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ECOG-ACRIN opens trial of treatment sequencing in advanced melanoma

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A new phase III cancer treatment trial has opened for patient enrollment that examines two treatments that work in completely different ways yet have both been shown in previous clinical trials to be effective in treating patients with advanced melanoma, the ECOG-ACRIN Cancer Research Group announced today.

Half of the patients in the trial will be randomly assigned to begin treatment with an investigational combination of two immunotherapy drugs, given together, that work by unleashing parts of a person's immune system to kill tumor cells. If the treatment stops working and the disease gets worse, patients will receive a second, different treatment of two other drugs, also given together, that work by blocking molecular pathways that drive tumor cell growth and survival.

For the other half of the patients in the trial, the scenario will be reversed. They will be randomly assigned to begin treatment with the two molecularly targeted drugs, and if those drugs stop working and the disease gets worse, they will be treated with the investigational immunotherapy combination.

Researchers in the ECOG-ACRIN Melanoma Committee are conducting trial EA6134 to find out which sequence of treatments provides the best outcome for patients.

"After many years of research we've ended up with exciting and effective new combination treatment regimens. Now we need to figure

out how to sequence these treatment regimens in order to best extend the lives of our patient," said study chair Michael B. Atkins, MD, a medical oncologist and deputy director of the Georgetown Lombardi Comprehensive Cancer Center in Washington, DC.

"To be better, one sequence should significantly improve the number of patients alive at two and three years from the start of treatment when compared to the other sequence," said Dr. Atkins.

Melanoma skin cancer is the fifth most common cancer in American men and the seventh most common cancer in American women. When found in the early stages of growth in the body, melanoma can often be treated successfully with surgery. However, this trial will recruit 300 men and women aged 18 years and older who have advanced melanoma that has spread beyond its local area and cannot be removed by surgery.

To be considered for the trial, patients' melanoma cells must have a mutation called BRAFV600.

As Dr. Atkins explained: "We have an approved two-drug combination, dabrafenib and trametinib, which works by directly attacking BRAF-mutated melanomas. We also have two immunotherapy options, ipilimumab and nivolumab, each approved for separate use, that work in combination to unleash the body's own immune system to attack the cancer. The question that remains is which of the two drug combinations should be used first and in whom?"

The trial gives patients the potential to cross over and receive the other treatment approach because researchers already know that for many patients, melanoma can be highly aggressive and existing treatments often stop working. As a result, advanced melanoma patients and their physicians find themselves with many treatment options but few answers to questions surrounding how and when to use these new approaches.

Patients in study EA6134 will be treated with the ipilimumab-nivolumab combination for a maximum of two years. The dabrafenib-trametinib combination will be given for as long as it is controlling patients' tumors. Patients will be followed for as long as they are on therapy. After they finish the treatment regimens, their physicians will continue to watch them for side effects and follow their condition for up to five years from the time that they entered the trial.

Patients will not be eligible if they have been treated previously with systemic therapy (oral or intravenous treatment) for existing melanoma or have previously received the study agents or similar agents in any disease setting.

EA6134 trial information is posted online on the ECOG-ACRIN website and is continually updated.

Provided by ECOG-ACRIN Cancer Research Group