

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

Date of Report (Date of earliest event reported): March 29, 2016

NovoCure Limited

(Exact name of registrant as specified in its charter)

Jersey
(State or Other Jurisdiction of Incorporation or
Organization)

001-37565
(Commission File Number)

98-1057807
(IRS Employer
Identification No.)

Le Masurier House
La Rue Le Masurier
St. Helier, Jersey JE2 4YE
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **+44 (0)15 3475 6700**

N/A

(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. to Form 8-K):

- 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))
-

Item 7.01 Regulation FD Disclosure.

On March 29, 2016, NovoCure Limited (the “Company”) posted on its web site (www.novocure.com) the slides containing the information attached to this Current Report on Form 8-K as Exhibit 99.1 (the “Slides”). The Company expects to use the Slides, in whole or in part, in connection with presentations to investors, analysts and others. By filing this Current Report on Form 8-K and furnishing the information contained herein, the Company makes no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD. The information contained in the Slides is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission (“SEC”) filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

The information in Item 7.01 (including any exhibits furnished under Item 9.01 relating thereto) in this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (as amended, the “Exchange Act”) or otherwise subject to the liabilities of that Section, and shall not be or be deemed to be incorporated by reference in any Company filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Relations presentation (furnished only)

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: March 29, 2016

By: /s/ Wilhelmus Groenhuysen
Name: Wilhelmus Groenhuysen
Title: Chief Financial Officer

Index to Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Relations presentation (furnished only)

Novocure (NVCR) Overview

updated March 1, 2016



Notice

This presentation contains certain forward-looking statements with respect to the business of Novocure and certain of its plans and objectives, including with respect to the development and commercialization of its lead product candidate, Optune, for a number of oncology indications. These forward-looking statements can be identified in this presentation by the fact that they do not relate only to historical or current facts. Forward-looking statements often use words "expect", "intend", "anticipate", "plan", "may", "should", "would", "could" or other words of similar meaning. These statements are based on assumptions and assessments made by Novocure in light of industry experience and perception of historical trends, current conditions, expected future developments and other appropriate factors. By their nature, forward-looking statements involve risk and uncertainty, and the factors described in the context of such forward-looking statements in this presentation could cause actual results and developments to differ materially from those expressed in or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this presentation. Novocure assumes no obligation to update or correct the information contained in this presentation, whether as a result of new information, future events or otherwise, except to the extent legally required.

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 only FDA-approved for glioblastoma, or GBM, and its approval for other indications is not certain. Novocure can provide no assurances regarding market acceptance of Optune or its 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.

Tumor Treating Fields

Novel, anti-mitotic solid tumor cancer therapy

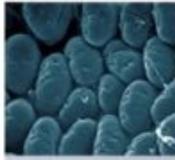
Used as monotherapies or in combination to treat solid tumors for over 100 years

Surgery	Radiation	Pharmacological Treatments	Tumor Treating Fields
<ul style="list-style-type: none">• Most frequently employed therapy• Reduces size of a tumor prior to initiation of additional therapies	<ul style="list-style-type: none">• Kills cells when delivered at high doses• Injures healthy tissues with numerous potential toxic side effects	<ul style="list-style-type: none">• Includes chemotherapy, targeted therapies and immuno-oncology• Limited by side effects• Resistance often develops over time	<ul style="list-style-type: none">• Low-intensity, alternating electric fields• Mild side effect profile• No known resistance or cumulative toxicity• Can be used in combination with other treatment modalities• Additive or synergistic with radiation, chemotherapy, and immunotherapy

Frequency Tuned to Specific Cell Types

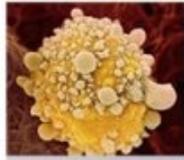
Treatment does not harm normal cell growth

Effects on Cells Are Frequency Specific and Inversely Related to Cell Size



Normal Intestine

~ 50 kHz



Pancreatic Cancer

150 kHz



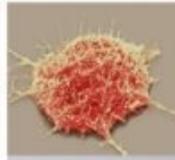
NSCLC

150 kHz



Ovarian Cancer

200 kHz



GBM

200 kHz

Non-invasive, Portable Delivery

- Battery or wall-powered electric field generator
- Single-use transducer arrays replaced 2-3 times a week



Home Use, Quality of Life Maintained

- Should be used at least 18 hours a day
- Mild side-effect profile with no known systemic toxicity



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Second Generation Optune System

- Half the size and weight of the first generation – only 2.7 pounds
- CE marked and available in Europe
- PMA supplement filed with FDA in December 2015 (180-day review)



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Extensive Preclinical Research

