FDA continues recent trend of approval with new second generation lung cancer treatment

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The International Association for the Study of Lung Cancer (IASLC) is once again gratified to see the approval of a new second-generation lung cancer treatment that can help many patients in their battle against the disease. Lung cancer patients got another round of hope with the FDA's rapid progression of lung cancer drug approvals - this time for alectinib (Alecensa, Roche/Genenetech) for patients with advanced (metastatic) ALK-positive non-small cell lung cancer (NSCLC) if their disease deteriorated after treatment with another therapy called crizotinib (Xalkori, Pfizer). Patients who could not tolerate treatment with crizotinib also qualify for use of alectinib.

Lung cancer is the leading cause of cancer deaths around the world, responsible for claiming more lives than prostate, colon and breast cancer combined. Medications that target the individual characteristics of a patient's disease continue to create new options and hope for those with lung cancer. For example, tumor cells in about 5 percent of lung cancer patients with NSCLC contain the ALK (anaplastic lymphoma kinase) genetic mutation. In patients with metastatic cancer, the disease spreads to new part of the body. For ALK-positive NSCLC metastatic patients, the disease often spreads to the brain.

Many ALK-positive patients benefit from treatments called ALK inhibitors, such as crizotinib which blocks the activity of the ALK protein and can prevent NSCLC cells from growing and spreading. Alectinib is an oral medication that performs similarly. Patients can also develop resistance to ALK inhibitors such as crizotinib, so alectinib

gives health professionals a new option to continue to extend their patients' life span. The FDA previously approved ceritinib (Novartis) in the same treatment setting.

"These types of medications that take advantage of a patient's specific genetic mutations are the future of lung cancer treatments and these treatments create a blueprint of how we can turn some cancers into a chronic disease and eventually create a cure," said Fred R. Hirsch, MD, PhD, Professor of Medicine and Pathology at the University of Colorado Cancer Center and School of Medicine and CEO of the IASLC.

Alectinib is the fifth lung cancer treatment approved by the FDA since early October. The others include:

- Necitumumab in combination with standard chemotherapy to treat patients with advanced squamous NSCLC who did not previously received systemic therapy;
- Two immunotherapy treatments: nivolumab and pembrolizumab;
- And osimertinib, a 3rd-generation EGFR TKI.

"It is so fulfilling to see the FDA respond to the rapid pace of developments in lung cancer treatments. It is also a recognition of the dedication scientists and health professionals show every day as they work to find new ways to move us forward, but first and foremost; this gives hope for many lung cancer patients who need it," Dr. Hirsch said.

Provided by International Association for the Study of Lung Cancer