



# Attack the electrical vulnerability of NSCLC cells to extend 2L+ survival<sup>1</sup>

Optune Lua<sup>®</sup> is the first FDA-approved, wearable device that uses Tumor Treating Fields (TTFields) to disrupt and kill cancer cells, without adding systemic toxicity<sup>1</sup>

- Optune Lua concurrent with a PD-1/PD-L1 inhibitor or docetaxel provided a statistically significant, clinically meaningful improvement in median overall survival (mOS) vs PD-1/PD-L1 inhibitor or docetaxel alone, 13.2 vs 9.9 months; HR: 0.76 (95% CI: 0.58-0.99);  $P=0.041$ <sup>1</sup>
- Optune Lua did not add systemic toxicity. Dermatologic adverse events (dAEs) were the only device-related AEs (occurring in >5% of patients), and were observed in 63.1% of patients<sup>1,2</sup>

2L+, second line or later; FDA, US Food and Drug Administration; mNSCLC, metastatic non-small cell lung cancer; NSCLC, non-small cell lung cancer; PD-1/PD-L1, programmed cell death 1 protein/programmed cell death 1 ligand 1.

## Indication For Use

Optune Lua<sup>®</sup> is intended as a treatment concurrent with PD-1/PD-L1 inhibitors or docetaxel for adult patients with metastatic non-small cell lung cancer who have progressed on or after a platinum-based regimen.

## Selected Safety Information

### Contraindications

Do not use Optune Lua in patients with an electrical implant. Use of Optune Lua together with electrical implants has not been tested and may lead to malfunctioning of the implanted device.

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# An innovative, wearable treatment for patients with 2L+ mNSCLC, leveraging biophysical principles to disrupt tumor progression<sup>1</sup>

## mNSCLC remains an incurable disease with limited 2L treatment options<sup>3,4</sup>

- Combining systemic therapy options can have an incremental survival benefit, but at the cost of a compounded overall AE profile that many patients can't or won't bear



Actor portrayal.

Transducer array application shown here.

### What is Optune Lua®?

- A noninvasive, portable, wearable device that continuously delivers electric fields—known as Tumor Treating Fields (TTFields)—to fight cancer<sup>1,\*</sup>

### What are TTFields?

- TTFields are alternating electric fields that exert physical forces on electrically charged components in dividing cancer cells, resulting in cell death. TTFields are delivered by pairs of transducer arrays that adhere directly to the skin<sup>1</sup>
- Optune Lua is the first device to use electric fields for the treatment of mNSCLC, but electric fields have been utilized as treatment for other diseases<sup>1,5-7</sup>:
  - **Low frequency:** pacemakers, TENS (transcutaneous electrical nerve stimulation), deep brain stimulation
  - **High frequency:** microwave ablation, x-rays

Optune Lua is the first FDA-approved treatment that uses TTFields to disarm tumor cells by tapping into their electrical properties<sup>1</sup>

\*Effect is enabled when device is powered; transducer arrays should be changed at least 2 times per week (every 4 days at most).<sup>1</sup>

2L, second line; 2L+, second line or later AE, adverse event; FDA, US Food and Drug Administration; mNSCLC, metastatic non-small cell lung cancer.