- 15+ years of research and multiple peer-reviewed publications
- Deep understanding of the underlying mechanism



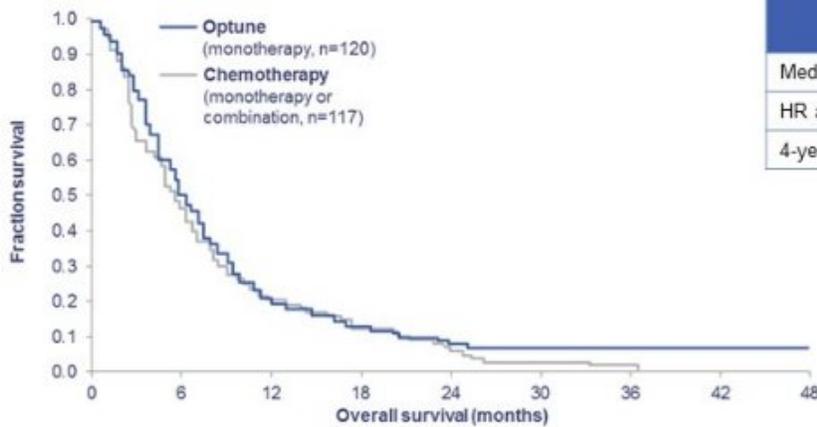
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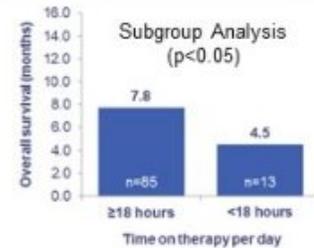
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Initial FDA Approval in 2011

Monotherapy treatment for recurrent GBM



	Optune (n=120)	Chemotherapy (n=117)
Median OS, months	6.6	6.0
HR and p value	HR=0.86, p=0.27	
4-year survival	8%	0%



FDA Approved Summary of Safety and Effectiveness Data

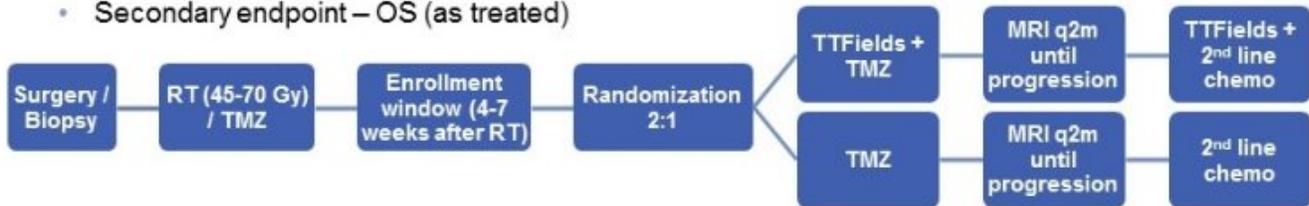
"...NovoTTF-100A treatment exhibits minimal toxicity, clinically comparable primary and secondary effectiveness, and better quality of life compared to the chemotherapies used in the control arm of the study."

EF-14 Phase 3 Trial Initiated in 2009

Combination Therapy for Newly Diagnosed GBM

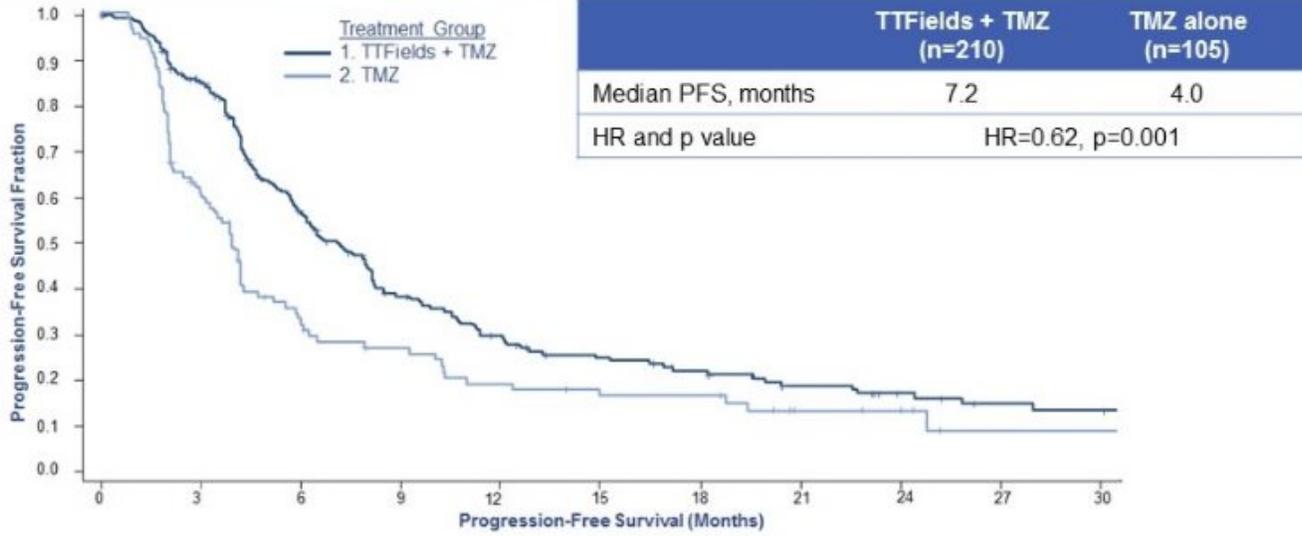
A prospective, multicenter trial of TTFields together with temozolomide compared to temozolomide alone in patients with newly diagnosed GBM

