date of this presentation, Optune is FDA-approved for the treatment of adults with supratentorial glioblastoma, or GBM, and for the treatment of adults with malignant pleural mesothelioma (MPM) and its approval for other indications is not certain. Novocure can provide no assurances regarding market acceptance of Optune or Optune Lua or their successful commercialization, and can provide no assurances regarding the company's results of operations or financial condition in the future. This presentation is for informational purposes only and may not be relied upon in connection with the purchase or sale of any security.

a comprehensive strategy for long-term growth

drive awareness and commercial adoption
in approved indications

advance clinical trials
to reach new patient populations

deliver product innovation
to increase dose and duration of therapy

Built upon a foundation of financial strength and a robust intellectual property portfolio

enrollment complete and pivotal data anticipated in multiple phase 3 trials by year-end 2024

LUNAR Lung Cancer	METIS Brain Metastasis	PANOVA-3 Pancreatic Cancer
TRIAL COMPLETE MET PRIMARY ENDPOINT	**ENROLLMENT COMPLETE**	**ENROLLMENT COMPLETE**
• Patients treated with TTFields + standard therapies saw a 3.3-month extension in median overall survival (HR=0.74) versus those treated with standard therapies alone • Patients treated with TTFields + ICI saw a 7.7-month increase in median overall survival (HR=0.63) versus those treated with ICI alone	• Evaluating TTFields after stereotactic radiosurgery • 270 patients with minimum 12-month follow-up • Primary endpoint: time to intracranial progression (HR ≤ 0.57)	• Evaluating TTFields with nab-paclitaxel + gemcitabine • 556 patients enrolled with minimum 18-month follow-up • Primary endpoint: overall survival (HR ≤ 0.75)
PMA SUBMISSION ANTICIPATED H2 2023	**TOP-LINE DATA ANTICIPATED Q1 2024**	**TOP-LINE DATA ANTICIPATED H2 2024**

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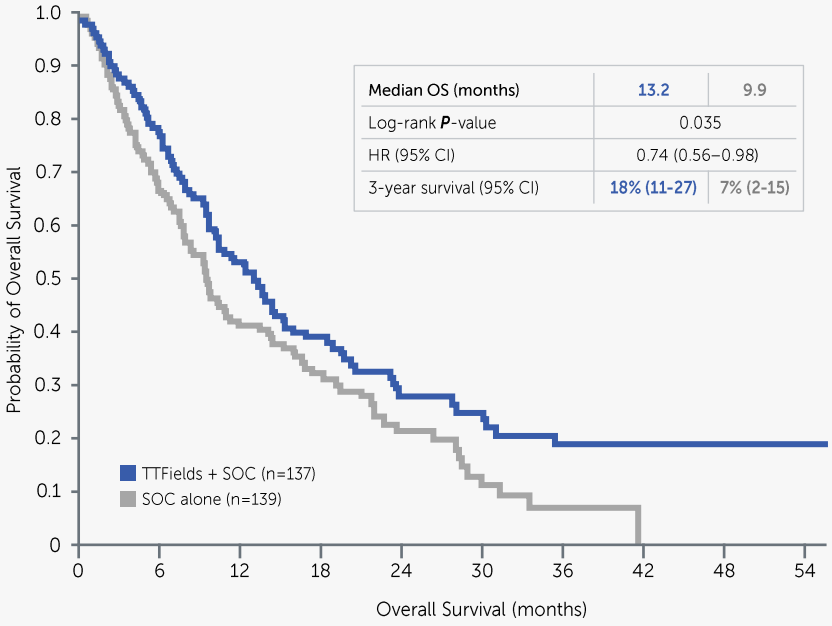
HR, hazard ratio; ICI, immune checkpoint inhibitor; TTFields, Tumor Treating Fields.