### Selected Safety Information

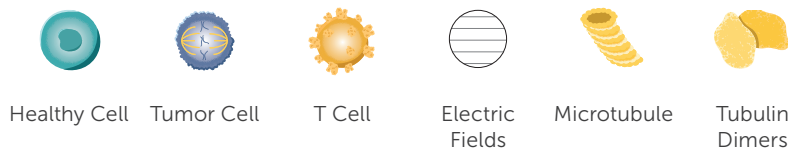
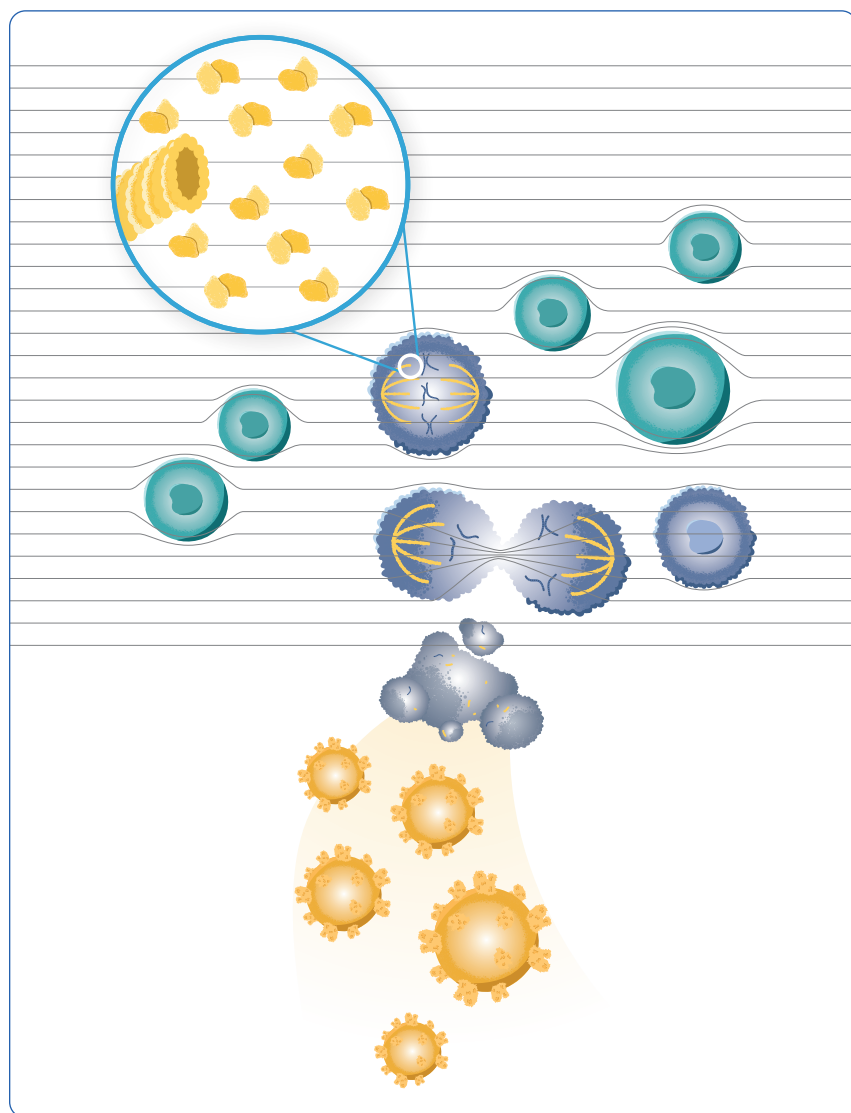
#### Contraindications (cont'd)

Do not use Optune Lua in patients known to be sensitive to conductive hydrogels. In this case, skin contact with the gel used with Optune Lua may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions, such as a fall in blood pressure and breathing difficulty.

# Optune Lua uses electrical fields to disrupt cancer cell viability without affecting healthy cells<sup>1</sup>

## Why are healthy cells not affected by Optune Lua?

- Healthy cells have different properties (including division rate, morphology, and electrical properties), than cancer cells, and therefore are not significantly affected by Optune Lua treatment<sup>1,5,8</sup>



TTFields, Tumor Treating Fields.

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## Disrupt Mitosis<sup>1,9,10</sup>

