PBTC-007 - A SUMMARY FOR PATIENTS AND FAMILIES

TITLE: A Phase I/II Trial of Iressa™ (ZD1839) and Radiation in Pediatric Patients Newly Diagnosed with Brain Stem Tumors or Incompletely Resected Supratentorial Malignant Gliomas; Phase II is Limited to Brain Stem Tumors

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-007?

Children may participate who are between the ages of 3 and 21, who have a newly diagnosed brain stem glioma or other kind of malignant glioma (brain tumor). Patients without brain stem gliomas will have had surgery which was unable to remove the entire tumor.

Children who have already received chemotherapy, radiation therapy or bone marrow transplant are not eligible for PBTC-007. Children diagnosed with brain stem glioma, who are taking certain kinds of anti-seizure medications, may not be eligible to participate.

Patients who are pregnant or breast-feeding cannot participate in this clinical trial.

Patients will need medical tests to assess whether they can participate in PBTC-007. These tests may include a medical history, physical examination, blood and urine tests and scans (MRI) of the brain and spine. Other tests may be required if doctors believe they are necessary.

About 126 children from all over the U.S. will take part in PBTC-007.

WHY IS PBTC-007 BEING DONE?

Current treatment for highly malignant gliomas in children is radiation therapy, and survival rates are poor. PBTC-007 tests a new drug in combination with radiation therapy in the hopes that this combination may produce a more effective treatment for malignant brain tumors in children.

PBTC-007 uses a new drug, Iressa (ZD1839), which, in laboratory and animal research, affects a molecule that signals a brain tumor cell to divide. This molecule is called “epidermal growth factor receptor” or EGFR. A patient’s brain tumor may or may not express the molecule, EGFR. While Iressa can stop EGFR signals in animal studies, we do not know if it can stop these signals in pediatric brain tumors.

The purposes of PBTC 007 are to:

- Treat children with highly malignant gliomas at the highest safe dose of Iressa (ZD1839) that can be given with radiation therapy without causing bad side effects
• Learn the effects (good or bad) of Iressa on a child and the brain tumor.
• Learn how a child’s body uses Iressa
• Learn if different children with malignant brain tumors have genes that may change the way a body uses Iressa.

WHAT IS INVOLVED IN PBTC-007?

Iressa comes in a tablet that can be swallowed whole with food or dissolved in water or apple juice. Patients will take Iressa once a day. Children will not need to be hospitalized when they take Iressa. But hospitalization may be necessary if severe side effects from the drug or serious illness related to the tumor.

Patients will receive radiation therapy for approximately 6 weeks. Doctors will then determine whether the tumor appears unchanged or is shrinking. Patients may continue to receive Iressa for about one year.

To monitor patients’ progress during the clinical trial, blood tests and various other tests will be required similar to those given at the beginning of the study. These tests will be repeated every 4 or 8 weeks until the study is over.

Doctors will request permission from parents and participants to study small amounts of blood during the time and after Iressa is given. These research studies will assess how much of the drug remains in the body and whether a child has certain genes that may relate to the body uses Iressa drug. The information from these blood tests will only be used in the laboratory for this purpose. The data are not given to anyone outside of the PBTC unless all patient identifying information is removed. The results of these studies will help doctors understand better how Iressa works.

WHAT ARE THE RISKS OF PARTICIPATING IN PBTC-007?

Patient will be watched carefully for any side effects or other problems. They may be given other medications to make side effects less serious and uncomfortable. Some of the known side effects of Iressa include skin problems, pain, stomach upset, abnormal liver tests, muscle weakness, fatigue and other problems.

There may be unknown risks and discomforts involved in participating in this or any clinical trial. Doctors will notify parents and patients immediately of any important information or treatment findings discovered during the study that may affect their willingness to continue to participate.

QUESTIONS ABOUT PBTC-007?

For more information, please contact the PBTC member institution closest to you. You can also contact the doctors 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 visit the National Cancer Institute’s websites:

- cancer.gov
- CancerTrials: comprehensive clinical trial information
- CancerNet: accurate cancer information