In newly diagnosed GBM, Optune® has a proven dose-response relationship over time

In a clinical trial, Optune used at incrementally higher ratios of time increased the median OS benefit vs TMZ alone

Median OS by Percentage of Monthly Time on Optune*

- Monthly usage was a predictor of survival benefit, independent of other prognostic factors such as KPS, age, or MGMT methylation status

*Based on amount of time Optune was turned on and providing therapy over the course of a month. These data reflect the average patient usage of Optune for the first 6 months of treatment (months 1-6).

1Approximation, based on monthly usage.

86% of patients received a survival benefit from Optune because they used it more than half the time (n=388/450). Visit Optune.com/hcp for more information

GBM, glioblastoma; KPS, Karnofsky Performance Status; MGMT, 0-6-methylguanine—DNA methyltransferase; OS, overall survival; TMZ, temozolomide.

Indications For Use

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.

Please see the Important Safety Information for Optune on the reverse side and the Optune Instructions For Use (IFU) for complete information regarding the device’s indications, contraindications, warnings, and precautions at Optune.com/IFU.
Important Safety Information

Contraindications

Do not use Optune in patients with an active implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. 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 in patients that are known to be sensitive to conductive hydrogels. In this case, skin contact with the gel used with Optune may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions

The most common (≥10%) adverse events involving Optune used together with TMZ were thrombocytopenia, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, convulsions, and depression.

A slightly higher incidence of grade 1 to 2 AEs was seen in some of the systems in Optune + TMZ arm of the study. This is most likely a reflection of the longer duration of TMZ treatment due to the increase in PFS seen in the treatment group.

The rate of grade 1 to 2 medical device site reaction was 52% for Optune + TMZ compared with 0% for TMZ alone.

Grade 3 to 4 AEs were well balanced between arms. None of the systemic grade 3 to 4 AEs were considered related to Optune by any of the investigators.

Mild-to-moderate skin irritation, the most common device-related side effect with Optune, was typically manageable, reversible, and did not result in treatment discontinuation.

AEs, adverse events; PFS, progression-free survival.

References:

5. Novocure Data on File OPT-103.

In newly diagnosed GBM, Optune was safely used together with TMZ with no significant increase in serious AEs compared with TMZ alone

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Recommended usage is ≥75% of time

- Patients can benefit most from wearing Optune when turned on for 18 or more hours per day (≥75% of the time)
- 75% of patients used Optune ≥75% of the time in the pivotal trial.

Flexible use is available for various patient needs

- 50% daily use was the threshold for significant survival benefit over TMZ alone.

Recommended daily usage

- ≥18 hours OR MORE
- ≤6 hours

Recommended usage is ≥75% of time

Flexible use is available for various patient needs

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If the patient has an underlying serious skin condition on the scalp (e.g. ulcers, open wound, broken skin) evaluate whether this may prevent or temporarily interfere with Optune treatment.

Use of Optune in patients with an inactive implanted medical device in the brain has not been studied for safety and effectiveness, and use of Optune in these patients could lead to tissue damage or lower the chance of Optune being effective.

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

Optune can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure (the device manufacturer).

Please see Important Safety Information throughout and the Instructions for Use (IFU) at Optune.com/IFU.

References:

5. Novocure Data on File OPT-103.