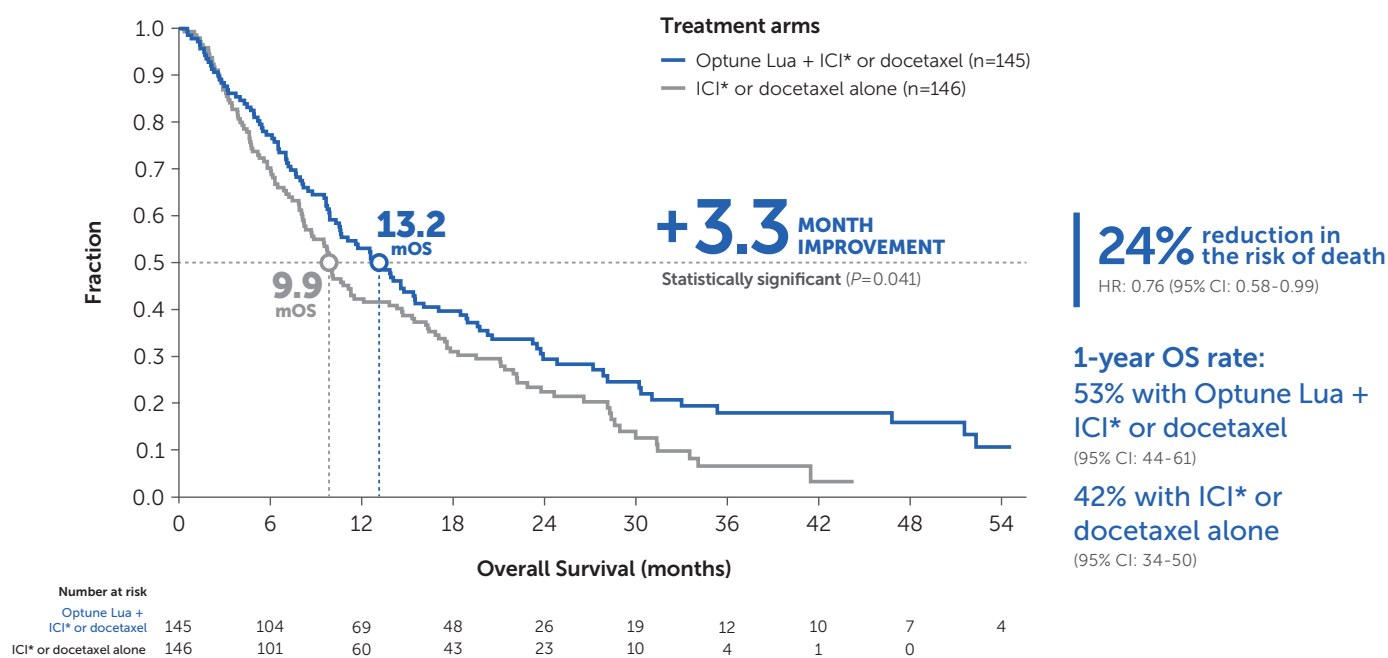
As cancer cells divide rapidly, they are vulnerable to the antimitotic effects of TTFields. Preclinical evidence has shown that by exerting physical forces on electrically charged components of cancer cells, TTFields can disrupt mitotic processes, such as assembly of the mitotic spindle, leading to impaired cell division and downstream immunogenic cell death.

## Activate Downstream Immune Response<sup>1,11</sup>

According to preclinical data, immunogenic cell death leads to expansion of T cells that target cancer-specific antigens, increased T-cell infiltration at the tumor site, and increased cancer cell surveillance throughout the body.

# Demonstrating a significant OS improvement in 2L+ mNSCLC, offering an innovative option in a challenging treatment landscape<sup>12</sup>

Primary endpoint: OS for Optune Lua® + PD-1/PD-L1 inhibitor or docetaxel vs PD-1/PD-L1 inhibitor or docetaxel alone<sup>1</sup>



## LUNAR study design<sup>1</sup>

LUNAR was a phase 3, open-label, randomized trial testing the safety and effectiveness of Optune Lua concurrent with a PD-1/PD-L1 inhibitor<sup>†</sup> or docetaxel for patients with mNSCLC who progressed on or after a platinum-based regimen (N=291<sup>‡</sup>). Patients were 1:1 randomized to receive either Optune Lua + a PD-1/PD-L1 inhibitor or docetaxel vs a PD-1/PD-L1 inhibitor or docetaxel alone. The primary endpoint was overall survival (OS). Key secondary endpoints included OS in subpopulations receiving either a PD-1/PD-L1 inhibitor or docetaxel. Clinical follow-up (CT scan) took place every 6 weeks (+/- 1 week) until disease progression with ongoing survival follow-up.

\*ICI refers to PD-1/PD-L1 inhibitor.<sup>1</sup>

<sup>†</sup>Nivolumab, pembrolizumab, or atezolizumab, as assigned by the physician.<sup>1</sup>

<sup>‡</sup>After interim analysis, the independent data monitoring committee recommended reducing patient accrual to 276 patients with 12 months follow-up. Initial planned accrual was 534 patients with 18 months follow-up. The final enrollment was 291. The expected hazard ratio for overall survival was <0.75.<sup>1,13</sup>

2L+, second line or later; CT, computed tomography; ICI, immune checkpoint inhibitor; mNSCLC, metastatic non-small cell lung cancer; mOS, median overall survival; OS, overall survival; PD-1/PD-L1, programmed cell death 1 protein/programmed cell death 1 ligand 1.

