## **novœure**®

# only the beginning





There's a particular energy at Novocure. It doesn't matter whether you're at our U.S. Operations Center in Portsmouth or at our Research and Development Center in Haifa, Israel, or meeting a colleague from the sales team at a meeting in Germany—you can feel it.

This energy originates, in part, from a collective drive toward innovation. From the first moment of Novocure's founding to the many significant milestones in the last 20 years, this energy has been the source of the big moments and the micro moments that comprise the whole.

This unifying factor possessed by Novocure colleagues across the globe comes from a joy in building. We create from nothing every day because we can see a vision for the future. We start from countless blank slates in unchartered territories, moving forward even when it feels impossible. After years of work to complete an initiative and in our day-to-day challenges to find solutions, we start over.

This spirit is the hallmark of our company—a dichotomy of making significant progress and starting over at the same time. Even after 20 years of innovation after innovation and milestone after milestone moving forward on our mission, it is only the beginning.

Please visit the online version of this annual report at 2019.novocure.com

## DEAR FELLOW SHAREHOLDERS,

#### 2019 was a transformative year.

We started Novocure with the novel insight that electric fields can be harnessed to disrupt cancer cell division selectively and cause cancer cell death. In the 20 years since, we have built an organization of more than 750 colleagues dedicated to delivering Tumor Treating Fields therapy to patients with glioblastoma (GBM) or mesothelioma and dedicated to advancing clinical research and product development programs intended to extend survivals in some of the most aggressive cancers. We made noteworthy advancements in 2019, and we are poised to continue building on this momentum in 2020 and beyond.

We believe we are in a virtuous cycle of execution and innovation supporting the future growth of our company. Tumor Treating Fields therapy is a foundational platform, enabling our efforts to make a difference in cancer. We are focused on growing our commercial business to bring Tumor Treating Fields therapy to as many patients who can benefit as possible. Commercial growth provides us the financial strength and flexibility to increase investments in clinical research and product development programs that will help more patients and propel further growth. We believe we are just beginning our journey.

### Commercial execution drove strengthening financial performance.

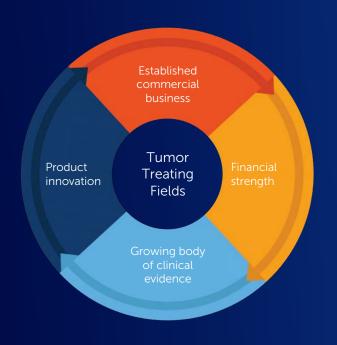
Our 2019 commercial performance reinforces our confidence in the long-term potential of Tumor Treating Fields therapy. In 2019, we received FDA approval via the Humanitarian Device Exemption (HDE) pathway for the treatment of adults with malignant pleural mesothelioma, or MPM, our first FDA-approved torso indication. Medicare established coverage of Optune for the treatment of adults with newly diagnosed GBM. Through our partnership with Zai Lab, we developed our foundation in Greater China. Notably, we accomplished these milestones while generating over \$350 million in annual net revenues and adding \$80 million in cash to our balance sheet.

With more than 14,000 GBM patients treated to date, we believe Optune has established its central role in the treatment of GBM. As proud as we are of our progress in treating GBM, we believe multiple levers remain to drive near-term growth. We remain focused on working with physicians to expand adoption in our current markets, on laying the groundwork for access in new markets, on extending the duration of therapy for patients and on improving reimbursement for Optune.

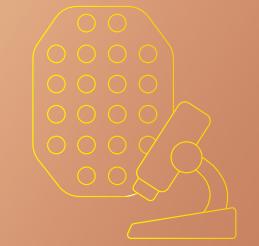


Bill Doyle, Executive Chairman

Asaf Danziger, CEO



striving to extend survival in some of the most aggressive forms of cancer



FDA-APPROVED **INDICATIONS** 

CASH ON HAND\*

AS OF DECEMBER 31, 2019

INDICATIONS IN LATE-STAGE PIPELINE ISSUED PATENTS AND PENDING

APPLICATIONS GLOBALLY

Beyond GBM, we launched our second commercial business in 2019 treating patients diagnosed with MPM. Our MPM launch was the first FDA-approved treatment for MPM in over 15 years, and our first approved torso indication. We believe this is an important harbinger of the promise of Tumor Treating Fields in many additional solid tumor indications.

Heading into 2020, our focus is unwavering on growing the awareness and acceptance of Tumor Treating Fields therapy in our approved indications and driving global adoption. With over \$320 million of cash on hand at year end, we believe we are well positioned to execute our strategic objectives. We will not be satisfied until all eligible cancer patients are offered an opportunity for long-term quality survival.

#### A growing body of preclinical and clinical evidence supports an advancing pipeline.

Tumor Treating Fields therapy selectively targets the electrical properties of proteins involved in cancer cell division with electric fields tuned to specific frequencies to disrupt mitosis.

Tumor Treating Fields therapy is backed by a growing body of preclinical and clinical evidence. We believe the evidence supports that Tumor Treating Fields' mechanism of action may be broadly applicable to solid tumor cancers. Our scientific research spans two decades and in all of our preclinical and clinical research to date, Tumor Treating Fields has demonstrated a consistent anti-mitotic effect. Additionally, research has shown that Tumor Treating Fields may have an additive or synergistic effect when combined

with certain other cancer therapies without evidence of any dose-limiting, cumulative toxicity. In 2019, there were more than 250 presentations on Tumor Treating Fields at key medical congresses, the majority by independent researchers, underlining the recognition Tumor Treating Fields therapy is gaining in the global oncology community.

We are executing our strategy to make Tumor Treating Fields therapy available in additional indications through phase 2 pilot trials and phase 3 pivotal trials and in current indications through phase 4 post-marketing studies based on a foundation of significant preclinical evidence.

In 2019, we initiated clinical trials studying Tumor Treating Fields in two additional cancers: the INNOVATE-3 trial in recurrent ovarian cancer and the EF-31 trial in gastric cancer. Now, we have four ongoing randomized, phase 3 pivotal trials in brain metastases, non-small cell lung cancer, pancreatic cancer and ovarian cancer, and two phase 2 pilot studies in liver cancer and gastric cancer; creating the potential for substantial market expansion over the next five years.

