

UAB18113 - A SUMMARY FOR PATIENTS AND FAMILIES

Title: Phase I Clinical Trial of HSV G207 in Children with Recurrent or Refractory Cerebellar Brain Tumors

This is a brief summary of a clinical research trial or study. Participation is entirely voluntary. When we say “you”, we mean you or your child; “we” means the doctors and other staff.

WHY IS THIS STUDY BEING DONE?

We are using HSV G207 because it has been shown to be safe in Phase I trials in adults and children with brain tumors and some responded to the treatment. The goal of this study is to determine the highest safe dose (maximum tolerated dose) without causing severe side effects. We also want to learn what kind of side effects can be caused by G207 and what side effects can be caused by G207 when given in combination with a single dose of radiation therapy. G207 is an experimental herpes simplex virus (HSV). HSV causes cold sores and rarely causes a severe brain infection. G207 has been genetically changed and weakened, in the hope that only cancer cells will be infected and killed by the virus, without harming normal brain tissue. A dose of radiation combined with G207 may increase the virus' ability to kill cancer cells. The purpose of this study is to test the human safety of G207 alone or combined with a single dose of radiation to see what effects (good or bad) it has on you and your brain tumor. It is our hope that G207 will be a safe and an effective treatment for childhood brain tumors.

WHO MIGHT BE ELIGIBLE TO PARTICIPATE IN THE STUDY?

Patients who are age 3-18 years old with pathology confirmed diagnosis of recurrent or progressive brain tumor not involving the ventricle or brainstem may be eligible for the study. Patients must have fully recovered from acute treatment related toxicities of all prior chemotherapy, immunotherapy or radiotherapy prior to entering this study. It is anticipated that 15 patients will take part in the study. Prior to participation in the study, medical tests are required to determine whether a patient can participate. These tests may include a medical history, physical exam, blood, urine, and saliva tests, and an MRI scan of the brain and spine. Other tests may be required.

WHAT IS INVOLVED IN THIS STUDY?

If you qualify and volunteer for this study, you will have a neurosurgery to confirm that the tumor is growing back and to place one to four catheters (flexible tube) into the tumor which will come outside the scalp through a surgical opening where the skin will be closed around it. A postoperative CT scan will be obtained to confirm the location of each catheter within the tumor, and then the catheter(s) will be hooked up to a syringe pump and the virus will be pumped in during a 6 hour infusion. After the infusion, the catheters will be removed. Some patients will receive a single dose of radiation within 24 hours of the virus infusion. The radiation will be directed to areas of tumor by a trained Radiation Oncologist. The radiation treatment is expected to take 10-30 minutes. If there are no complications after you recover, you will remain in a regular hospital room for an estimated 2-3 days to be watched, in case you have any side effects.

After the treatment, you will be required to return to the clinic for evaluation at 7, 14, and 28 days; 3, 5, 7, 9, 12, 18 and 24 months while on the study. Each time, you will have many exams and tests repeated, including a physical exam, blood tests and MRI scans, and your doctor will ask about side effects and about medications you may be taking. Patients who are unable to follow-up in person will be contacted by telephone on a yearly basis to monitor for delayed events.

WHAT ARE THE RISKS OF PARTICIPATING IN THE STUDY?

G207 has been tested on very few people (less than 50), and little is known about side effects in humans. Side effects that have been seen in patients shortly after experimental treatment with G207 so far include headache, nausea, vomiting, decreased appetite, dizziness, increased seizure activity, fever, fatigue, and temporary enlargement of tumor on MRI. There may also be side effects that we cannot predict. Your healthcare team will discuss potential side effects with you prior to you deciding whether to participate. If you elect to participate, you will be immediately notified of any important information or treatment findings discovered during the study that may affect your willingness to continue to participate.

WHERE CAN I GET MORE INFORMATION?

For more information, please refer to the clinicaltrials.gov page (NCT03911388) at:

<https://clinicaltrials.gov/ct2/show/NCT03911388>

You may also call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also contact the study coordinator, Kara Kachurak at (205) 638-9285 or kkachurak@peds.uab.edu, or the doctor in charge of this study:

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