## Selected Safety Information

### Warnings and Precautions (cont'd)

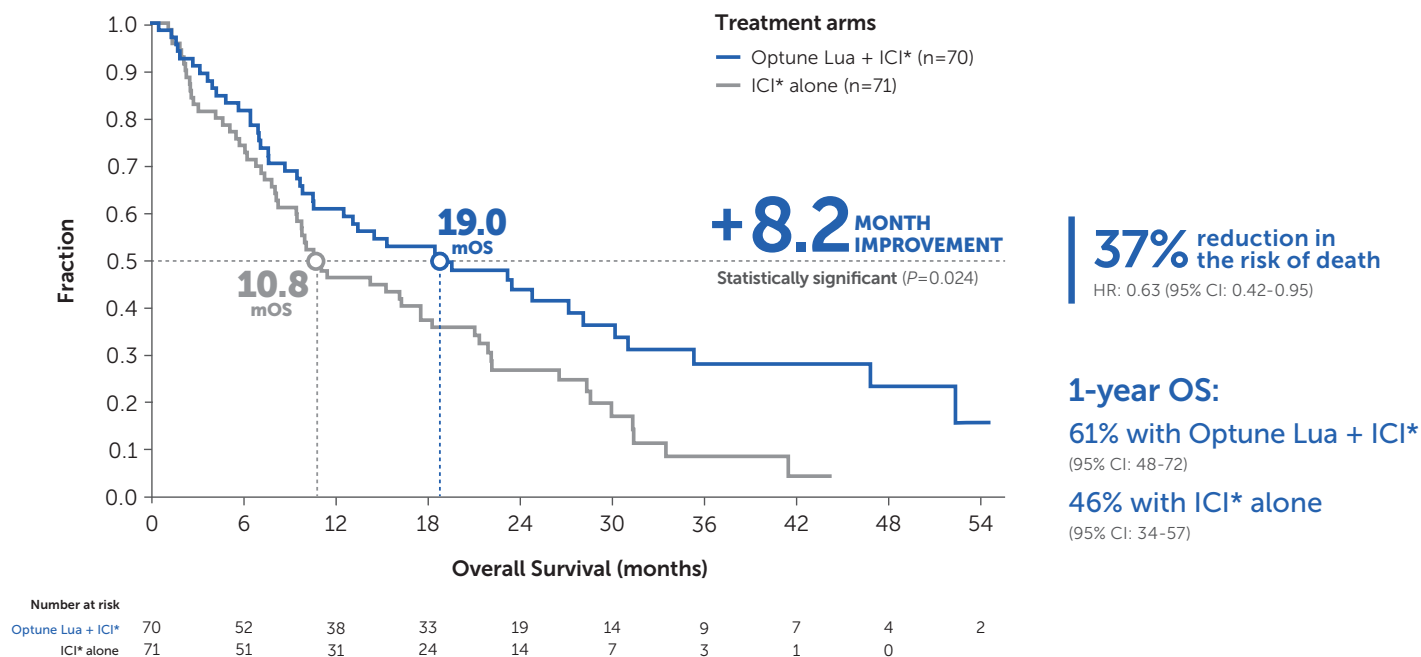
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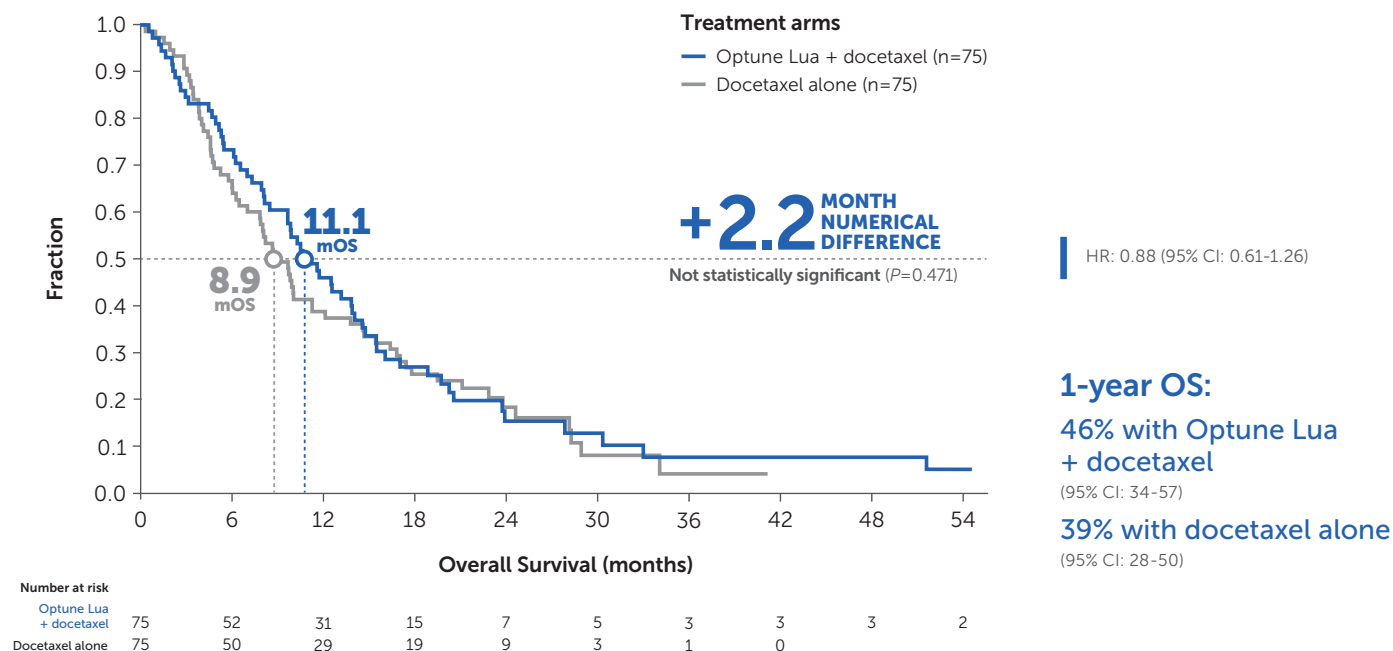