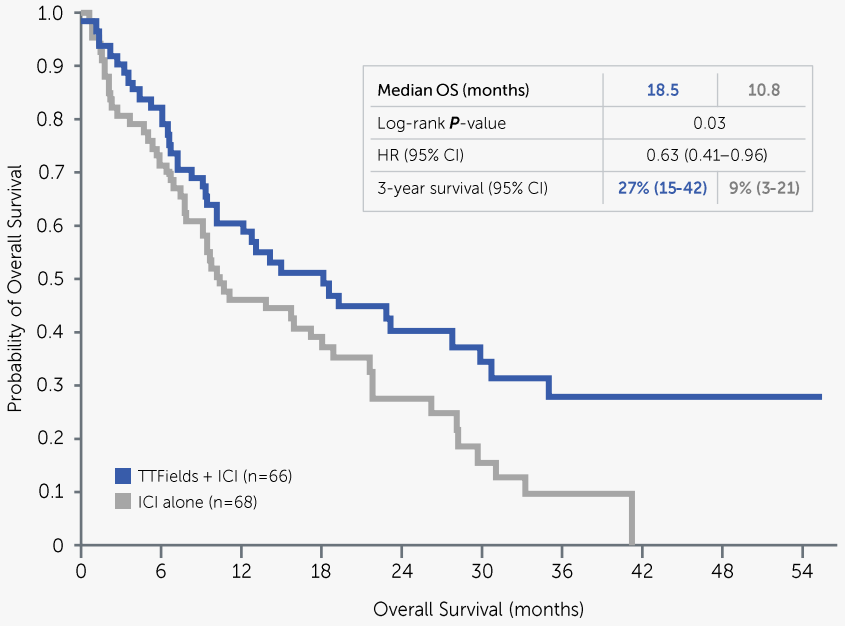
phase 3 LUNAR trial met primary overall survival endpoint

Overall survival (ITT population)



Median OS (months)	13.2	9.9
Log-rank *P*-value	0.035	
HR (95% CI)	0.74 (0.56–0.98)	
3-year survival (95% CI)	18% (11-27)	7% (2-15)

Overall survival (ICI-treated patients)

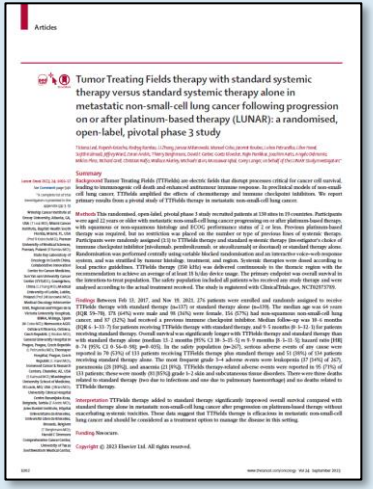


Median OS (months)	18.5	10.8
Log-rank *P*-value	0.03	
HR (95% CI)	0.63 (0.41–0.96)	
3-year survival (95% CI)	27% (15-42)	9% (3-21)

CI, confidence interval; HR, hazard ratio; ICI, immune checkpoint inhibitor; ITT, intent-to-treat; OS, overall survival; SOC, standard of care; TTFields, Tumor Treating Fields.

growing foundation of pre-clinical and clinical research supporting the use of TTFields

CLINICAL JOURNAL PUBLICATIONS



Articles

Tumor Treating Fields therapy with standard systemic therapy versus standard systemic therapy alone in metastatic non-small-cell lung cancer following progression on or after platinum-based therapy (LUNAR): a randomised, open-label, pivotal phase 3 study

Summary

Background Tumour Treating Fields (TTFields) are electric fields that disrupt processes critical for cancer cell survival, leading to immunogenic cell death and enhanced antitumour immune response. In preclinical models of non-small-cell lung cancer, TTFields amplified the effects of chemotherapy and immune checkpoint inhibitors. We report primary results from a pivotal study of TTFields therapy in metastatic non-small-cell lung cancer.

Methods This randomised, open-label, pivotal phase 3 study recruited patients at 130 sites in 19 countries. Participants were aged ≥22 years or older with metastatic non-small-cell lung cancer progressing on or after platinum-based therapy, with squamous or non-squamous histology and ECOG performance status of 2 or less. Previous platinum-based therapy was required, but no restriction was placed on the number or type of previous lines of systemic therapy. Participants were randomly assigned (1:1) to TTFields therapy and standard systemic therapy (investigator's choice of immune checkpoint inhibitor [nivolumab, pembrolizumab, or atezolizumab] or docetaxel) or standard therapy alone. Randomisation was performed centrally using variable blocked randomisation and an interactive voice-web response system, stratified by ECOG performance status (0–1 vs 2), histology (squamous vs non-squamous), and region, with no local practice guidelines. TTFields therapy (200 kHz) was delivered continuously to the thoracic region with the recommendation to achieve an average of at least 18 h/day device usage. The primary endpoint was overall survival in the intention-to-treat population. The safety population included all patients who received any study therapy and were analysed according to the actual treatment received. The study is registered with ClinicalTrials.gov, NCT02973789.