- 80 centers; 695 newly diagnosed GBM patients randomized 2:1 (TTFields plus TMZ vs TMZ alone)
- Treated until second progression or 24 months
- Pre-specified interim analysis 18 months after enrollment of the 315th patient
- Endpoints:
 - Primary endpoint – PFS (intent to treat)
 - Secondary endpoint – OS (as treated)



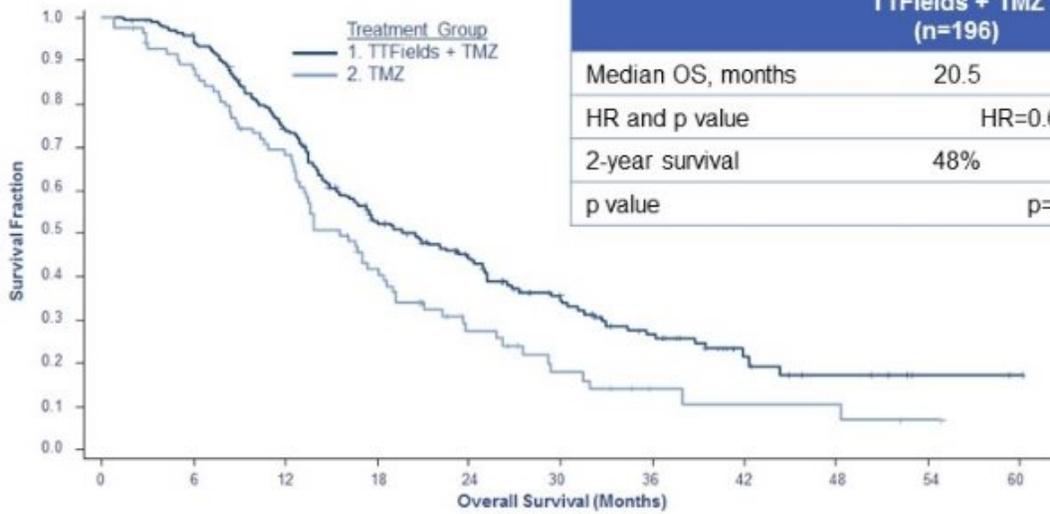
EF-14 Progression Free Survival

Intent-to-treat Population



EF-14 Overall Survival

As-treated Population



	TTFields + TMZ (n=196)	TMZ alone (n=84)
Median OS, months	20.5	15.6
HR and p value	HR=0.66, p=0.004	
2-year survival	48%	32%
p value	p=0.0058	

FDA Approval on October 5, 2015

Combination treatment for newly diagnosed GBM

Opdivo is FDA approved for newly diagnosed GBM

i am proof
of extended survival in newly
diagnosed GBM**

- OS and PFS Results**
See the data in newly diagnosed GBM
- New publication in JAMA**
Access the abstract on PubMed®
- National Broadcast**
Hear from leading experts about
Opdivo + TMZ in newly diagnosed GBM