# Optune Lua significantly extended median OS when used together with a PD-1/PD-L1 inhibitor<sup>1</sup>

## Secondary endpoint: OS for Optune Lua + PD-1/PD-L1 inhibitor vs PD-1/PD-L1 inhibitor alone<sup>1</sup>



## Secondary endpoint: OS for Optune Lua + docetaxel vs docetaxel alone<sup>1</sup>



\*ICI refers to PD-1/PD-L1 inhibitor.

ICI, immune checkpoint inhibitor; mOS, median overall survival; OS, overall survival; PD-1/PD-L1, programmed cell death 1 protein/programmed cell death 1 ligand 1.

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# Optune Lua® did not add systemic toxicity<sup>1</sup>

## The only device-related AEs (>5%) were skin-related and mild to moderate<sup>1,2</sup>

- Dermatologic adverse events (dAEs) under the transducer arrays were experienced by 63.1% of patients (n=89/141)<sup>1</sup>
  - Majority were mild-to-moderate (grade 1 to 2)
  - Only 6 patients (4%) reported a grade 3 skin toxicity that required a break from treatment; in all cases the skin issue resolved
  - There were no grade 4 or grade 5 toxicities related to Optune Lua, and no device-related AEs that caused death

## Serious adverse events (SAEs) in LUNAR<sup>1</sup>

System Organ Class Preferred Term	Optune Lua + PD-1/PD-L1 inhibitor or docetaxel (n=141)	PD-1/PD-L1 inhibitor or docetaxel (n=141)
<b>Any SAE</b>	54.6%	39.0%
<b>SAEs</b>		
Blood and lymphatic system disorders	7.1%	6.4%
Cardiac disorders	4.3%	2.8%
Endocrine disorders	0.7%	0%
Gastrointestinal disorders	6.4%	4.3%
General disorders and administration site conditions	4.3%	5.0%
Hepatobiliary disorders	0%	1.4%
Infections and infestations	22.7%	16.3%
Injury, poisoning, and procedural complications	2.1%	0%
Investigations	0.7%	0.7%
Metabolism and nutrition disorders	3.5%	1.4%
Musculoskeletal and connective tissue disorders	0%	1.4%
Neoplasms benign, malignant, and unspecified (incl. cysts and polyps)	5.0%	2.1%
Nervous system disorders	5.7%	3.5%
Renal and urinary disorders	0.7%	0.7%
Respiratory, thoracic, and mediastinal disorders	18.4%	16.3%
Skin and subcutaneous tissue disorders	1.4%	0%
Vascular disorders	0.7%	0%

