Optune® Fact Sheet

- Optune is a FDA-approved medical device for glioblastoma multiforme (GBM), the most common and deadliest type of primary brain cancer.¹
- Optune is the first FDA-approved therapy in more than a decade for newly diagnosed GBM.²
- Optune is a wearable, portable device that has been shown in clinical trials to safely deliver continuous therapy to the location of GBM tumors.³
  - Optune creates low-intensity electric fields, Tumor Treating Fields (TTFields), which help slow or stop GBM cancer cells from dividing and may also cause some of them to die.
  - TTFields work when cancer cells are dividing and do not disrupt healthy resting cells.
- For patients with newly diagnosed GBM, Optune is used together with the chemotherapy temozolomide (TMZ) after surgery and radiation with TMZ.
- A large clinical study showed that adding Optune to temozolomide provided the best chance to live longer.
  - Optune demonstrated an unprecedented five-year survival advantage. Analyses showed 2.5 times greater survival at five years with Optune plus TMZ (13%) compared to TMZ alone (5%) (p=0.0037)⁴
  - Nearly half, or 43%, of the people who used Optune with TMZ were alive at 2 years or longer, compared to 31% who were on TMZ alone (p=0.0008).⁴
  - Patients lived longer with Optune in combination with TMZ compared to TMZ alone. In the interim analysis of the Phase 3 trial:⁵⁶
    - Median progression-free survival was 7.2 months compared to 4 months (p=0.0013)
    - Overall survival was 20.5 months compared to 15.6 months (p=0.0042)
  - The 5-year survival benefit was consistent with the interim analysis in patients who received Optune in combination with TMZ compared to TMZ alone.⁴
- Because TTFields do not enter the bloodstream like a drug, they did not cause many of the side effects of chemotherapy, like infections, nausea, vomiting, diarrhea, and lowered blood counts.³ The most common (≥10%) adverse events seen when using Optune alone were scalp irritation from device use and headache.
- Optune weighs approximately 2.7 lbs. Its lightweight design allows patients to go about their daily activities while receiving treatment.
- Optune uses 4 adhesive patches, called transducer arrays, to deliver therapy. These transducer arrays are applied to the shaved scalp and are connected to the device and battery.⁷
- The transducer array placement is determined based on each patient's MRI results to help optimize the effect that TTFields have on the tumor.
- The FDA previously approved Optune in 2011 for the treatment of recurrent GBM after surgery and radiation options have been exhausted.
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.

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.

Important Safety Information

Contraindications

Do not use Optune if you have 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 if you 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

Use Optune only after receiving training from qualified personnel, such as your doctor, a nurse, or other medical personnel who have completed a training course given by Novocure™ (the device manufacturer).

Do not use Optune if you are pregnant, you think you might be pregnant or are trying to get pregnant. It is not known if Optune is safe or effective in these populations.

The most common (≥10%) adverse events involving Optune in combination with temozolomide were low blood platelet count, nausea, constipation, vomiting, fatigue, scalp irritation from device use, headache, convulsions, and depression.

The most common (≥10%) adverse events seen when using Optune alone were scalp irritation from device use and headache.

The following adverse reactions were considered related to Optune when using the device alone: scalp irritation from device use, headache, malaise, muscle twitching, fall and skin ulcer.

All servicing procedures must be performed by qualified and trained personnel.

Do not use any parts that do not come with the Optune Treatment Kit, or that were not sent to you by the device manufacturer or given to you by your doctor.

Do not wet the device or transducer arrays.

If you have an underlying serious skin condition on the scalp, discuss with your doctor whether this may prevent or temporarily interfere with Optune treatment.

References: