FDA approves drug that extends survival in the most common type of lung cancer

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The U.S. Food and Drug Administration today approved a new drug to treat non-small-cell lung cancer (NSCLC), offering patients new hope in fighting this difficult disease. Lung cancer is expected to lead to over 150,000 deaths in the United States this year alone, and NSCLC accounts for about 85 percent of all lung cancers.

The drug, Cyramza (ramucirumab), was tested on more than 1,200 patients with NSCLC whose cancer worsened during or after first-line chemotherapy. The research was conducted as part of a multi-year, phase 3 clinical trial at UCLA and other centers in 26 countries on six continents. The study is the first in previously treated NSCLC patients to demonstrate a survival benefit in the entire study population in approximately a decade.

Cyramza is an antibody that targets the extracellular domain of VEGFR-2, an important protein in the formation of vessels that supply blood to cancer cells. Patients were given the experimental drug in combination with docetaxel, a clinically approved therapy that is considered the cornerstone of second-line treatment in advanced NSCLC, said Dr. Edward Garon, the national principal investigator and a researcher at UCLA's Jonsson Comprehensive Cancer Center.

Results of the study were recently published by Dr. Garon and colleagues in *The Lancet*.

The usual standard therapy for patients when disease worsens during or after initial therapy is chemotherapy with a single drug. This is a patient population for whom an overall survival of several months is usual, with approximately 10 percent of patients responding to therapy.

The response and period of time prior to disease worsening when Cyramza was added to docetaxel were greater than what was seen with docetaxel alone, Garon said. In the study, 23 percent of patients responded to the drug, meaning that their tumors shrank more than a specific threshold used in clinical trials. Overall, the median survival was over 10 months.

"It is exciting to see that by adding ramucirumab (Cyramza) to docetaxel, patients were able to live longer than those who were treated with the standard approach," said Garon. "We are pleased to have access to a drug that lengthens survival time in a population of lung cancer patients who often have few treatment options."

Although adverse effects were experienced by patients, most commonly neutropenia (low levels of white blood cell that fight infection), fatigue and high blood pressure, these were largely manageable with appropriate dose reductions and supportive care, and without substantial reduction in planned dose intensity.

Garon said that in the future Cyramza will be evaluated in combination with other drugs to treat lung cancer. In addition, he noted that efforts are underway to understand which patients are most likely to benefit when Cyramza is added to docetaxel.

More information: "Ramucirumab plus docetaxel versus placebo plus docetaxel for second-line treatment of stage IV non-small-cell lung cancer after disease progression on platinum-based therapy (REVEL): a multicentre, double-blind, randomised phase 3 trial," *The Lancet*, Volume 384, Issue 9944, 23–29 August 2014, Pages 665-673, ISSN 0140-6736, dx.doi.org/10.1016/S0140-6736(14)60845-X.

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