The rate of SAEs did not differ clinically or significantly when accounting for follow-up time<sup>1</sup>

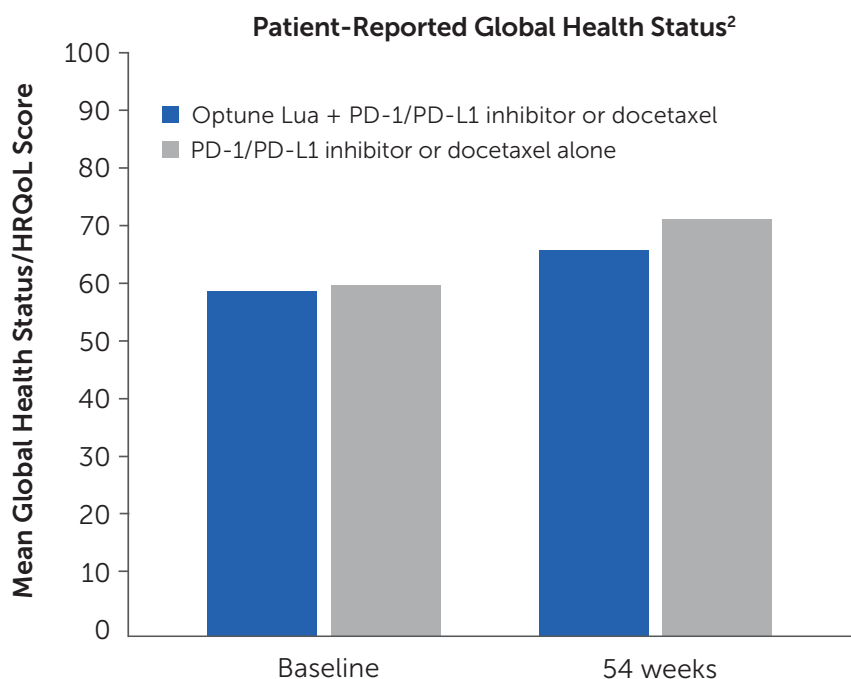
No difference in the rate of grade 3-4 pneumonitis (1.4% vs 2.1%)<sup>2,\*</sup>

No difference in the rate of other systemic AEs<sup>2</sup>

AE, adverse event; PD-1/PD-L1, programmed cell death protein 1/programmed cell death 1 ligand 1.

# There was no notable difference in health-related QoL in patients treated with Optune Lua<sup>1,17</sup>

Patients using Optune Lua + PD-1/PD-L1 inhibitor or docetaxel reported stable QoL scores across predefined daily functioning domains<sup>1,13,\*</sup>



Adding Optune Lua to your 2L+ treatment approach may improve survival without impairing QoL<sup>1,13,14</sup>

\*Patient-reported data collected per EORTC QLQ-C30 at baseline and months 3, 6, 9, and 12. This 30-question survey covered 5 daily functioning domains (including Physical, Role, Social, Emotional, and Cognitive).<sup>1,13,14</sup>

EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HRQoL, health-related quality of life; PD-1/PD-L1, PD-1/PD-L1, programmed cell death protein 1/programmed cell death 1 ligand 1; QoL, quality of life.

## Selected Safety Information

### Warnings and Precautions (cont'd)

The most common ( $\geq 10\%$ ) adverse events involving Optune Lua concurrent with PD-1/PD-L1 inhibitors or docetaxel were dermatitis, musculoskeletal pain, fatigue, anemia, dyspnea, nausea, cough, diarrhea, anorexia, pruritus, leukopenia, pneumonia, respiratory tract infection, localized edema, rash, pain, constipation, skin ulcers, and hypokalemia.

Other potential adverse effects associated with the use of Optune Lua include treatment related skin toxicity, allergic reaction to the adhesive or to the gel, overheating of the array leading to pain and/or local skin burns, infections at the site where the arrays make contact with the skin, local warmth and tingling sensation beneath the arrays, medical device site reaction, muscle twitching, and skin breakdown or skin ulcer.

