

PBTC-020 - A SUMMARY FOR PATIENTS AND FAMILIES

TITLE: A Phase I Clinical Trial of AZD2171 in Children with Recurrent or Progressive Central Nervous System (CNS) 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-020?

Children less than 21 years of age may be eligible to participate in PBTC-020. Eligible patients may have any type of brain or spinal cord tumor for which there is no known curative therapy. Eligible patients' tumors have recurred, progressed or been unresponsive to prior treatment.

Patients will need medical tests to assess whether they can participate in PBTC-020. These procedures may include a medical history, physical examination, blood tests and scans (MRI) of the brain and spine. Other tests may be required if doctors believe they are necessary.

WHY IS PBTC-020 BEING DONE?

PBTC-020 uses a new investigational drug, AZD2171 to study whether it is useful to treat pediatric brain or spinal tumors. Recent findings show shown that AZD2171 can block the formation of new blood vessels which tumor cells need to grow and survive. PBTC-020 is the first time AZD2171 will be tested in children.

The purposes of this study are to:

- Find the highest dose of AZD2171 that can safely be given without causing severe side effects
- See what effects (good or bad) AZD2171 has on a child and the child's tumor
- Learn how a child's body processes AZD2171 by studying fluids of the body
- Measure certain cells and proteins in the blood to see if changes are related to how the tumor responds to AZD2171.

WHAT IS INVOLVED IN PBTC-020?

AZD2171 comes in tablet form. Study participants will swallow the tablets on an empty stomach or 1 hour before or 2 hours after a meal once a day. The tablets need to be taken at same time each day. Tablets need to be swallowed whole and cannot be crushed.

Participants will take AZD2171 every day for 28 days. Then they will receive standard medical tests at that time, which may include a physical exam, blood and urine tests and brain scans. After each 28-day period of taking AZD2171, patients will have a similar medical assessment. Participants may receive up to 52 weeks (13 28-day periods) of AZD2171.

Doctors will request permission from parents and patients to study very small amounts of blood and urine from participants to find out what effects AZD2171 is having on the cancer cells and on the body. They will also request permission for patients to have one additional MRI scan between 7 and 14 days after starting the AZD2171. Because AZD2171 is intended to block the development of blood vessels in the tumor, this MRI will look for early changes in blood flow to the tumor.

WHAT ARE THE RISKS OF PARTICIPATING IN PBTC-020?

Doctors monitor patients carefully for any side effects or other problems. They may give patients other medicines to lessen the side effects.

Some of the side effects that may be related to AZD2171 are high blood pressure, fatigue, rash, diarrhea, nausea, vomiting, head pain, headache, abnormal thyroid tests, voice changes and other problems. Certain anti-seizure medicines (anticonvulsants) may affect the activity of AZD2171. Certain anticonvulsants may be made less effective while patients are on AZD2171.

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-020?

If you would like 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 through the National Cancer Institute's websites:

- cancer.gov
- [CancerTrials](#): comprehensive clinical trial information
- [CancerNet](#): accurate cancer information