SUMMARY FOR PATIENTS AND FAMILIES

PBTC-058: Phase 2 Study of Intraventricular Omburtamab-based Radioimmunotherapy for Pediatric Patients with Recurrent Medulloblastoma and Ependymoma

This study is being undertaken by the Pediatric Brain Tumor Consortium (PBTC). The PBTC is a group dedicated to improving treatment options for childhood brain tumors. It is made up of eleven academic centers and children's hospitals in the United States.

The following 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-058?

Patients with medulloblastoma or ependymoma that has grown or come back after receiving chemotherapy (anti-cancer therapy) and/or radiation therapy. Patients must not be older than 22 years of age at the time of enrollment. Pregnant women are excluded from this study.

Why is PBTC-058 being undertaken?

For patients who have medulloblastoma or ependymoma, there is a clear need to develop more effective therapies. This research will study an investigational drug called ^{131}I-omburtamab to see if it is safe for children when added to standard chemotherapy (anti-cancer therapy). The research will also investigate whether the addition of ^{131}I-omburtamab lowers the chance of tumor growth and improves survival compared to patients in the past who only received chemotherapy and/or radiation therapy.

What is involved in this study?

Most patients are expected to complete 2 courses of induction chemotherapy (Irinotecan + temozolomide + bevacizumab) before receiving ^{131}I-omburtamab. However, some patients might receive 4 courses of induction chemotherapy. The duration of each course will be 28 days. The induction chemotherapy will be followed by 4-6 weeks of observation during which the patient will undergo a surgery to place an intraventricular access device (i.e., Ommaya or programmable VP shunt). Following the observation period, patients who meet criteria to start treatment will proceed to radioimmunotherapy (56 days in length) which consists of two therapeutic doses of ^{131}I-omburtamab. Following radioimmunotherapy, patients will continue to receive maintenance chemotherapy (28 days/course) for up to 12 total courses in the absence of progressive disease or unacceptable toxicities.

What are the risks of participating in PBTC-058?

There is a risk that patients may experience side effects from the study drug. Some of the most common side effects that the study doctors know about are headaches, dizziness, nausea and vomiting. Other rare adverse effects include chemical meningitis, cough, allergic rhinitis, dermatologic side effects, hematuria, development of other cancers and lower white blood cell counts, leading to a high risk of infection. A potential

incidence of anemia or low platelet counts may require the administration of red blood cells and platelets. There may be some risks that the study doctors do not yet know about.

There may be unknown risks and discomforts involved in participating in this or any clinical trial. In the event of adverse effects, the health care team may modify the treatment and/or incorporate additional medical tests to monitor adverse effects. 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 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 1-800-422-6237or TTY: 1-800-332-8615 or through the National Cancer Institute's websites www.Cancer.gov and www.cancer.gov/clinicaltrials.