Actor portrayed

OPT-403.1

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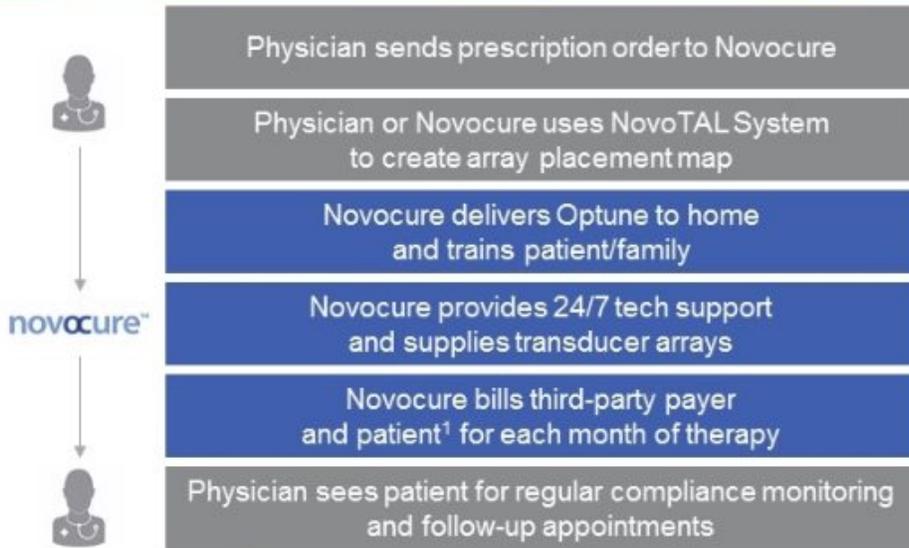
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Established Commercial Organization

- Recurrent GBM patients primarily treated in academic hospitals; early commercial efforts focused on neuro oncologists at academic centers
- Estimate 60% of newly diagnosed GBM treated in community setting
- U.S. sales team expanded in 2015 to reach community-based practices and radiation and medical oncologists
- European commercial launch in 2014, initially focusing on Germany

U.S. Commercial Statistics	2014	2015	% growth
Sales Colleagues	14	31	121%
Certified Centers	154	244	58%
Prescriptions	669	1,607	148%

Direct to Patient Distribution Model



Physician economics

- Physician can bill for incremental services
- Physician does not have to buy and hold inventory
- Physician does not take on reimbursement risk for Optune therapy

¹ Subject to patient assistance programs

Established Reimbursement History

- Nine U.S. payers have positive coverage covering >107 million people



- Have secured coverage for approximately 98% of U.S. patients with commercial and privately-administered government plans
- Appealing Medicare fee-for-service denials (20-25% of US patients)
- Pursuing defined reimbursement in Germany, Switzerland and Japan

Novocure's Key Operating Statistics

Prescriptions

Filled
Prescriptions

Active
Patients

Gross Billings

Cash
Payments per
Month

- Prescriptions - leading indicator of demand (counted only once per patient)
- Conversion to new patients driven by fill rate and time to fill
- 73% fill rate in 2015
- Relationship between filled prescriptions and active patients driven by duration of therapy
- Treatment duration should increase as percentage of newly diagnosed patients increases
 - 9.0 months for newly diagnosed in EF-14 trial and 4.1 months for recurrent in PRiDe registry
 - ~35% of prescriptions were newly diagnosed in Q4 2015
- Monthly charge of \$21,000 in the United States and €21,000 in the European Union
- Cash payments of ~\$14,000 per charged month in the United States^{1,2}
- 2015 average time to collect between four and five months²

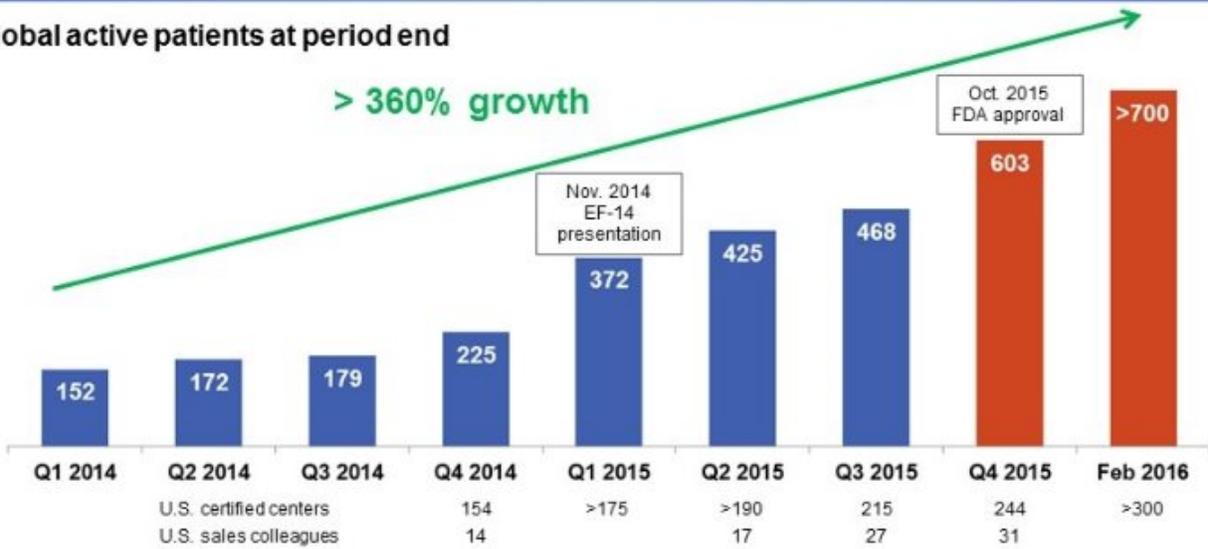
¹ Difference between billed and paid amounts consists of indirect taxes, disputed underpayments, patient financial assistance, charitable care and discounts