If approved, the indications in our late-stage pipeline will create a more than 20-fold increase in our addressable U.S. market, alone. We are optimistic about the role Tumor Treating Fields may play in oncology, and we are determined to provide our therapy to cancer patients with a variety of solid tumor types who may benefit from the treatment

#### Product innovation remains core to our long-term value creation strategy.

Beyond our ongoing preclinical and clinical research, we believe we have a considerable opportunity to improve the efficacy and usability of Optune through product innovation.

A key publication in the Red Journal in April 2019 detailed the dose-efficacy dependence of Tumor Treating Fields. The dose response of Tumor Treating Fields therapy is determined by total energy delivered. Total energy delivered is a function of time on therapy and electric field intensity.

The research published in the Red Journal was pivotal in guiding our product development programs. We are increasing investments in engineering efforts intended both to improve time on therapy and to maximize the energy delivered to patients' tumors. Specifically, our teams are working to design and develop improvements to our transducer arrays and to our transducer array layout mapping software intended to increase Tumor Treating Fields intensity and, as a result, survival.

We believe innovation has the potential to improve patient outcomes and to extend our intellectual property protection into the future as we invent enhancements to our products. Our commitment to innovation resulted in 33 new patent applications in 2019, alone. Supported by our financial strength, we remain committed to investing in clinical research and product development to extend survival in our current and future indications and to unlock future value for our patients, employees and shareholders.

#### Courage and focus to pioneer a new modality in cancer care.

Re-imagining the possible is the essential theme of Novocure's story.

We have a remarkable 20-year history of building Novocure from Professor Palti's vision into an established global oncology company. As proud as we are of the accomplishments of our first 20 years, the responsibility to treat more patients diagnosed with some of the most aggressive cancers remains before us. Our mission is grounded in this reality.

Each day, we see our patients for the people they are with families, friends, hopes and dreams. Each day, we see the physical and emotional pain cancer causes. Each day, we do not look away, rather we look forward to work to provide access to Tumor Treating Fields therapy to more patients in our approved indications, to complete clinical research in new indications, and to further improve the efficacy of Tumor Treating Fields therapy through product development.

Thank you for your continued support.

Ash Danzeyn Spel STagle

Asaf Danziger, CEO

**Executive Chairman** 

# 20 STORIES AND BUILDING



## the beginning

Professor Yoram Palti sets up a laboratory in his basement in Haifa, Israel, and founds Novocure in 2000.

More than 20 years ago, Novocure founder Professor Yoram Palti had a vision. His vision was grounded in belief—what he knew to be true about physics, biology and medicine, and what he knew to be possible. He unearthed his PhD thesis on the distribution of electric fields in nerve fibers from 40 years prior, and he sought to apply it to cancer.

"I was sort of the odd guy in the medical class that was also interested in physics rather than just biology and medicine," Yoram said of the breadth of his scientific interests and expertise.

With pencil and paper, Yoram began computing how to use electric fields to destroy cancer cells.

"I'm a believer in science and physics, as essential to the progress of medicine," he said. "I came to the conclusion that it's possible, and we set up a laboratory to try to prove it."

"If you just believe that something is, you know that it is working and you know all the scientific facts behind it, then you just know that you have to fight until you get it."

Professor Yoram Palti,Founder and Chief Technology Officer





# 'going in the right direction'

Novocure establishes its preclinical research center.

In his basement laboratory, Yoram and Novocure's first three employees captured a video of alternating electric fields killing cancer cells, adding to Yoram's confidence in what would eventually become Novocure's cancer therapy, Tumor Treating Fields. The success of this initial experiment and the receipt of Novocure's first investment allowed for the opening of a preclinical research center in Haifa, Israel, later in 2000.

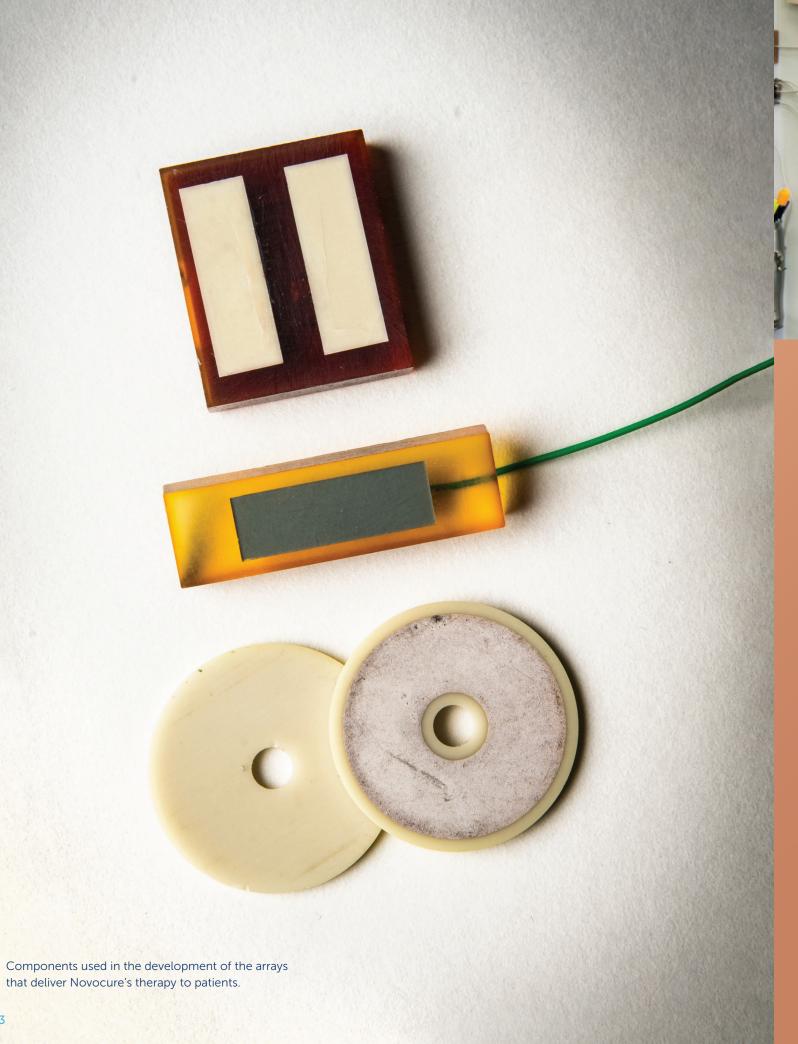
Rosa Shnaiderman, Novocure's first employee who still works at Novocure today as Head of the Biology Lab, recalled the move from Yoram's basement to a professional research facility.

