Keynote 158

What is immunotherapy?

Immunotherapy is a type of therapy that may help the body's immune system attack cancer cells. The investigational immunotherapy used in this study is called pembrolizumab (or MK-3475) and targets a protein called PD-1 found on some cells of the immune system. Pembrolizumab blocks the interaction of PD-1 with another protein called PD-L1, sometimes found on tumor cells. Blocking this interaction may help the immune system recognize tumors and attack them.

Why is this study being done?

This study is being done to see if an investigational immunotherapy, pembrolizumab, is safe and effective in slowing down or stopping the progression of cancer. It is not known if the investigational immunotherapy is effective at treating the specific cancer being studied.

Why would I consider a clinical trial?

Clinical trials or clinical studies are research studies that involve and test new ways that may help prevent, detect, diagnose, and/or treat cancer or other diseases. Clinical trials help determine if investigational medications are safe to use and work to improve the health of people. Researchers are continuing to study and develop new options for patients with cancer, including those patients who may have progressed on other cancer therapies. Deciding to participate in a clinical trial is something only you, those close to you, and your doctors and nurses can decide together.

If you are interested in the possibility of receiving an investigational immunotherapy, this clinical research study may be an option for you to consider. Before deciding to participate, you should make sure you understand the potential side effects or risks of participating in the study. These will be explained to you by the study doctor. If there is anything you do not understand; you are encouraged to ask the study doctor.

If I participate, what will happen during visits?

Initially, you'll undergo tests to determine if you're eligible for the study. You may have a sample of the metastatic tumor tissue tested for the protein PD-L1. Metastatic tumor tissue is the tissue in which the cancer cells have spread outside of the original tumor. Procedures completed during routine study visits may include blood tests, physical exams, administration of medication(s), and imaging scans such as CAT scans or MRIs. Visits will occur at regular intervals to enable your doctors to assess your response to the investigational medication. You may have the option to continue on the study for a longer period of time if you respond well to the investigational medication and you and your doctor agree it is appropriate for you to continue.

Since the study is being conducted to help determine the effectiveness of the investigational medication, it will be important for your doctor to maintain contact with you, even after you've completed study related visits. Please be sure to ask your doctor any questions you might have related to procedures completed during study visits and the frequency at which they will occur.

Additional requirements for participating in the study will be explained to you by the study doctor.

Who can participate?

There are eligibility requirements that you must meet in order to participate. You and your study doctor should discuss them to help decide if this study might be a good option for you.

What requirements are in place to help protect clinical trial participants?

Regulations and policies have been developed to help protect the rights, safety, and well-being of people who take part in clinical research studies and to help ensure that these studies are conducted according to strict scientific and ethical principles.

Before a clinical research study can begin, a review board must review and approve the study. This group is called an IRB or institutional review board, and is comprised of doctors, scientists, and members of the community.

What is the informed consent process?

Since many clinical trials involve new drugs or test drugs in new ways, there are risks associated with participation. It is important that patients understand these risks before agreeing to participate. The possible benefits and risks should be discussed with your study doctor. You are encouraged to bring up any concerns you may have and to ask as many questions as you would like.

Once you have had an opportunity to ask questions, and if you decide to become a study participant, you will be asked to sign an informed consent form. Informed consent is a process through which you learn the important facts about a clinical trial to help you decide whether or not to participate. You will receive a copy of the informed consent form to take with you.

Can I leave the study if I change my mind?

You can choose to leave the study at any time—either before it starts or during the study. If you decide to leave the trial, it is important to get information from your study doctor about how to leave the study safely. Your doctor will still provide care for you if you leave the study at any time.

What are my options if my health declines while participating in the study?

If your health declines while you are on study, your doctor will determine if discontinuing your treatment is appropriate and will discuss next steps with you. Your doctor will continue to provide health care to you regardless of whether or not you complete the study.

Thank you

for thinking about participating in this study. The information presented here is to support your discussions with your doctor about this study.

Pharmaceutical companies use medical research studies like this one to learn more about investigational medications. These studies help to determine if investigational medications work and are safe to use. The results of this study will provide additional information about how safe and effective this investigational treatment may be in people with your type of cancer. By taking part in this study, you will be making an important contribution to cancer research.

For more information,

talk to your study doctor or

Contact

Notes:

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