New therapy on the horizon for ALK+ non-small cell lung cancer

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A new compound that targets anaplastic lymphoma kinase-positive (ALK+) non-small cell lung cancer is well-tolerated by patients and is already showing early signs of activity, including in patients who no longer respond to crizotinib-the only approved ALK inhibitor. Results of this Novartis-sponsored sudy will be presented by a researcher from Fox Chase Cancer Center during the 2012 Annual Meeting of the American Society of Clinical Oncology on Sunday, June 3.

The compound LDK378, developed by Novartis, targets ALK-a key cancer gene in a subset of lung cancer, lymphoma and the childhood cancer neuroblastoma, and may be associated with other cancers, including breast and colorectal cancer. The study's authors looked at patients with ALK+ lung cancer, as well as other ALK+ solid tumors. Early data from the phase I study show that the majority of patients treated with active doses of LDK378 responded, including those who had progressed after treatment with crizotinib.

"These results are encouraging," says study author Ranee Mehra, M.D., assistant professor and medical oncologist at Fox Chase. "They offer hope to patients who have tumors with alterations involving ALK, even if they have relapsed from previous treatments.

In its first test in people, designed to determine the compound's safety and optimal dose, 56 people with various types of ALK+ solid tumors (primarily lung cancer) were enrolled, receiving doses between 50 to 750 milligrams per day (mg/day). LDK378 was well-tolerated in most patients up to 750 mg/d, with the most common side effects being nausea, vomiting, and diarrhea.

"Whenever you do a trial with a drug, even if it's just designed to look for safety and dosage, you are interested in whether patients responded," says Mehra. "These results are definitely encouraging, and mean we can go forward with additional research looking at whether LDK378 is effective in various types of cancers that have alterations involving ALK."

The fact that patients appeared to tolerate LDK378 at doses up to 750 mg/d is also encouraging, she adds, since preclinical research has suggested this dose would have therapeutic effects.

In the meantime, Mehra and investigators at other centers around the world are continuing to enroll patients in the trial. The next phase of the study will test the maximum tolerated dose of LDK378 in all patients enrolled.

Provided by Fox Chase Cancer Center