**NOW FDA-APPROVED for mNSCLC** concurrent with a PD-1/PD-L1 inhibitor or docetaxel after progression on or after a platinum-based regimen<sup>1</sup>

# Optune Lua® Patient Profiles

Optune Lua 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>

The images and profiles used throughout this brochure do not depict or describe actual patients. Depictions are actor portrayals and profiles were developed for illustrative purposes, based on patient population from clinical trial.

### **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 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.

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.

mNSCLC, metastatic non-small cell lung cancer.





## **David** 55 years old 25% PD-L1, stage IVa squamous cell NSCLC

# Durable response to IO + platinum-based chemotherapy, now with slow progression

## **Patient History**

- Divorced, 3 school-aged children, teacher
- Current smoking history: 30 pack-years
- Coronary artery disease, hypertension
- ECOG PS 0

## **History of Present Illness**

- Stage IVa NSCLC: 5-cm mass and a 1.5-cm nodule in the right lung, with mediastinal and supraclavicular lymphadenopathy
- Squamous cell carcinoma with no targetable driver mutations
- 25% PD-L1 expression

## **Treatment History**

• Pembrolizumab + carboplatin-paclitaxel Q3W for 4 cycles, with continuation of pembrolizumab Q3W for 25 cycles



\*Example patient case; actor portrayal.

ECOG PS, Eastern Cooperative Oncology Group performance status; IO, immuno-oncology agent; NSCLC, non–small cell lung cancer; PD-1/PD-L1, programmed cell death 1 protein/programmed cell death 1 ligand 1; Q3W, every 3 weeks.

### **Selected Safety Information**

#### Warnings and Precautions

Optune Lua can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure<sup>®</sup> (the device manufacturer).

Do not prescribe Optune Lua for patients who are pregnant, whom you think might be pregnant, or who are trying to get pregnant, as the safety and effectiveness of Optune Lua in these populations have not been established.

I've already completed chemotherapy and prefer not to do it again.\*

## **Current Disease Status**

"

- Demonstrated slow progression in the right lung after 20 months on pembrolizumab.
   Pembrolizumab was continued with expectant observation
- Four months later, right lung continues to progress
- Now with a nodule close to 1 cm in size and mild pleural-based progression, but remaining mostly asymptomatic



Is Optune Lua<sup>®</sup> appropriate for this patient?

View the results from the Optune Lua + PD-1/PD-L1 inhibitor subgroup

#### **Selected Safety Information**

#### Warnings and Precautions (cont'd)

The most common (≥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.



## Laura 73 years old PD-L1 negative, stage IVb squamous cell NSCLC

## Motivated patient with rapidly progressing multiple new lesions

## **Patient History**

- Married, adult children, retired
- Person with smoking history
- Coronary artery disease, hypertension, type 2 diabetes
- ECOG PS 1

## **History of Present Illness**

- Stage IVb NSCLC: multiple small, bilateral lung nodules and a liver lesion
- Squamous cell carcinoma with no targetable driver mutations
- PD-L1 negative

## **Treatment History**

• Nivolumab + ipilimumab + carboplatin-paclitaxel for 2 cycles, followed by nivolumab + ipilimumab for 6 cycles



\*Example patient case; actor portrayal.

ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non–small cell lung cancer; PD-1/PD-L1, programmed cell death 1 protein/programmed cell death 1 ligand 1.

## **Selected Safety Information**

#### Warnings and Precautions (cont'd)

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.

Please see the full Important Safety Information on pages 10-11 and the Optune Lua Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions at OptuneLuaHCP.com.

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I'm willing to try whatever treatment option my doctor recommends.\*

## **Current Disease Status**

• Five months after initiating treatment, the patient experienced progressive disease with new bone lesions in the lower spine and a few small liver lesions



Is Optune Lua<sup>®</sup> appropriate for this patient?

View the results from the Optune Lua + docetaxel subgroup

### **Selected Safety Information**

#### Warnings and Precautions (cont'd)

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



## Susan 60 years old 75% PD-L1, stage IVa nonsquamous NSCLC

# Avoided 1L IO due to autoimmune comorbidity

## **Patient History**

- Widowed with a caregiver, adult children. First grandchild due in 6 months
- Never smoker
- On active treatment for her autoimmune comorbidity
- ECOG PS 1

## **History of Present Illness**

- Stage IVa NSCLC: referred from rheumatologist. Single lung mass of 6 cm in diameter, with a 1.3-cm liver lesion
- Non-squamous cell carcinoma with no targetable driver mutations
- 75% PD-L1 expression

## **Treatment History**

• Carboplatin/pemetrexed for 4 cycles with continued pemetrexed. IO was avoided given the history of her autoimmune comorbidity



\*Example patient case; actor portrayal.

1L, first line; ECOG PS, Eastern Cooperative Oncology Group performance status; IO, immuno-oncology agent; NSCLC, non-small cell lung cancer; OS, overall survival; PD-1/PD-L1, programmed cell death 1 protein/programmed cell death 1 ligand 1.

### **Selected Safety Information**

#### Contraindications

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I am exploring treatment options that may help extend my survival.\*

## **Current Disease Status**

"

• Radiologic assessment showed stable disease for 3 months, but she now has progressive disease in the lung and liver



Is Optune Lua<sup>®</sup> appropriate for this patient?

