THE KICKSTART STUDY

Cohort A

Are you or a loved one being treated with pembrolizumab (Keytruda®) for stage IIIb or stage IV non-small cell lung cancer (NSCLC)?

If so, you or your loved one may qualify to join the KICKSTART study, a research study investigating the potential cancer-fighting ability of tomivosertib, a new investigational immunotherapy to be added to pembrolizumab (Keytruda®).

For some people with NSCLC, immunotherapy is a good option. Generally, immunotherapy for cancer seeks to make the body's natural defense system more effective against the particular type of cancer that a person has. Pembrolizumab (Keytruda®) is an immunotherapy that targets a process used by cancer cells to fight back against the immune system.

Immunotherapy with Keytruda® is known to be effective in treating NSCLC for many, and if it is working well for you, we hope that it continues to do so. Unfortunately, for some people taking Keytruda®, their NSCLC can progress (grow) while on treatment. If your cancer begins to progress while on Keytruda®, you may have the option to participate in the KICKSTART study.

Please read on to learn more about the KICKSTART study. Even if your NSCLC has not progressed while on Keytruda®, you may want to be aware of the KICKSTART study because the status of your cancer can change.

What drug is being researched in the KICKSTART study?

The battle between the immune system and cancer is very complex. This complexity means that there are multiple ways through different drugs to help the immune system get an upper hand in this battle. The purpose of the KICKSTART study is to see whether adding tomivosertib (called "Tomi" in this brochure) to Keytruda® will be more effective than Keytruda® alone.

Tomi, the drug being researched, is said to be investigational because it has not been approved by regulatory authorities. Tomi is taken by mouth and works by hindering the activity of proteins that help tumor cells grow and go unnoticed by the immune system. The way that Tomi helps the immune system is different from the way that Keytruda® works, and it is expected that helping the immune system in both ways at the same time will achieve better results for people whose NSCLC has progressed on Keytruda®.

What is the treatment plan for the KICKSTART study?

There will be 2 groups (called "cohorts") participating in this study. This brochure is for Cohort A, which consists of people whose NSCLC has progressed while taking Keytruda®. Please ask to see the brochure for Cohort B if you have never been treated with Keytruda®.

Study participants in Cohort A will continue receiving Keytruda® throughout the treatment period of the study. In addition, study participants will be assigned to receive either Tomi or a placebo. The placebo has no active ingredients and is designed to look like Tomi. Neither the study participant nor the study doctor will know whether Tomi or placebo has been assigned. The chance of receiving Tomi or placebo is the same, 50%.

Who can participate in the KICKSTART study?

To join this study, potential study participants must:

- be diagnosed with Stage IIIb/IV NSCLC
- have a PD-L1 level of 50% or more
- have not received prior chemotherapy in the advanced metastatic setting
- have received pembrolizumab (Keytruda®) prior and developed progressive disease while on the medication

Additional requirements to participate must also be met. The staff at the study center will explain the complete list of requirements.

The KICKSTART study will involve approximately 120 participants in approximately 60 sites in the United States.

What will happen during the KICKSTART study?

The study is divided into 3 parts.

Screening Period
At the screening visit, the study staff will first give a detailed explanation of this study and its potential risks and benefits. This explanation will be made verbally and in writing. Only after obtaining written informed consent from the potential participant will study-specific procedures take place. Next, the study doctor and the staff will conduct a series of examinations and tests to determine whether the potential participant meets all study requirements to enter the treatment period. All exams and testing must occur within 25-30 days of the start of the treatment period. The study staff will arrange for the examinations and tests.

Treatment Period
Participants who qualify will then be assigned to their treatment group (Tomi or placebo) and the appropriate treatment will be dispensed. Participants will take the assigned treatment by mouth in the morning and again in the evening with meals. In addition, participants will continue to receive Keytruda® in the same 3-week or 6-week intervals as they did prior to joining the study. Regardless of the Keytruda® schedule, participants will visit the study clinic every 3 weeks.

The length of the treatment period will depend on how well each participant tolerates their assigned treatment and how their cancer responds.

Follow-up Period
Safety follow-up visits will occur at approximately 30 days and 100 days after the last dose of assigned study treatment or last Keytruda® infusion. Additional follow-up information will be collected at routine clinic visits or by email or telephone about every 3 months for up to 3 years.

Does it cost anything to participate?

There is no cost to participate. Qualified participants receive Tomi, the investigational drug, or placebo and all required study-related medical assessments and examinations at no cost. The cost of Keytruda® is not included as a part of the study.

Are there any risks to participating in this study?

There may be potential risks to participating in this study. All drugs and medical procedures carry a risk of side effects; therefore, it is possible that participants may experience some discomfort or other reactions from use of the research study drug. If you decide to participate, the study staff will explain the potential risks to you before any study procedures are conducted.

What are the potential benefits of participating?

Participants may or may not receive any benefit from being in this study. It is possible that participants may get better, stay the same, or get worse. The information learned from this study may help find new treatment options for people diagnosed with NSCLC in the future.

KICKSTART