"We had better equipment," she said. "We had a proper microscope. I started to see things better, and I started getting results on cells, which showed that it was going in the right direction."

"We had a proper microscope. I started to see things better, and I started getting results on cells, which showed that it was going in the right direction."

Rosa Shnaiderman,Head of Biology Lab







## moving from petri dish to patient

Novocure discovers a ceramic disc to insulate the electrodes that deliver the electric fields in 2003.

take the technology behind Tumor Treating Fields from the same high dielectric properties could be that adhere to the patient's body.

the team worked for about two years to find this

"It was a breakthrough," Yoram said. "We have done so for preclinical, clinical and commercial devices. We

Everything that I touch, I need to understand."

Yoram Wasserman,



## treating the first patient

Novocure's first clinical trial patient receives therapy.

In December 2003, Novocure began its first clinical trial of Tumor Treating Fields in multiple solid tumor types in Switzerland.

Novocure's Chief Executive Officer Asaf Danziger recalled how he and Eilon Kirson, Novocure's former Chief Science Officer and Head of Research and Development, traveled to Ormalingen, a village near Basel, to begin conducting the trial. Eilon booked a hotel nearby the patient's house for three weeks.

"I still remember the name of the patient," Asaf said.

The patient had cancer and underwent resective surgery. She had reached the dose limit of radiation and had a lesion remaining after surgery when she started Tumor Treating Fields therapy.

Asaf and Eilon brought Novocure's original Tumor Treating Fields delivery system to her house, set it up and showed her how to administer the therapy. They monitored her condition and progress daily. After a couple of weeks of treatment, the lesion began to shrink.

"You could see the lesion on the skin, getting smaller," Asa said. "It was very exciting, and it was a big achievement.

I was very proud."

"It was very exciting, and it was a big achievement. I was very proud."

Asaf Danziger,CEO

5

## confronting glioblastoma

A phase 2 pilot trial begins in one of the most aggressive forms of cancer.

Prof. Dr. Josef Vymazal remembers the day that he met the Novocure team. Eilon Kirson, Novocure's former Chief Science Officer and Head of Research and Development, visited Dr. Vymazal in 2004 at Na Homolce Hospital in Prague, where Dr. Vymazal worked as a clinical neurologist and radiologist, to discuss running a clinical trial on Tumor Treating Fields for glioblastoma (GBM) patients. Earlier in his career, including six years at the National Institute of Neurological Disorders and Stroke, National Institutes of Health, Dr. Vymazal saw many clinical trials in GBM fail.

"I was quite skeptical because nothing worked at that time," said Dr. Vymazal, Chairman of the Department of Radiology at Na Homolce Hospital in Prague, Czech Republic. "There were no breakthroughs."

Dr. Vymazal recalled Eilon's persistence and diligence when they met. He remembered the difficulty that came with not having anything additional to offer recurrent GBM patients once the standard of care treatments at the time failed. Josef decided to take a chance on Tumor Treating Fields because of the therapy's non-invasive nature and the in vitro research conducted to date.

The phase 2 pilot trial EF-07 included 10 patients with recurrent GBM, and tested the safety and efficacy of Tumor Treating Fields. Several months into the trial, Dr. Vymazal said, tumors of some of the patients began to shrink.

"We were surprised," he said. "More and more patients were surviving longer than the expected survival.

We started to believe in this technology."

Dr. Vymazal, the first external researcher to collaborate with Novocure on a clinical trial, went on to participate in both EF-11 and EF-14, a phase 3 pivotal trial in newly diagnosed GBM. He continues to conduct research on Tumor Treating Fields today. Dr. Vymazal said he feels lucky that he connected with Novocure more than 15 years ago.

"This is one of my life achievements," he said. "We are very proud that we are the first institution to hold a clinical trial with Tumor Treating Fields. I am very happy and very satisfied that I can share our experience with this technology all over the world. I'm extremely happy that I have helped some patients."



Daniel Torres,

a GBM clinical trial patient

## publication in a peer-reviewed journal

*Proceedings of the National Academy of Sciences (PNAS)* publishes preclinical and clinical research on Tumor Treating Fields in 2007.

After completing several years of preclinical and clinical research on Tumor Treating Fields, Novocure believed it needed to begin building a strong foundation within the scientific community to translate Tumor Treating Fields research into an approved and accepted therapy.

To the outside world, research on using alternating electric fields at specific frequencies to treat cancer was completely new. Novocure believed it had made great strides with its research internally and in its first clinical trials. To bring a new modality to market, the company would need external validation and acceptance.

In 2007, those initial years of persistence and diligence in the lab and in the clinic paid off. Novocure's clinical research was published for the first time in a top-tier, peer-reviewed scientific journal, *Proceedings of the National Academy of Sciences (PNAS)*. The publication included preclinical results of Tumor Treating Fields research in cell culture and animal models, as well as data from EF-07, the phase 2 pilot trial of Tumor Treating Fields in recurrent GBM. The published results were the first evidence of the safety

and efficacy of Tumor Treating Fields used to treat cancer patients. Prior to the publication in *PNAS*, *Cancer Research* published Novocure's earliest preclinical data in 2004.

"Before the Cancer Research and PNAS publications, there was limited knowledge available to the world or scientific community regarding the effects of alternating electric fields at these ranges and these intensities on biological systems," said Dr. Uri Weinberg, Novocure's Chief Science Officer. "Without such publications, we would not have had the ability to step forward to build a company, to build more advanced science, to take the basis of the science itself and translate it, develop it into a therapy—into something that works on humans."