View the results from the Optune Lua + PD-1/PD-L1 inhibitor subgroup

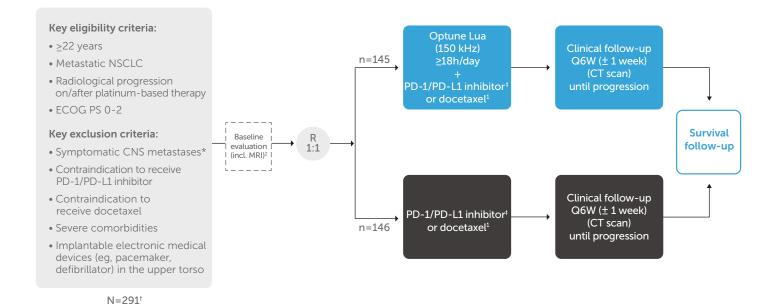
### **Selected Safety Information**

#### 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 reactions, such as a fall in blood pressure and breathing difficulty.



# LUNAR: A phase 3, open-label, randomized study demonstrating an OS benefit<sup>1</sup>



Stratification:

- PD-1/PD-L1 inhibitor vs docetaxel
- Histology (squamous vs nonsquamous)
- Geographic region

#### Study sites:

• 68 (United States, Europe, China, and Canada)

#### Primary endpoint:

 OS with Optune Lua + PD-1/PD-L1 inhibitor or docetaxel vs PD-1/PD-L1 inhibitor or docetaxel alone

### Key secondary endpoints:

• OS in subpopulations receiving either a PD-1/PD-L1 inhibitor or docetaxel

\*Patients with brain metastases were excluded under the original study design, later amended to allow stable brain metastases.<sup>3</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>12</sup>

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

CNS, central nervous system; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non–small cell lung cancer; MRI, magnetic resonance imaging; OS, overall survival; PD-1/PD-L1, programmed cell death 1 protein/programmed cell death 1 ligand 1; Q6W, every 6 weeks; R, randomized.

## **Selected Safety Information**

#### Warnings and Precautions

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# The first significant OS improvement demonstrated by a 2L+ mNSCLC treatment in 8 years<sup>4</sup>

## Primary endpoint<sup>1</sup>:

OS for Optune Lua + PD-1/PD-L1 inhibitor or docetaxel vs PD-1/PD-L1 inhibitor or docetaxel alone



## Key secondary endpoints<sup>1</sup>:

- PD-1/PD-L1 inhibitor group: **Statistically significant** 8.2-month improvement in mOS vs PD-1/PD-L1 alone (19.0-month mOS vs 10.8 months); HR: 0.63 (95% CL: 0.42-0.95); *P*=0.024
- Docetaxel group: Not significant 11.1-month mOS vs 8.9 months; HR: 0.88 (95% Cl: 0.61-1.26); P=0.471

## The only device-related AEs (>5%) were skin-related and mild to moderate, and were observed in 63.1% of patients $(n=89/141)^{1.5}$

- Majority were mild-to-moderate (grade 1 to 2)<sup>1</sup>
- Only 6 patients (4%) reported a grade 3 skin toxicity that required a break from treatment; in all cases the skin issue resolved<sup>1</sup>
- There were no grade 4 or grade 5 toxicities related to Optune Lua, and no device-related AEs that caused death<sup>1</sup>

Adding Optune Lua improved survival without adding systemic toxicity<sup>1</sup>

2L+, second line or later; AE, adverse event; 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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## Indication and Important Safety Information

### **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.

### **Important Safety Information**

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### **Important Safety Information**

#### Warnings and Precautions (cont'd)

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.

**References: 1.** Optune Lua for Non-Small Cell Lung Cancer (NSCLC). Physician Instructions for Use. Novocure; 2024. **2.** 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 **3.** Leal T, Kotecha R, Ramlau R, et al. *Lancet Oncol*. 2023;24(9):1002-1017. **4.** Novocure Data on File 2024. US-DOF-0040. **5.** Novocure Data on File 2024. US-DOF-0040. **5.** Novocure Data on File 2024. US-DOF-0046. **6.** Novocure Data on File 2023. GLB-DOF-0020.





# Could Optune Lua<sup>®</sup> be a good fit for your patients with 2L+ mNSCLC?

## Considerations to keep in mind for Optune Lua

## Key Clinical Characteristics<sup>1</sup>

Stage: IV
Line: 2L+

- Progression on or after a platinum-based regimen
- Not pregnant, trying to get pregnant, might be pregnant, or breastfeeding
- ECOG PS: 0-2
- Adult patients

- Does not have a known sensitivity to get used with Optune Lua
- No implantable electronic medical devices in the upper torso (eg, pacemaker) or active CNS metastases

## Based on the broad study population, Optune Lua may be appropriate regardless of<sup>1,6</sup>

- Histology
- PD-L1 status: <1%, 1-49%, ≥50%
- Smoking status
- Site of metastases

• Driver mutation status

## Patient Motivation and Goals

- Patients who want more control over their therapy (ie, want to be active participants)
- Chemo-averse patients: reject/resist chemo overall or don't want it again after 1L
- Motivated to extend survival
- Patients looking for the latest treatment options



Learn more about the efficacy of Optune Lua at OptuneLuaHCP.com

1L, first line; 2L+, second line or later; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; mNSCLC, metastatic non–small cell lung cancer; PD-L1, programmed cell death 1 ligand 1.

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