² Metrics do not include patients covered by the Medicare fee-for-service program

Significant QoQ Active Patient Growth

Active patients drive revenues

Global active patients at period end



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Selected Financial Data

- Per U.S. GAAP, revenue is recognized when cash is collected
- Cost of revenues reflects costs incurred for patients on Optune in the period

U.S. dollars in thousands	2015	2014	% Growth
Net revenues	33,087	15,490	114%
Cost of revenues	<u>20,610</u>	<u>10,036</u>	105%
Gross profit	<u>12,477</u>	<u>5,454</u>	129%
Research, development and clinical trials	43,748	40,381	8%
Sales and marketing	38,861	21,177	84%
General and administrative	<u>33,864</u>	<u>24,052</u>	41%
Total operating costs and expenses	<u>116,473</u>	<u>85,610</u>	36%
Operating loss	(103,996)	(80,156)	30%
Cash, cash equivalents and short-term investments	269,424	102,612	163%

Total Addressable GBM Market >\$2.5B

United States

12,500 GBM incidence
9,300 medically eligible
for treatment
\$1.2 Billion TAM

Target EU Markets

13,500 GBM incidence
10,000 medically eligible
for treatment
\$1.3 Billion TAM

Japan

1,500 GBM incidence
1,100 medically eligible
for treatment
\$139 Million TAM

- Assumes net collections of 14,000 USD equivalent per month of therapy
- Assumes average treatment duration of 9 months (median treatment duration in the EF-14 trial)
- Medically eligible populations are management estimates

Broad Applicability to Solid Tumors



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Multiple Ongoing Clinical Trials



Phase 2 EF-15 Trial

Non-small cell lung cancer

- Open label study (n=41) of TTFields at 150 kHz in combination with pemetrexed for advanced non-small cell lung cancer
- Trial results published in *Lung Cancer*¹ in July 2013

Efficacy endpoints	TTFields with pemetrexed	Pemetrexed-alone historical control ²
Median in-field PFS	6.5 months	n/a
Median PFS	5 months	2.9 months
Median OS	13.8 months	8.3 months
One-year survival rate	57%	29.7%
Partial response rate	14.6%	9.1%

¹ Pless M, et al. A phase III trial of Tumor Treating Fields (TTFields) therapy in combination with pemetrexed for advanced non-small cell lung cancer. *Lung Cancer* (2013)
² Hanna N, Shepherd FA, Fossella FV, Pereira JR, De Marinis F, von Pawel J, et al. Randomized phase III trial of pemetrexed versus docetaxel in patients with non-small-cell lung cancer previously treated with chemotherapy. *J Clin Oncol* 2004;22(9):1589-97

Phase 2 PANOVA Trial

Pancreatic cancer

- Open label study (n=20) of TTFields at 150 kHz with gemcitabine for front-line therapy of advanced pancreatic adenocarcinoma
- Second cohort (n=20) of TTFields at 150 kHz with gemcitabine plus nab-paclitaxel for front-line therapy of advanced pancreatic adenocarcinoma
- First cohort results presented at ASCO GI in January 2016

Efficacy endpoints	TTFields with gemcitabine	Gemcitabine-alone historical control ¹
Median PFS	8.3 months	3.7 months
Median OS	14.9 months	6.7 months
One-year survival rate	55%	22%
Partial response rate	30%	7%

¹ Increased Survival in Pancreatic Cancer with nab-Paclitaxel plus Gemcitabine, *The New England Journal of Medicine*, October 2013, DOI: 10.1056/NEJMoa1304369

Anticipated 2016 Milestones

NCCN guidelines update

Increase positive coverage policies of Optune

Phase 2 pilot PANOVA trial 2nd cohort last patient in

Phase 3 pivotal METIS trial first patient in

Phase 3 pivotal LUNAR trial first patient in

FDA approval of second generation device

Newly diagnosed GBM approval in Japan