7

## 'culmination of 10 years'

U.S. Food and Drug Administration approves Tumor Treating Fields in recurrent GBM.

On April 8, 2011, Novocure's Tumor Treating Fields delivery system, then referred to as the NovoTTF-100A System and now called Optune®, was approved for recurrent GBM patients in the U.S. This milestone marked Novocure's first commercial approval for a cancer indication. At the time, Novocure's Executive Chairman Bill Doyle described the approval as "the culmination of 10 years of research, development and clinical trials conducted by an exceptional team of scientists, engineers and clinicians, and built on the original insights of our founder and Chief Technology Officer Yoram Palti."

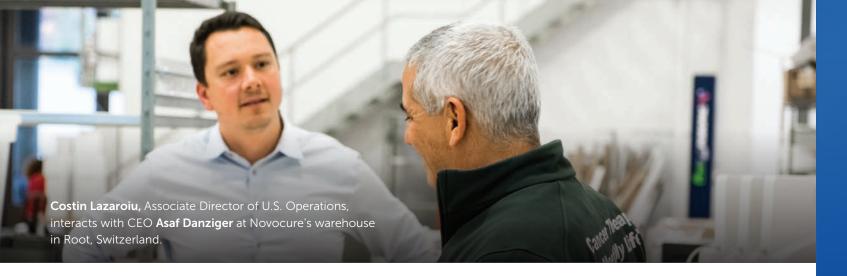
Alyssa Vinas joined Novocure five years before the FDA approval in recurrent GBM as a Device Support Specialist (DSS), providing technical support on Novocure's cancer treatment to clinical trial patients and their caregivers. Alyssa, who joined Novocure as a recent college graduate and built her career at the company, recalled thinking about the possibilities for Novocure if it received a first FDA approval.

"I remember feeling when we got that FDA approval, that moment of, 'We've made it,'" said Alyssa, now U.S. DSS Manager of New Indications. "We did something truly groundbreaking in oncology, in the world of medical devices and in brain cancer, specifically. I knew in my heart that it was only going to go up from there."

"We did something truly groundbreaking in oncology, in the world of medical devices and in brain cancer, specifically. I knew in my heart that it was only going to go up from there."

Alyssa Vinas,U.S. DSS Manager of New Indications

Uri Weinberg, Chief Science Officer



## 'everything flowed through Switzerland'

#### Novocure creates a supply chain to support a global oncology company.

In summer 2012, on the recommendation of a recruiter, Jens Hult met with Novocure's Chief Operations Officer Mike Ambrogi about an open position at Novocure's Root, Switzerland location. He could feel Mike's energy and passion for Novocure while they spoke about the role over breakfast, and Jens knew there had to be something special about Novocure.

"Mike told me, 'I want you to build the supply chain for a future successful global oncology company," Jens said. "I thought that was amazing. For me, within my profession, that was the ideal job."

Jens, now Vice President of the Global Supply Chain, joined the company in May 2013 and set out to accomplish the challenge, creating a three- to five-year strategic plan for the supply chain and building a warehouse and office in Root in his first months on the job.

By the end of 2012, Novocure had roughly 75 patients on therapy. With a lower volume of patients, most of Novocure's treatment systems were delivered to patients through local decentralized distribution channels relying heavily on the involvement of Novocure's field employees.

Over the course of 2013, the number of patients grew to 180. Novocure was preparing for a projected period of growth in the coming years, with the EF-14 phase 3 pivotal trial in newly diagnosed GBM nearing its interim analysis. Novocure needed a global supply chain and central warehouse designed to ensure that patients received the therapy on time and in a compliant manner, and to support anticipated commercial launches in new approved markets around the world.

To build the global supply chain, Jens and the team chose global partners from Europe, Israel, the U.S., Mexico and China.

"Everything flowed through the warehouse here in Switzerland," Jens said. "All of the equipment that ended up with a patient, be it in the U.S. or in Japan or anywhere in the world, was managed here in our Global Operations Center."



Jens Hult. Vice President Global Supply Chain

Jens said the strategic approach to building the supply chain and creation of a centralized warehouse in Switzerland was designed to ensure a secure supply of Novocure's therapy for patients globally. This involved building support systems for product planning, procurement, manufacturing, warehousing and distribution, and service.

"As you grow, one of the key pieces is that you trust your supply chain to deliver what you need when you need it," Jens said. "That sense of security is what we in the supply chain team strived to provide to the business since I started, and that's what we intend to continue to provide to the business as we grow. Our number one priority—today and in the future—is to ensure that we do not have patients going off treatment based on not having product."

## a trial stopped for early success

Novocure announces the EF-14 phase 3 pivotal clinical trial stopped for early success at interim analysis.

In 2014, Novocure faced unanswered questions from the scientific, medical and investment communities regarding the potential of its innovative therapy. That changed when Society for Neuro Oncology Annual Meeting. The EF-14 Bill Doyle, Novocure's Executive Chairman, learned that the EF-14 Independent Data Monitoring Committee recommended the trial be stopped for early success.

"If I had to put my finger on one really transformational moment for the company, I would pick the announcement that the EF-14 trial achieved statistical significance at the interim analysis and was terminated early for success," Bill said.

The EF-14 study was designed to test the safety and efficacy of adding Tumor Treating Fields to standard of care chemotherapy compared to standard of care chemotherapy alone in patients with newly diagnosed GBM. The trial achieved statistically significant and clinically meaningful results in overall survival and progression-free survival in a planned interim analysis of the first 315 patients enrolled.

Two months later, the trial data were presented by Dr. Roger Stupp as a late-breaking abstract at the 2014 results gave Novocure's leadership team confidence that FDA approval would be granted and that a business could be established helping patients with newly diagnosed GBM.

"We now had superiority data in one of the most difficult to treat cancer indications," Bill said. "This was the foundation that allowed us to move forward to build the Novocure we know today."



Michael Davies, a GBM patient

## 'building for this moment'

#### The initial presentation of EF-14 data also marked the beginning of a brand.

Pritesh Shah, Novocure's Chief Commercial Officer, remembers the conference call when he and the team learned in November 2014 that the EF-14 phase 3 pivotal trial in newly diagnosed GBM was positive and met the statistical threshold at the interim analysis. As he digested the news, he tried to stay present to allow the accomplishment to sink in, yet could not help but allow his mind to propel into the future.

