

## **SUMMARY FOR PATIENTS AND FAMILIES**

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

This is a brief summary of a clinical trial, a type of therapeutic research study. Clinical trials include only patients who choose, or whose parents permit them to take part in the research study. Participation is entirely voluntary.

#### **Who might be eligible to participate in PBTC-048?**

Patients may be eligible who are between 5 and 21 years of age, who have been diagnosed with supratentorial malignant glioma or ependymoma that has grown or recurred, and no further standard curative therapies are known. 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.

#### **Why is PBTC-048 being done?**

The purpose of this study is to test the safety of a medical device called Optune. The Optune System is a portable battery or power-supply operated device which produces changing electrical fields, called tumor treatment fields (“TTFields”) within the human body. TTFields are applied to the head of the patient by electrically-insulated transducer arrays, which need to be changed every 4 to 7 days. This device has only been tested in adults but not in children.

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. There will be 20 people taking part in this study.

Specifically, the main goals of this research study are to:

- Learn the feasibility of treatment with the Optune device in pediatric patients with recurrent/refractory/progressive supratentorial malignant glioma and ependymoma
- Learn what side effects (good or bad) may occur when patients are treated with Optune device

#### **What is involved in this study?**

You will wear the Optune device for a minimum of 18 hours a day, with a recommendation of 22 hours per day for at least 23 days in a 28-day cycle. Cycle 1 includes 7 days training period prior to 28-day treatment (total 35 days). 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. Benefit means your disease is at least clinically and radiographically stable and you have not had any significant side effects. The study doctor will continue to watch you for side effects and follow your condition till disease progression or death.

No other anticancer treatments (chemotherapy or radiation) may be given during the period of participation in the clinical trial.

You will be fitted and will receive the Optune device at your participating institution during a regular study visit.

During the course of the study, it will be necessary for certain data to be downloaded from the Optune Device. These data downloads will be performed by a Novocure Device Support Specialist (DSS). Effort will be made to schedule data downloads to occur during regularly scheduled study visits at your study site. However, under some circumstances it may be necessary, or for your convenience, you may prefer to schedule the data downloads to occur in your home.

Adjustments to the Optune device or other troubleshooting measures may be necessary during the course of the study. You may elect for any necessary adjustment or troubleshooting to occur at your study site; or, for convenience, you may elect for this technical support to be provided in your home by the device specialist.

In the event that it is necessary or you elect for a data download, Optune device adjustment or troubleshooting to occur in your home, efforts will be made for a representative from your study doctor's team to be available by phone during any home visits by the device specialist; however, due to scheduling and personnel availability, it may not be possible for a representative from your study doctor's team to be available.

Please note that your study doctor is responsible for your medical care, and the device specialist is strictly an Optune technician who works for Novocure and not your study site. The device specialist will not provide any type of medical care or advice, including routine or urgent, or make any medical recommendations to you during your home visit. Please contact your study doctor for all medical questions, opinions, and treatment.

Prior to and during the study, you or your child will have routine medical tests including a physical exam, blood tests, a pregnancy test for females of child-bearing potential, cardiac tests, brain scan (MRI), and health-related Quality of Life (QoL) assessment. Most of these tests and procedures are all part of routine cancer care, but they may be done more often to monitor you or your child during the PBTC-048 study.

### **What are the risks of participating in PBTC-048?**

Doctors watch study participants very carefully for any side effects or other problems. However, doctors do not know all the side effects which may occur. Side effects may be mild or very

serious. In some cases, side effects may be long lasting or may never go away. There also is a risk of death. Many side effects may go away soon after someone stops using the Optune device.

Treatment with the Optune device is not expected to cause any serious side effects. However, it is possible that investigational treatment could cause any of the following:

- Local warmth and tingling sensation beneath the transducer arrays
- Allergic reaction to the plaster or to the gel that is part of the apparatus
- Skin breakdown
- Infection at the sites of transducer arrays contact with the skin
- Transducer arrays overheating leading to pain and/or local skin burns
- Headache
- Fatigue
- Seizure

There might be other side effects that researchers do not yet know about. If important new side effects are found, your study doctor will discuss these with you.

The health care team may give study participants medicines to help lessen side effects. Doctors will notify patients and patients immediately of any important information or treatment findings discovered during the study that may affect their willingness to continue to participate.

### **What if I have more questions about PBTC-048?**

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

#### **Stewart Goldman, MD**

Ann & Robert Lurie Children's Hospital of Chicago

*Tel:* 312-227-4844

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Other information will be available through the following:

The National Cancer Institute's (NCI) Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or through the NCI's Web site such as [www.cancer.gov](http://www.cancer.gov) and [www.cancer.gov/clinicaltrials](http://www.cancer.gov/clinicaltrials). There is additional accurate and reliable information at [www.cancernet.org](http://www.cancernet.org)