

International clinical trial tests targeted drug for melanoma

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Rush University Medical Center has just enrolled the first U.S. patient in an international clinical trial testing a novel drug to treat certain kinds of melanoma, a deadly skin cancer that in its advanced stages currently has few effective treatments.

Rather than blocking or killing all rapidly dividing [cells](#), whether malignant or not, the drug, called nilotinib, is one of a new class of agents that have been designed to sabotage aberrant molecules characteristic of individual cancers – in this case, the c-kit protein.

Dr. Howard Kaufman, director of the Rush University Cancer Center and lead investigator of the study at Rush, said that this kind of "targeted" therapy holds out hope of transforming cancer from a lethal disease into a chronic, but manageable disease.

"For advanced melanoma, there are currently few satisfactory treatments," Kaufman said. "But new targeted therapies, including vaccines, antibodies and small molecules like nilotinib are in clinical trials now, adding to an arsenal of treatments that appear to be promising. This trial is especially significant since the c-kit mutation is found more commonly in melanoma arising from the mucosa and foot, which are historically very difficult types of melanoma to treat."

Nilotinib, marketed by Novartis under the brand name Tasigna, is an oral drug approved by the Food and Drug Administration for the treatment of chronic myelogenous leukemia but is now being tested for the first time

for the treatment of melanomas that express the c-kit gene. As a small molecule, nilotinib is able to slip across the cell's membrane and into the machinery inside. There it targets, and turns off, the abnormal c-kit protein, created by a mutated c-kit gene, shutting it down and thus disrupting the relay team of molecular signals the protein participates in that ultimately spur cell growth and cause melanoma lesions to proliferate.

Patients with melanomas expressing a mutated c-kit gene are eligible to participate in the study. These types of melanomas, which typically occur in mucosal tissue, the eye or the foot, are extremely aggressive. The aim of the trial is to determine whether nilotinib can block the growth and spread of this kind of melanoma and extend life.

Participants will receive either nilotinib or dacarbazine, a chemotherapy drug commonly used to treat advanced melanoma. Those in the latter group will be able to begin receiving nilotinib if their cancer progresses after dacarbazine treatment.

Melanoma is a rare but deadly disease whose incidence is rising faster than that of any other solid tumor. According to the National Cancer Institute, there were 68,700 new cases of [melanoma](#) in 2009, and more than 8,500 deaths caused by the disease. The cancer typically begins in a mole, but can also lodge in other pigmented tissues, such as in the eye or in the intestines. If caught early, when the disease is superficial, the lesions can easily be removed surgically. But if it advances, the prognosis is poor. Median survival is six months to two years.

Provided by Rush University Medical Center

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