"We had been building for this moment for such a long time," he said. "To be a part of it, to watch it unfold playby-play in front of my eyes...as much as I wanted the time to stand still, I knew that we had so much to do to get our therapy in the hands of providers so that it can help patients."

As Novocure worked toward obtaining FDA approval in newly diagnosed GBM, Pritesh and the commercial team kicked into gear to develop a brand for Novocure's therapy and to prepare for launch.

Novocure's device used to treat recurrent GBM was called the NovoTTF-100A System. When Pritesh joined in 2012 to lead Novocure's U.S. marketing efforts, he knew the therapy needed a name that was easy to say and an identity. After conducting research and working through branding exercises, the team aligned on Optune. The prefix "op" signifies the opportunity to offer patients an innovative treatment optimized to target tumors that are difficult to treat. The suffix "tune" alludes to a tuning fork for a piano and evokes the idea of using the therapy as a tool.

"I really liked the simplicity of it," Pritesh said. "It really resonated with us in terms of the functionality of what we wanted the product to do. It allowed us to capitalize on what we believe is really the essence of Tumor Treating Fields."

The Optune brand also included a color palette of blue and orange—with blue representing innovation and the trailblazing nature of Novocure, and orange representing hope.

"We wanted to give patients the ability to think about a future, to think about another treatment, to have hope in an underserved disease," Pritesh said.





## 11

## a public company

#### Novocure launches its initial public offering to help fund the company's future.

The outcome of the EF-14 study in newly diagnosed GBM transformed the company

"Starting with the successful EF-14 interim analysis, Novocure delivered a cadence of good news," recalled Bill Doyle, Novocure's Executive Chairman. By 2015, Novocure was building commercial operations on three continents and establishing a clinical pipeline studying Tumor Treating Fields in multiple additional solid tumor indications.

As the business evolved, so did the capital needs of the company.

"In the early R&D days, we would raise funding in rounds of \$5 million, and then rounds of \$10 million," Bill said. "All of a sudden, we needed to raise \$100 million to build a global oncology company."

To meet the capital requirements of commercialization, Novocure's leadership team decided to take the company public and began to educate the investor community to build support for an initial public offering, or IPO. Company-wide preparations culminated in a two-week roadshow to meet investors in 10 cities across the U.S. and Europe. On October 2, 2015, after months of tremendous effort, Novocure went public on the NASDAQ Global Select Market with a market capitalization of \$1.8 billion, raising \$165 million in funding for the company.

"We pulled it off," Bill said. "We all went to NASDAQ headquarters in Times Square and rang the bell."

Reflecting on 20 years of fundraising to support the company's growth, Bill put the importance of the IPO into perspective.

"For us, the Novocure journey has always been about bringing a new cancer therapy to patients," Bill said. "The IPO was pivotal for the company, but it was really just one of the tools we used to finance our mission to bring Tumor Treating Fields therapy to patients, not an end in itself."

Pritesh Shah, Chief Commercial Officer

## a smaller and lighter Optune

#### Novocure's engineering team develops second generation Optune system to improve patient experience.

In 2005, when Novocure designed its first generation Optune system to begin conducting clinical trials, the team spearheading the project knew that someday it would be possible to advance the technology further. Mike Ambrogi, Novocure's Chief Operating Officer, said the next evolution of the device hinged on advancements in signal amplification technology.

Over the next several years, Novocure's Vice President of Engineering Yoram Wasserman kept the idea of a lighter and smaller device in mind until signal amplification technology had come far enough to make enhancements. The advancements would switch Optune from analog amplification to digital amplification, which would allow for a more efficient system and a dramatic reduction in weight and size. Yoram and his team began designing the software and hardware for second generation Optune system.

Novocure's engineers created a system that was half the size and less than half the weight of the first generation Optune system. Including its battery, the second generation Optune system weighs 2.7 pounds, compared to the first generation system that weighs 6 pounds.

Novocure started offering second generation Optune system to GBM patients in Germany in October 2015 and then made it available to all new patients in Europe. In July 2016, the U.S. FDA approved second generation Optune system for GBM patients in the U.S.

Mike recalled the relief he felt when the project was completed.

"The ability to make it smaller and lighter is such a benefit to make the treatment more accessible," Mike said. "Second generation Optune system is a symbol of what we can do and a precursor of things to come."



## **13**

## bigger than glioblastoma

In the last several years, Novocure has expanded and bolstered its clinical pipeline by growing its clinical operations and establishing clinical partnerships.

After watching a TEDMED Talk on Novocure's cancer therapy by Executive Chairman Bill Doyle, Leszek Bialecki wanted to be a part of Novocure.

Leszek, Novocure's Senior Director of Global Clinical Operations, joined in 2017 with the role of leading clinical operations as a department and to prepare for growth of the clinical program. Clinical operations is responsible for the management of clinical trials.

"We knew that the growing pipeline will require changes in the way we work, increase the size of the team, and expand geographically," said Leszek, who works at Novocure's Root, Switzerland, office.

At the time, Novocure had recently begun its phase 3 pivotal trials in brain metastases and non-small cell lung cancer, was planning a phase 3 pivotal trial in pancreatic cancer and was wrapping up its registrational trial in mesothelioma. Novocure was becoming bigger than GBM.

Leszek took the knowledge from his nearly 20-year career working for large pharmaceutical companies and applied it to Novocure, mapping out the journey for his team. Over the last several years, his team grew from nine employees to more than 40. Leszek said it isn't as simple as hiring people with specific qualifications for the role—it takes a certain type of person who will succeed as an individual and in turn contribute to the success of the organization.

"We need a specific type of talent that will fit Novocure's culture," he said. "This is our strength. This is what makes us go. We hire people driven by ideas and by purpose. This is something that we live by."

