Summary of Changes – YOUTH INFORMATION SHEET

For protocol v10 to:

NCI Protocol #: PBTC-049
Local Protocol #: PBTC-049

NCI Version Date: November 14, 2024
Protocol Version Date: November 14, 2024

I. INVESTIGATOR-INITIATED CHANGES:

#	Section(s)	Comments
1.	General	• Version date has updated in header of document. • Minor administrative updates including corrections of typos and formatting changes have been updated throughout.

Information Sheet Regarding Research Study
(for children from 7 through 12 years of age)

PBTC-049: Testing Savolitinib in Patients with Recurrent, Progressive, or Refractory Medulloblastoma, High-Grade Glioma, Diffuse Intrinsic Pontine Glioma, and CNS Tumors Harboring MET Aberrations

1. We have been talking with you about your (*List child's condition*). (*List child's condition*) is a type of cancer that grows (*Location)*.

2. We are asking you to take part in a research study because you have (*List child's condition*) that has grown back or has not responded to the usual treatment. A research study is when doctors work together to try out new ways to help people who are sick. This study is being done to find the safest dose of the study medicine, Savolitinib, which can be given to children.

3. Children who are part of this study must be able to swallow tablets every day. If you are doing ok, you can continue to take the study medicine for up to 3 years. If your study doctor thinks you may be benefiting from the study medicine, you may be allowed to take it longer than 3 years. During that time, you will return to clinic to be seen by your doctor where you will have blood tests and from time to time some tests to check your heart, x-rays of your right knee and MRIs of your brain and spine.

   Some of the blood we collect is for tests that tell us how much of the study medicine you have in your blood. We will also use a piece of the tumor removed during your previous surgery and another blood sample to get specific information about your tumor by comparing the DNA in your tumor and blood cells.

4. Sometimes good things can happen to people when they are in a research study. These good things are called "benefits." We hope that a benefit to you of being part of this study is that your brain tumor will not grow for a longer period of time or maybe even shrink but we don't know for sure if there is any benefit of being part of this study.

5. Sometimes bad things can happen to people when they are in a research study. These bad things are called "risks." The risks to you from this study are stomach problems such as nausea, vomiting or feeling tired. Less common effects are swelling in your arms or legs, not feeling like eating or a rash. Other things may happen to you that we don't yet know about.

6. Your family can choose to be part of this study or not. Your family can also decide to stop being in this study at any time once you start. There may be other treatments for your illness that your doctor can tell you about. Make sure to ask your doctors any questions that you have.

7. We are asking your permission to collect additional blood and tumor material. We want to collect samples to store in a research bank to do tests in the future. These samples would be taken when other standard blood tests are being performed, so there would be no extra procedures. You can still take part in this study even if you don't allow us to collect the extra blood samples for research.

Information Sheet Regarding Research Study
(for teens from 13 through 17 years of age)

PBTC-049: Testing Savolitinib in Patients with Recurrent, Progressive, or Refractory Medulloblastoma, High-Grade Glioma, Diffuse Intrinsic Pontine Glioma, and CNS Tumors Harboring MET Aberrations

1. We have been talking with you about your (*List child's condition*). (*List child's condition*) is a type of cancer that grows (*Location)*.

2. We are asking you to take part in a research study because you have (*List child's condition*) that has grown back or has not responded to the usual treatment for your kind of brain tumor. A research study is when doctors work together to try out new ways to help people who are sick. The reason for this study is to find the safest dose of the study medicine, Savolitinib, which can be given to children.

3. Children and teens who are part of this study must be able to swallow tablets every day. If you are doing ok, you can continue to take the study medicine for up to 3 years. If your study doctor thinks you may be benefiting from the study medicine, you may be allowed to take it longer than 3 years. During that time, you will return to clinic to be seen by your doctor where you will have blood tests and from time to time some tests to check your heart, x-rays of your right knee and MRIs of your brain and spine.

   Some of the blood we collect is for tests that tell us how much of the study medicine you have in your blood. We will also use a piece of the tumor removed during your previous surgery and another blood sample to get specific information about your tumor by comparing the DNA in your tumor and blood cells.

4. Sometimes good things can happen to people when they are in a research study. These good things are called "benefits." We hope that a benefit to you of being part of this study is that your brain tumor will not grow for a longer period of time or maybe even shrink but we don't know for sure if there is any benefit of being part of this study.

5. Sometimes bad things can happen to people when they are in a research study. These bad things are called "risks." The risks to you from this study are stomach problems such as nausea, vomiting or feeling tired. Less common effects are swelling in your arms or legs, not feeling like eating or a rash. Other things may happen to you that we don't yet know about.

6. Your family can choose to be part of this study or not. Your family can also decide to stop being in this study at any time once you start. There may be other treatments for your illness that your doctor can tell you about. Make sure to ask your doctors any questions that you have.

7. We are asking your permission to collect additional blood. We want to see if there are ways to tell how the cancer will respond to treatment. These samples would be taken when other standard blood tests are being performed, so there would be no extra procedures. You can still take part in this study even if you don't allow us to collect the extra blood samples for research.