Findings Between Feb 10, 2017, and Nov 19, 2021, 276 patients were enrolled and randomly assigned to receive TTFields therapy with standard therapy (n=137) or standard therapy alone (n=139). The median age was 64 years (IQR 59–70); 178 (64%) were male and 98 (36%) were female. 154 (57%) had non-squamous non-small-cell lung cancer, and 87 (32%) had received a previous immune checkpoint inhibitor. Median follow-up was 38·6 months (IQR 4·3–53·7) for patients receiving TTFields therapy with standard therapy, and 9·5 months (0·5–52·1) for patients receiving standard therapy. Overall survival was significantly longer with TTFields therapy and standard therapy than with standard therapy alone (median 13·2 months [95% CI 10·3–15·5] vs 9·9 months [8·3–11·5]; hazard ratio [HR] 0·74 [95% CI 0·56–0·98]; p=0·035). In the safety population (n=267), serious adverse events of any cause were reported in 79 (57%) of 135 patients receiving TTFields therapy plus standard therapy and 51 (38%) of 134 patients receiving standard therapy alone. The most frequent grade 3–4 adverse events were leukopenia (17 [16%] of 267), pneumonia (10 [9%]), and anaemia (11 [8%]). TTFields therapy-related adverse events were reported in 95 (71%) of 133 patients; these were mostly (91 [83%]) grade 1–2 skin and subcutaneous tissue disorders. There were three deaths related to standard therapy (two due to infections and one due to pulmonary haemorrhage) and no deaths related to TTFields therapy.

Interpretation TTFields therapy added to standard therapy significantly improved overall survival compared with standard therapy alone in metastatic non-small-cell lung cancer after progression on platinum-based therapy without exacerbating systemic toxicities. These data suggest that TTFields therapy is efficacious in metastatic non-small-cell lung cancer and should be considered as a treatment option to manage the disease in this setting.

Funding Novocure.

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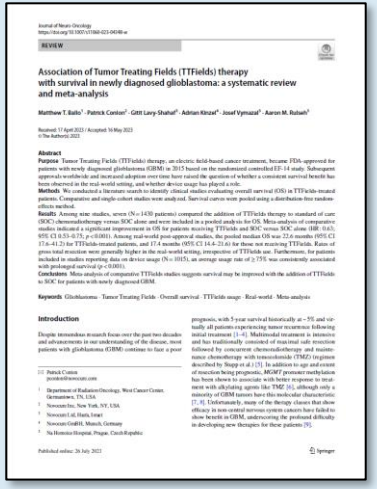

Journal of Neuro-Oncology

REVIEW

Association of Tumor Treating Fields (TTFields) therapy with survival in newly diagnosed glioblastoma: a systematic review and meta-analysis

Matthew T. Ballo[1] · Patrick Conlon[2] · Gitit Lavy-Shahaf[3] · Adrian Kinzel[4] · Josef Vymazal[5] · Aaron M. Rulseh[5]

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Abstract

Purpose Tumor Treating Fields (TTFields) therapy, an electric field-based cancer treatment, became FDA-approved for patients with newly diagnosed glioblastoma (GBM) in 2015 based on the randomized controlled EF-14 study. Subsequent approvals worldwide and increased adoption over time have raised the question of whether a consistent survival benefit has been observed in the real-world setting, and whether device usage has played a role.

Methods We conducted a literature search to identify clinical studies evaluating overall survival (OS) in TTFields-treated patients. Comparative and single-cohort studies were analyzed. Survival curves were pooled using a distribution-free random-effects method.

Results Among nine studies, seven (N = 1430 patients) compared the addition of TTFields therapy to standard of care (SOC) chemoradiotherapy versus SOC alone and were included in a pooled analysis for OS. Meta-analysis of comparative studies indicated a significant improvement in OS for patients receiving TTFields and SOC versus SOC alone (HR: 0.63, 95% CI: 0.53–0.75, p < 0.001). Among real-world post-approval studies, the pooled median OS was 22.6 months (95% CI: 17.6–41.2) for TTFields-treated patients, and 17.4 months (95% CI: 14.4–21.6) for those not receiving TTFields. Rates of gross-total resection were generally higher in the real-world setting, irrespective of TTFields use. Furthermore, for patients included in studies reporting data on device usage (N = 1015), an average usage rate of ≥75% was consistently associated with prolonged survival (p < 0.001).