Novocure has also established external partnerships to facilitate clinical trial enrollment and execution and continued to expand the pipeline. In 2019, Novocure partnered with the European Network for Gynaecological Oncological Trial groups (ENGOT) and the GOG Foundation, Inc. to run its phase 3 pivotal trial in ovarian cancer, INNOVATE-3. In 2019, Novocure collaborated with Zai Lab to begin a phase 2 pilot trial of Tumor Treating Fields in gastric cancer in Greater China.

**Leszek Bialecki,** Senior Director of Global Clinical Operations

Today, with four phase 3 pivotal trials and two phase 2 pilot trials under way, Leszek said Novocure's Clinical Operations team continues to adapt and change every day to prepare for the future.

"Almost every day, we do something unique," he said.

Leszek said he has felt the support of Novocure's management team from day one in his effort to grow the company's clinical operations. He has also recognized the role of each individual on his team.

"I am extremely proud of my team—each and every one of them," he said. "I know how much they put into their work and I love that about them."





## championing the story

Acceptance of Tumor Treating Fields grows across the scientific community.

With increasing frequency over the last decade, Novocure was earning external validation of its science. Investigators, authors and conference organizers increasingly expressed interest in understanding Tumor Treating Fields. This rising acceptance and interest helped to amplify Novocure's message.

"Our story never changed," said Katherine Tiku, Senior Director of Global Medical Affairs Publications. "What we were saying on day one about electric fields' ability to disrupt cancer cell division was the same story we were telling more than 10 years later. We gained a number of advocates along the way, but suddenly all our accomplishments added up into something bigger—and people started coming to us to help champion the story."

Novocure saw examples of increased acceptance of Tumor Treating Fields across the global scientific community. There were notable publications in peer-reviewed journals, including *JAMA*, *The Lancet Oncology* 

and the *Red Journal*. Optune was recognized in clinical guidelines globally, including the National Comprehensive Cancer Network (NCCN) guidelines in the U.S and equivalent guidelines in Europe, Japan and China.

"The best science is reproducible, and we didn't have to retract or restate anything," Katherine said. "As the community became more familiar with our data, authors began approaching us for input, conference organizers started inviting us to speak, and news outlets wanted to know more. Tumor Treating Fields had established itself, and we were gaining prestige and press in the scientific community."

# 15

## a pathway to reach more patients

#### Novocure partners with Zai Lab to bring its innovative therapy to Greater China.

After years of growing the Optune brand in the U.S., Europe and Japan, it was time to turn attention to China, the world's most populated country. In September 2018, Novocure and Zai Lab, a Shanghai-based biopharmaceutical company, announced a strategic collaboration to make Optune available to the Chinese market.

"There are certain parts of the world, such as China, where it makes sense to have a trusted partner," said Matt Thaeder, Novocure's Associate Director of Business Development.

Sharing best practices, Novocure ensured that Zai Lab could replicate the high standards of Novocure's patient-forward business model. In only three months, Zai Lab was treating its first GBM patient in Hong Kong.

"Going from an agreement to treating the first patient with Optune in that short amount of time was the moment when it finally felt real that this treatment had moved to a new part of the world," Matt said.

It didn't stop with GBM. Together, Novocure and Zai Lab are also pursuing clinical development, regulatory approvals and treatment expansion to other cancer types with high unmet needs.

"Our collaboration with Zai Lab is another way to expand patient access," Matt said. "I think that there's so much untapped potential in Tumor Treating Fields, and I feel proud that we are moving to a new arch in providing our therapy to more patients."

"I think that there's so much untapped potential in Tumor Treating Fields, and I feel proud that we are moving to a new arch in providing our therapy to more patients."

- Matt Thaeder,

Associate Director of Business Development

25

## Medicare reimbursement

#### A partnership with a patient re-energized Novocure on its journey to obtain coverage for Medicare recipients.

Frank Leonard's first project after joining Novocure became a quest that took nearly a decade to complete.

In 2010, the year before Novocure received its first FDA approval in recurrent GBM, Frank was tasked with determining how Novocure would launch a product commercially. He zeroed in on the fact that Novocure's cancer therapy did not yet have a classification from a reimbursement standpoint. Eventually, Optune and Tumor Treating Fields became classified as durable medical equipment (DME). This posed a challenge because most DME are simple devices like wheelchairs, canes and walkers, and decision-makers were not used to evaluating advanced therapeutic technologies in the DME space.

After launching its first commercial product, Novocure began working to educate insurers and countries with national reimbursement about the value of Novocure's therapy. The company also continued to build its data.

Over the years, nearly every major health insurer in the U.S., along with several governments, began reimbursing for Optune. Medicare was the last major healthcare payer in the U.S. that did not reimburse for Novocure's therapy.

"Going back to the beginning, we were approaching Medicare to introduce an entirely new concept in medicine," said Frank, Novocure's Senior Vice President of Corporate Strategy and Health Policy. "There was definitely a point, maybe five years into the process, where it felt like the process may never end."

In 2016, Frank formed a partnership that helped reenergize him on his journey. He began working with Steve Welhoelter, an Optune patient, to advocate for Medicare reimbursement on Capitol Hill by educating lawmakers on the importance of Novocure's therapy.

"It made it very real to me, that no matter how long the process took, we had to get all the way through the process to be successful and ensure coverage for our patients," Frank said.

Steve of Ponce Inlet, Florida, had recently retired. Teaming up with Novocure gave him a renewed sense of purpose. He told his story of living with GBM and receiving Optune therapy to lawmakers and to panels of decision-makers. Steve said he believed in Novocure's mission and wanted to help ensure the therapy was available to patients who needed it.

"I'm privileged to be a part of a team that cares so much about people," Steve said.

In July 2019, Medicare released a final local coverage determination providing coverage of Optune for Medicare beneficiaries with newly diagnosed GBM. Frank said it took him two weeks to digest the news.

"Securing Medicare reimbursement was only possible because every department at Novocure contributed to the mission, we worked as a team, and we partnered with our patients," he said. "Everything had to come together."

**Frank Leonard,** Senior Vice President of Corporate Strategy and Health Policy



Maty Ayal Hershkovitz, Vice President of Global Regulatory Affairs

# **17**

## a platform therapy

In May 2019, the U.S. FDA approved Novocure's therapy for the treatment of malignant pleural mesothelioma.

