Summary for Patients and Families

PBTC-048 Feasibility Trial of Optune for Children with Recurrent or Progressive Supratentorial High-Grade Glioma and Ependymoma

PBTC 048:

For patients with a recurrent or progressive supratentorial high-grade glioma or ependymoma, the primary objectives are: 1) to evaluate the feasibility of treatment with Optune, which involves the application of electrical fields, in pediatric patients with recurrent/refractory/progressive supratentorial malignant glioma or ependymoma, and 2) to describe the Optune device treatment-related toxicities in children with recurrent/refractory/progressive supratentorial malignant glioma or ependymoma.

For patients with a newly diagnosed diffuse intrinsic pontine glioma (DIPG), the primary objectives of this study are: 1) to describe the safety and tolerability of concurrent Optune therapy, which involves the application of electrical fields, and radiation therapy, 2) to evaluate the feasibility of treatment with concurrent Optune and radiation therapy, and 3) to estimate the overall survival in patients with DIPG treated with concurrent Optune therapy and radiation therapy.

The Pediatric Brain Tumor Consortium (PBTC) is conducting this research study. The PBTC is a group dedicated to improving the treatment of childhood brain tumors. It comprises sixteen academic centers and children's hospitals in the United States and Canada.

The following is a summary of a clinical trial, a therapeutic research study. Clinical trials include only patients who choose or whose parents permit them to participate. Participation is entirely voluntary.

Who might be eligible to participate in PBTC-048?

Patients with a recurrent or progressive supratentorial high-grade glioma or ependymoma or who are newly diagnosed with a brain stem tumor called Diffuse Intrinsic Pontine Glioma (DIPG) are eligible to participate in this study.

Patients who have been diagnosed with a supratentorial malignant glioma or ependymoma that has grown or recurred, and no further standard curative therapies are known, may be eligible. Patients may be eligible who are between 5 and 21 years of age. People who choose not to participate in a study are usually treated with more chemotherapy and/or radiation. Sometimes, combinations of these are used and your study doctor can explain which may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for several months or more. Eligible patients must be finished with other therapies, depending on the type of therapy, between 7 days prior and 3 months prior to enrollment on this study. The neurological status needs to be stable for at least 1 week prior to enrollment. Patients must have adequate organ and marrow function.

Patients who have been newly diagnosed with a diffuse intrinsic pontine glioma (DIPG) may also be eligible to participate in this study. Patients must be between 3 and 21 years of age.

Patients may not have had any prior antitumor therapy except surgery and/or steroids. Radiation therapy and Optune device application start date must be at least 5 days after the date of a tumor biopsy is obtained. Stable neurologic deficits are not an eligibility criterion. Patients must have adequate organ and marrow function. During concurrent Optune therapy and RT and Optune therapy alone, patients must be willing to keep their heads shaved throughout treatment. Patients receiving any other anticancer or investigational drug therapy are not eligible.

Patients with primarily infra-tentorial or spinal cord tumors are not eligible. Patients with major skull defects are not eligible. Patients with active implanted electronic devices in the brain or spinal cord, such as programmable VP shunts, deep brain stimulators, and vagus nerve stimulators, are not eligible. Patients with pacemakers, defibrillators, or documented significant arrhythmia are not allowed. Patients with foreign body intracranially, such as bullet fragments, are not allowed, except VP-shunts (non-programmable) and Ommaya catheters. Patients with a history of hypersensitivity to conductive hydrogel are not eligible.

Why is PBTC-048 being undertaken?

We are doing this study to find out if this approach is better or worse than the usual approach for recurrent or progressive supratentorial high-grade glioma or ependymoma, or newly diagnosed DIPG.

This study also tests the feasibility of treatment with the Optune device in pediatric patients. Feasibility will be determined based on whether you are able to wear the device as instructed by your study doctor.

This study will also test whether it is safe and tolerable to treat children with newly diagnosed DIPG with the Optune device and radiation therapy simultaneously. We will also learn if children with DIPG who are treated with the Optune device during and after radiation therapy survive longer compared to children with DIPG treated in other studies in the past.

What is involved in this study?

For patients with recurrent or progressive supratentorial high-grade glioma or ependymoma, Cycle 1 includes a 7 day training period prior to 28-day treatment (total 35 days). During this period, you and your family will have time to learn about the Optune device, how to apply it, and how to change the arrays. All cycles of therapy after Cycle 1 will be 28 days long. You should wear the Optune device for 18 or more hours per day with a recommendation of 22 or more hours per day for at least 23 days in a 28-day cycle. No other anticancer treatments (chemotherapy or radiation) may be given during the period of participation in the clinical trial. The transducer arrays will need to be changed every 3 to 4 days throughout the study. If you have benefited from receiving Optune treatment, and the study doctor agrees, you may be able to continue using Optune for up to 24 months. You will have a study visit with your doctor before each new cycle of Optune therapy. During your study visits, you will have exams, tests, and procedures to help your doctor closely monitor your safety and health.

For patients with newly diagnosed DIPG, Cycle 1 will start on your first day of RT. You may start Optune treatment on the same day as RT or up to 5 days later. Your doctor will decide when you will start radiation and Optune therapy. On your first day of combined RT and Optune therapy, you will start a training period of up to 7 days. During this period, you and your family will have time to learn about the Optune device, how to apply it, and how to change the arrays. The transducer arrays will need to be changed every 3 to 4 days throughout the study. You should

wear the Optune device for 18 or more hours per day with a recommendation of 22 or more hours per day throughout treatment, including on days you receive radiation therapy. After the training period, you should wear the Optune device for at least 40 out of the remaining 49 days of Cycle 1. All cycles of therapy after Cycle 1 will be 28 days long and will only include treatment with the Optune device. You should wear the Optune device for 23 or more days per 28-day cycle. You can repeat 28-day cycles of the Optune device for up to 5 years if you and your doctor think it helps treat your cancer and the side effects do not become too severe. You will have a study visit with your doctor at the end of the first week and then every 2 weeks (Week 3 and Week 5). You will also have a study visit with your doctor after finishing radiation therapy, and before each new cycle of Optune therapy. During your study visits, you will have exams, tests, and procedures to help your doctor closely monitor your safety and health.

What are the risks of participating in PBTC-048?

There are risks associated with treatment with the Optune device. Some of the most common side effects of Optune therapy that the study doctors know about are:

- Warmth, tingling, or pain on your scalp
- Allergic reaction to the gel or plaster used between the device and your skin
- Skin breakdown that may lead to infection
- Headache
- Fatigue
- Seizure

Patients with a newly diagnosed DIPG will also receive radiation therapy, which also has risks. The common side effects of radiation therapy include:

- Tanning or reddening of the skin over the back of the scalp
- Hair loss over the back of the scalp

The study doctors do not know who will or will not have side effects. Some side effects may go away quickly, some may last a long time, and some may never go away. Some side effects may be mild. You can ask your study doctor questions about side effects at any time. Your study doctor will work with you to treat your side effects.

QUESTIONS ABOUT THIS STUDY?

If you would like more information, please contact the PBTC member institution closest to you. You can also contact the doctor in charge of this study:

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OTHER INFORMATION IS AVAILABLE THROUGH

The National Cancer Institute's Cancer Information Service at 1-800-422-6237 or TTY: 1-800-332-8615 or through the National Cancer Institute's websites www.Cancer.gov and www.cancer.gov/clinicaltrials.