Conclusions Meta-analysis of comparative TTFields studies suggests survival may be improved with the addition of TTFields to SOC for patients with newly diagnosed GBM.

Keywords Glioblastoma · Tumor Treating Fields · Overall survival · TTFields usage · Real-world · Meta-analysis

Introduction

Despite tremendous research focus over the past two decades and advancements in our understanding of the disease, most patients with glioblastoma (GBM) continue to face a poor prognosis, with 5-year survival historically at ~ 5% and virtually all patients experiencing tumor recurrence following initial treatment [1–4]. Multimodal treatment is intensive and has traditionally consisted of maximal safe resection followed by concurrent chemoradiotherapy and maintenance chemotherapy with temozolomide (TMZ) (regimen described by Stupp et al.) [5]. In addition to age and extent of resection being prognostic, *MGMT* promoter methylation has been shown to associate with better response to treatment with alkylating agents like TMZ [6], although only a minority of GBM tumors have this molecular characteristic [7, 8]. Unfortunately, many of the therapy classes that show efficacy in non-central nervous system cancers have failed to show benefit in GBM, underscoring the profound difficulty in developing new therapies for these patients [9].

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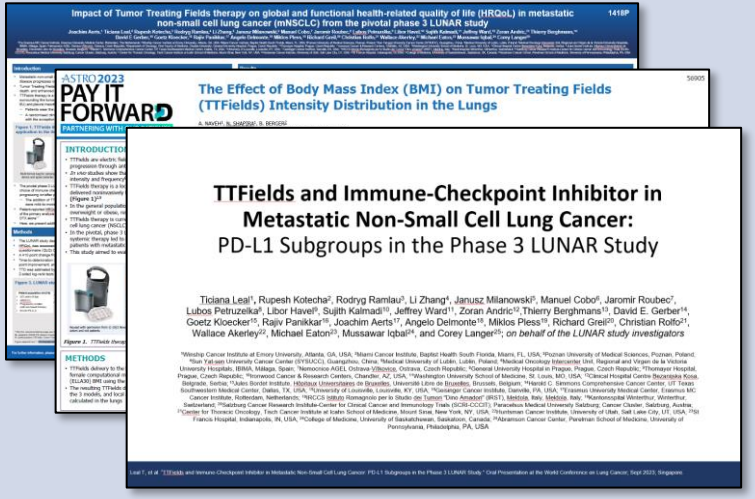
Springer

MEDICAL CONGRESS PRESENTATIONS



Impact of Tumor Treating Fields therapy on global and functional health-related quality of life (HRQoL) in metastatic non-small cell lung cancer (mNSCLC) from the pivotal phase 3 LUNAR study

1418P

ASTRO 2023 PAY IT FORWARD

The Effect of Body Mass Index (BMI) on Tumor Treating Fields (TTFields) Intensity Distribution in the Lungs

56905

TTFields and Immune-Checkpoint Inhibitor in Metastatic Non-Small Cell Lung Cancer:
PD-L1 Subgroups in the Phase 3 LUNAR Study

Ticiana Leal[1], Rupesh Kotecha[2], Rodryg Ramlau[3], Li Zhang[4], Janusz Milanowski[5], Manuel Cobo[6], Jaromir Roubec[7], Lubos Petruzelka[8], Libor Havel[9], Sujith Kalmadi[10], Jeffrey Ward[11], Zoran Andric[12], Thierry Berghmans[13], David E. Gerber[14], Goetz Kloecker[15], Rajiv Pankkar[16], Joachim Aerts[17], Angelo Delmonte[18], Miklos Pless[19], Richard Greil[20], Christian Rolfo[21], Wallace Akerley[22], Michael Eaton[23], Mussawar Iqbal[24], and Corey Langer[25]; *on behalf of the LUNAR study investigators*

TTFields, Tumor Treating Fields.

ongoing commercial pathway to treat NSCLC patients

CLINICAL DATA

- ✓ **Announced topline results**
- ✓ **Presented full dataset**
- ✓ **Submitted full dataset for publication**
- ✓ **Ongoing data generation & scientific publications**

REGULATORY PATHWAY

- ✓ **Initiate pre-PMA discussions with FDA**
- ✓ **Submit CE Mark application**
- Submit PMA application
- Pursue regulatory approvals in additional jurisdictions

COMMERCIAL LAUNCH

- Activate physician and patient education programs
- Treat on-protocol patients in U.S., Germany
- Establish commercial & national reimbursement