From fall of 2018 through spring of 2019, Novocure embraced a fast-paced dialogue with the U.S. FDA after submitting an application for approval of Optune Lua™, originally known as the NovoTTF-100L System, in combination with chemotherapy for the treatment of malignant pleural mesothelioma (MPM). Optune Lua was submitted for approval under the Humanitarian Device Exemption (HDE) pathway, which was created by the FDA to encourage companies to innovate in rare and underserved diseases.

Maty Ayal Hershkovitz, Vice President of Global Regulatory Affairs, lives and works in Israel, and managed a challenging time difference when questions from the FDA would come in with a tight timeline for response.

"I couldn't believe it myself, but I was writing emails from the supermarket to the FDA," she said.

As Vice President of Global Regulatory Affairs, Maty oversaw the submission of Optune Lua as a treatment for MPM to the FDA. The role of regulatory affairs, Maty said, is to tell regulatory authorities Novocure's story per specific device and cancer indication.

"A good story would be something that reflects the fact that we did quality work, that we have a quality device, that the data are solid, and that what we are offering patients is going to be safe and effective," she said.

Throughout the approval process, the FDA would ask for additional information from Novocure regarding its data in MPM and about the device.

"Whenever FDA had a question, we had the resources, we had the data, we had the science to go back and provide an answer," Maty said. "That was incredible because those back-and-forth exchanges happened many, many times."

In May 2019, the FDA approved Optune Lua in combination with pemetrexed plus platinum-based chemotherapy for the first-line treatment of unresectable, locally advanced or metastatic MPM. Optune Lua is the first new treatment for MPM in more than 15 years.

Maty acknowledged the high level of cooperation she received from colleagues across functions during the approval process.

"I don't take it for granted that you get that kind of cooperation at Novocure," Maty said. "People understood that if FDA had a question, the response had to be provided quickly."

Throughout her career, Maty has seen many companies strive to create a pipeline but their innovations may have only been specific to one disease. For Novocure, the FDA approval in MPM broadened the potential use of its therapy.

"This was a breakthrough," Maty said. "The FDA approval in MPM made Tumor Treating Fields a platform—a platform to our future."





## 'a massive, collective effort'

In October 2019, Novocure became a profitable company.

Reflecting on the past eight years as leader of Novocure's finance organization, Wilco Groenhuysen gestured toward to the blank whiteboard in his office. Wilco joined Novocure in 2012 with the objective of building a finance team and achieving finance excellence.

"The whiteboard was truly white," Wilco said. "There was nothing on it."

The metaphorical and physical white board in his office is still without writing. In his early days at Novocure, Wilco felt excited by the opportunity to start with a blank slate—an excitement that still drives him today as Chief Financial Officer.

"I knew what a successful finance organization should look like, but also wanted to create one that adds value," he said. "I'm a strong believer in hiring superior, highly motivated talent that can build their own jobs to some extent as long as it fits in the total."

In October 2019, Novocure reached a financial milestone: profitability. In the years leading up to profitability, Wilco said, leadership balanced the desire to become profitable with investing profits from the GBM business into Novocure's research and development. Over time, funds

generated by the GBM business exceeded Novocure's investments in research and development.

"It took a massive, collective effort," he said. "Becoming profitable from scratch is a remarkable achievement."

Wilco said Novocure's financial performance and improvement is not the company's primary objective, rather a positive consequence of Novocure's mission.

"What's remarkable about Novocure is the fact that its sole focus is on helping patients and extending survival in some of the most aggressive forms of cancer," he said. "We know if we stay focused and if we execute on that well in a disciplined way, financial success will also be achieved."

After nearly a decade at Novocure, Wilco still feels like he is starting fresh every day—and wouldn't have it any other way.

"We are building a company, going through stages that require substantial change," he said. "What is great today might not be good enough two years from now. This is a continuum. So you have to wipe the board, accept that status quo will be insufficient, and define the future."

# 19

## excitement for the next opportunity

#### Geographical expansion adds an additional lever for growth.

Entering 2019, Novocure had established commercial operations in seven active markets: the U.S., Austria, Germany, Israel, Japan, Sweden and Switzerland. As proud as the team was of the progress made in these seven active markets, Novocure believed that a significant number of patients remained who could benefit from Optune but who could not yet access treatment. In late 2019, Novocure announced its expansion into France, Europe's second most populous country.

Anne Calixte de Lembeye, one of Novocure's newest employees, was hired to lead those efforts. She joined the team in January 2020 as the French country manager for two reasons: the innovation and the patients. "I really enjoy working to bring something new and different to patients that's really needed," Anne said.

Energized by Novocure's mission and vision, Anne started to educate key stakeholders, building awareness of Optune. Anne's work is fueled positive feedback she received from the French scientific and medical communities.

"We are very enthusiastic about the opportunity," Anne said.
"It gives me a lot of energy to go as fast as we can to bring
Tumor Treating Fields therapy to market in France."

When asked what she hopes to achieve at Novocure, Anne said: "I will be very proud to put Optune on the French market for GBM first, and then I hope to do the same for other indications. I will be very proud doing that at an organization with a lot of tightness and cooperation between its people, and also one with a lot of patience."



Anne Calixte de Lembeye, Country Manager France



## more than 14,000 patients

20 years of milestones and progress results in thousands of patients treated to date.

Novocure CEO Asaf Danziger remembers the early days of the company when he knew every patient by name. At the time, he went to the home of patients to help them start Novocure's therapy. At night, when he wasn't sleeping, he thought about each patient as a person and hoped for better outcomes

Today, with more than 14,000 patients treated to date, the human connection between Novocure and patients remains the same. Asaf said it took many parts coming together at the right moments to reach the milestone of treating 14,000-plus patients.

"It's a huge machine," Asaf said of Novocure's business.

"The goal is to build it in the same way—it doesn't matter if it's Tokyo. Nashville or Munich."

He said he is proud of this milestone, and the fact that Novocure and its employees had the focus and drive to take it this far.

"I am lucky that there are very talented, passionate people working at Novocure," Asaf said. "I really mean it. Without them, it isn't going to happen." Whenever Novocure reaches a significant milestone, Asaf often says when addressing employees that it is only the beginning. In those moments of celebration, it's as if those words signal a call to see something greater than what exists today. In his time at Novocure, Asaf has seen countless beginnings, with every moment building on the ones before.

"It's a real thing right now," he said. "It's a real establishment. We built something strong and sustainable to move to the next level."

Today, when he's not sleeping at night, Asaf thinks about the number of people impacted by Novocure's therapy—every patient and their family and friends. He thinks about the potential future indications and all of the people who may one day benefit from Novocure's cancer treatment. He calls on Novocure employees to never lose sight of that and to keep moving forward.





Our continued commercial growth drives strengthening financial performance that allows us to invest in clinical and product development intended to unlock future value for our patients, employees and shareholders.

Since our IPO in 2015, we delivered double-digit or greater revenue growth every year, increased our gross margins from the mid-40s to the mid-70s and invested over \$250 million in research and development. In 2019 we began to generate cash flow from operations and reported our first two quarters of profitability. We believe our financial strength positions us well to achieve our strategic objectives, and we remain committed to maintaining a balanced focus across growth, profitability and liquidity.



YEAR-OVER-YEAR GROWTH 2019 VERSUS 2018

22%

GROWTH IN ACTIVE PATIENTS

56%

GROWTH IN RESEARCH & DEVELOPMENT INVESTMENTS

42%

GROWTH IN NET REVENUES

\$80M

CASH ON HAND\* ADDED TO THE BALANCE SHEET

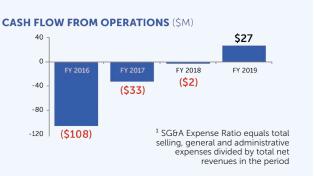
cash, cash equivalents and short-term investments

### financial strength funds investments in innovation









### consolidated statement of operations

#### Year ended December 31,

	real chaca becomber 31,									
U.S. dollars in thousands		2019		2018		2017		2016		
Net revenues	\$	351,318	\$	248,069	\$	177,026	\$	82,888		
Cost of revenues		88,606		80,048		55,609		39,870		
Impairment of field equipment		_		_		_		6,412		
Gross profit		262,712		168,021		121,417		36,606		
Research, development and clinical trials		79,003		50,574		38,103		41,467		
Sales and marketing		96,675		77,663		63,528		59,449		
General and administrative		87,948		73,456		59,114		51,007		
Total operating expenses		263,626		201,693		160,745		151,923		
Operating income (loss)		(914)		(33,672)		(39,328)		(115,317)		
Financial expenses (income), net		7,910		12,270		9,169		6,147		
Income (loss) before income taxes		(8,824)		(45,942)		(48,497)		(121,464)		
Income tax		(1,594)		17,617		13,165		10,381		
Net income (loss)	\$	(7,230)	\$	(63,559)	\$	(61,662)	\$	(131,845)		
Basic and diluted net income (loss) per ordinary share	\$	(0.07)	\$	(0.69)	\$	(0.70)	\$	(1.54)		

3

"What appeals to me about Tumor Treating Fields is that it is a simple and elegant response to a big problem. I'm proud to be a part of this journey."

Todd Longsworth
 General Counsel



## LEADERSHIP

#### CORPORATE OFFICERS AND EXECUTIVE LEADERSHIP

William F. Doyle
Executive Chairman

Yoram Palti, M.D., Ph.D. Founder

**Ely Benaim, M.D.**Chief Medical Officer

Mike Ambrogi Chief Operating Officer

Pritesh Shah
Chief Commercial Officer

**Asaf Danziger**Chief Executive Officer

Todd Longsworth
General Counsel

**Uri Weinberg, M.D., Ph.D.** *Chief Science Officer* 

Wilco Groenhuysen Chief Financial Officer

#### **BOARD OF DIRECTORS**

William F. Doyle
Executive Chairman

David T. Hung

Jeryl Hilleman

**Kinyip Gabriel Leung** 

**Asaf Danziger**Chief Executive Officer

Martin J. Madden

Sherilyn D. McCoy

William A. Vernon

#### market price of and dividends on the registrants' common equity and related stockholder matters

The following performance graph is being furnished as part of this annual report and shall not be deemed "filed" with the SEC or incorporated by reference into any of our filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph shows the total shareholder return of an investment of \$100 in cash at market close on October 2, 2015 (the first day of trading of our ordinary shares) through December 31, 2019 for (1) our ordinary shares, (2) the Russell 2000 Index, and (3) the Nasdaq Biotechnology Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however, no dividends have been declared on our ordinary shares to date. The shareholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

#### comparison of 15 month cumulative total return\*

Among NovoCure Ltd, the Russell 2000 Index, and the NASDAQ Biotechnology Index



\*\$100 invested on 10/2/15 in stock or 9/30/15 in index, including reinvestment of dividends. Fiscal year ending December 31. Copyright© 2019 Russell Investment Group. All rights reserved.

Russell 2000 - -△- -

#### cumulative total return summary

NovoCure Ltd --

	10/2/15	12/15	3/16	6/16	9/16	12/16	3/17	6/17	9/17	12/17	3/18	6/18	9/18	12/18
NovoCure Ltd	100.00	122.32	79.21	63.84	46.72	42.94	44.31	94.64	108.59	110.50	119.26	171.23	286.65	183.15
Russell 2000	100.00	103.59	102.02	105.89	115.47	125.67	128.77	131.94	139.42	144.07	143.95	155.11	160.66	128.21
NASDAQ Biotechnology	100.00	111.62	89.57	86.95	95.87	89.13	97.75	103.18	112.36	106.14	104.85	107.67	119.92	96.28

NASDAQ Biotechnology .....o....

36

#### Optune<sup>®</sup> and Optune Lua<sup>™</sup> 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.

#### 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

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.

#### forward-looking statements

In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forwardlooking 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, 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 27, 2020 and Quarterly Report on Form 10-Q filed on April 30, 2020 with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forwardlooking 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.













Second Floor No. 4 The Forum Grenville Street St. Helier, Jersey, JE2 4UF