If the patient has an underlying serious skin condition on the chest, evaluate whether this may prevent or temporarily interfere with Optune Lua treatment.

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# Optune Lua® is designed to fit into your patient's everyday life

## The flexibility to decide which times of day work best for them

**2.7lbs** Small and lightweight (with battery)<sup>1,13</sup>



Designed for enhanced carrying comfort and usability<sup>1</sup>



Wearable and portable for use during normal daily activities<sup>1</sup>



Optune Lua is intended for use of at least 12 hours a day on average<sup>1</sup>

### In LUNAR<sup>1</sup>:

- **The majority of patients** maintained an average monthly Optune Lua usage of 12+ hours per day, with a median of ~13 hours per day
- **Nearly 1 in 4 patients** were able to achieve an average monthly usage of 18+ hours/day

## Support for your patients and practice

Find 24/7 support from day 1, with MyNovocure®



1-855-281-9301 (toll-free)



[support@mynovocure.com](mailto:support@mynovocure.com)



[OptuneLuaHCP.com/Support](https://OptuneLuaHCP.com/Support)



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# Indication and Important Safety Information

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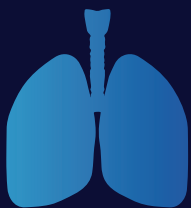
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**References:** **1.** Optune Lua for Non-Small Cell Lung Cancer (NSCLC). Physician Instructions for Use. Novocure; 2024. **2.** Novocure Data on File 2024. US-DOF-0046. **3.** Neal JW. In: Lilenbaum RC, Ed. *UpToDate*. Wolters Kluwer; 2023. Accessed March 21, 2024. <https://www.uptodate.com/contents/subsequent-line-therapy-in-non-small-cell-lung-cancer-lacking-a-driver-mutation> **4.** Moliner L, Spurgeon L, Califano R. *ESMO Open*. 2023;8(2):100879. doi:10.1016/j.esmoop.2023.100879 **5.** Karanam NK, Story MD. *Int J Radiat Biol*. 2021;97(8):1044-1054. doi:10.1080/09553002.2020.1837984 **6.** Krauss J, Lipsman N, Aziz T, et al. *Nat Rev Neurol*. 2021;17(2):75-87. doi:10.1038/s41582-020-00426-z **7.** Mulpuru S, Madhavan M, McLeod C, Cha Y-M, Friedman PA. *J Am Coll Cardiol*. 2017;69(2):189-210. doi:10.1016/j.jacc.2016.10.061 **8.** Ahmad MA, Al Natour Z, Mustafa F, Rizvi TA. *IEEE Access*. 2018;6:25979-25986. doi:10.1109/ACCESS.2018.2830883 **9.** Gera N, Yang A, Holtzman TS, Lee SX, Wong ET, Swanson KD. *PLoS One*. 2015;10(5):e0125269. doi:10.1371/journal.pone.0125269 **10.** Giladi M, Schneiderman RS, Voloshin T, et al. *Sci Rep*. 2015;5:18046. doi:10.1038/srep18046 **11.** Voloshin T, Kaynan N, Davidi S, et al. *Cancer Immunol Immunother*. 2020;69(7):1191-1204. doi:10.1007/s00262-020-02534-7 **12.** Novocure Data on File 2024. US-DOF-0040. **13.** Leal T, Kotecha R, Ramlau R, et al. Supplementary appendix. *Lancet Oncol*. 2023;24(9):1002-1017. Accessed March 21, 2024. [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(23\)00344-3/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(23)00344-3/fulltext). **14.** EORTC Quality of Life Group. EORTC QLQ-C30, Version 3.0. 1995. European Organisation for Research and Treatment of Cancer, Belgium. <https://www.eortc.org/app/uploads/sites/2/2018/08/Specimen-QLQC30-English.pdf>

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# Attack the electrical vulnerability of NSCLC cells to extend 2L+ survival with Optune Lua<sup>®1</sup>

Demonstrating a significant OS improvement in 2L+ mNSCLC, offering an innovative option in a challenging treatment landscape<sup>12</sup>



Learn more about Optune Lua for the treatment of 2L+ mNSCLC

**OptuneLuaHCP.com**



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