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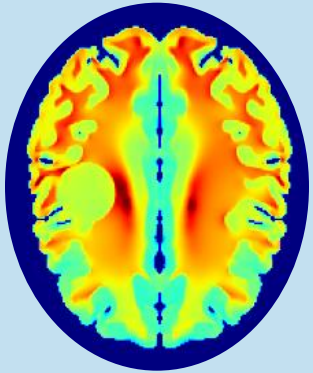
FDA, U.S. Food and Drug Administration; NSCLC, non-small cell lung cancer; PMA, Premarket Approval

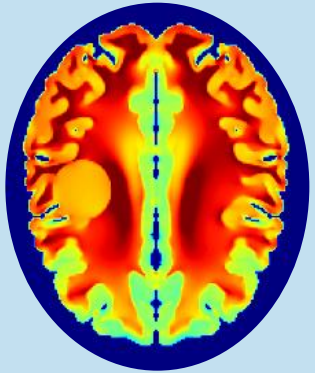
new lighter, thinner arrays deliver greater intensity

EXISTING ARRAYS
AP channel, 1,364 mAmps



VS.

NEW ARRAYS
AP channel, 1,685 mAmps



NEW ARRAYS NOW LAUNCHED IN GERMANY

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Array performance data obtained from patients utilizing the new array as part of Novocure's limited market release, initiated in Q4 2022.

q3 2023 selected financial highlights

U.S. DOLLARS IN THOUSANDS	Q3 2023	Q3 2022	% CHANGE
Net revenues	$ 127,321	$ 130,988	-3%
Cost of revenues	32,092	29,749	8%
Gross profit	95,229	101,249	-6%
Research, development and clinical trials	53,623	51,956	3%
Sales and marketing	57,964	41,395	40%
General and administrative	41,887	32,509	29%
Total operating costs and expenses	153,474	125,860	22%
Operating income (loss)	(58,245)	(24,611)	137%
Financial income (expenses), net	10,023	1,194	739%
Income (loss) before income taxes	(48,222)	(23,417)	106%
Income taxes	1,263	3,159	-60%
Net income (loss)	$ (49,485)	$ (26,576)	86%
Cash, cash equivalents and short-term investments	$ 921,248	$ 970,320	-5%

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Optune Lua® and Optune® indications for use and important safety information

INDICATIONS

- Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).
- Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.
- For the treatment of recurrent GBM, Optune is indicated following histologically-or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.
- Optune Lua is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

CONTRAINDICATIONS

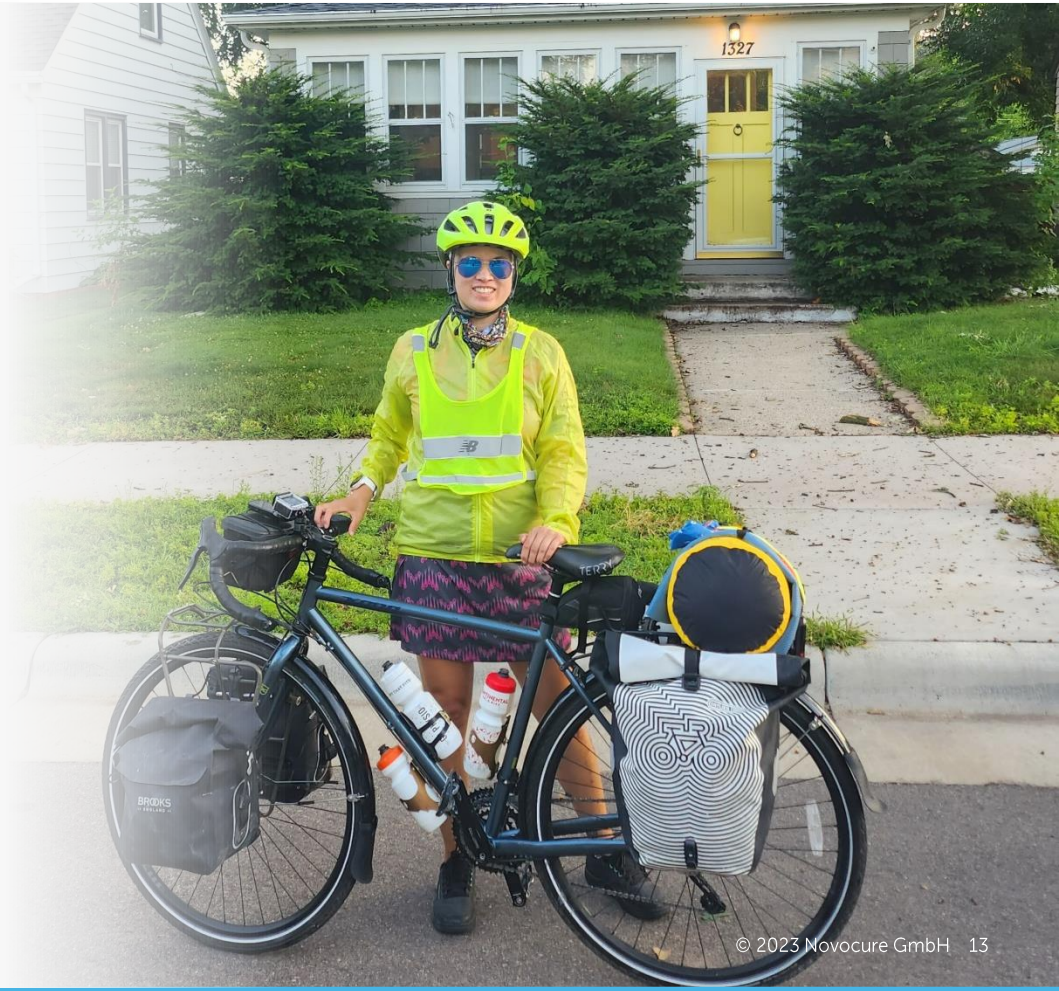
- Do not use Optune in patients with GBM with an implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective. Do not use Optune Lua in patients with MPM with implantable electronic medical devices, such as pacemakers or implantable automatic defibrillators, etc.
- Use of Optune for GBM or Optune Lua for MPM together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.
- Do not use Optune for GBM or the Optune Lua for MPM in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune or Optune Lua may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

Optune Lua® and Optune® indications for use and important safety information

WARNINGS AND PRECAUTIONS

- Optune and Optune Lua can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.
- The most common (≥10%) adverse events involving Optune in combination with chemotherapy in patients with GBM were thrombocytopenia, nausea, constipation, vomiting, fatigue, convulsions, and depression.
- The most common (≥10%) adverse events related to Optune treatment alone in patients with GBM were medical device site reaction and headache. Other less common adverse reactions were malaise, muscle twitching, and falls related to carrying the device.
- The most common (≥10%) adverse events involving Optune Lua in combination with chemotherapy in patients with MPM were anemia, constipation, nausea, asthenia, chest pain, fatigue, device skin reaction, pruritus, and cough.
- Other potential adverse effects associated with the use of Optune Lua include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical site reaction and skin breakdown/skin ulcer.
- If the patient has an underlying serious skin condition on the treated area, evaluate whether this may prevent or temporarily interfere with Optune or Optune Lua treatment.
- Do not prescribe Optune or Optune Lua for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune and Optune Lua in these populations have not been established.
- Please go to Optune.com to see the Optune Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.
- Please go to OptuneLua.com to see the Optune Lua IFU for complete information regarding the device's indications, contraindications, warnings, and precautions.

appendix



adjusted EBITDA reconciliation

Adjusted EBITDA is a non-GAAP measurement of earnings before interest, taxes, depreciation, amortization and share-based compensation. We believe Adjusted EBITDA is useful to investors in evaluating our operating performance because it helps investors compare the results of our operations from period to period by removing the impact of earnings attributable to our capital structure, tax rate and material non-cash items, specifically share-based compensation.

U.S. DOLLARS IN THOUSANDS	Three months ended September 30,		Nine months ended September 30,	
Adjusted EBITDA reconciliation	**2023**	**2022**	**2023**	**2022**
Net income (loss)	$ (49,485)	$ (26,576)	$ (159,964)	$ (55,231)
Add: income tax	$ 1,263	$ 3,159	$ 6,758	$ 5,943
Add: financial expenses (income), net	$ (10,023)	$ (1,194)	$ (27,948)	$ 2,743
Add: depreciation and amortization	$ 2,803	$ 2,659	$ 8,246	$ 7,924
EBITDA	$ (55,442)	$ (21,952)	$ (172,908)	$ (38,621)
Add: share-based compensation	$ 26,346	$ 26,305	$ 98,170	$ 77,173
Adjusted EBITDA	$ (29,096)	$ 4,353	$ (74,738)	$ 38,552

