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FDA approves new therapy option for lung cancer patients who develop resistance to early generation EGFR inhibitors

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The International Association for the Study of Lung Cancer (IASLC) commends the U.S. Food and Drug Administration's (FDA) decision to grant accelerated approval for osimertinib (Tagrisso), an oral medication for advanced non-small cell lung cancer (NSCLC) patients with a specific epidermal growth factor receptor (EGFR) mutation (T790M) and following progression after previous EGFR inhibitor therapies.

Several early generation EGFR inhibitor therapies are currently available for lung cancer patients whose tumors contain activating EGFR mutations (Exon 19 deletions and L858R mutations), which occur in approximately 10 percent of lung cancer patients in the U.S. and Western Europe, and nearly 40 percent in eastern Asia. However, 50 percent globally of the EGFR inhibitor treated patients develop another mutation (T790M) that creates a resistance to these early generation EGFR inhibitors. With the FDA's recent accelerated approval of osimertinib, patients with the T790M resistance mutation and whose tumors continued to grow after treatment with other EGFR-inhibitor therapy, now have a new therapy option.

"This gives physicians more resources for patients who develop a resistance after seeing success with other treatments customized to target their specific tumor mutations. It is exciting to see new advances in research come to fruition as we continually work to extend survival for lung cancer patients," said Dr. Fred R. Hirsch, Professor of Medicine

and Pathology at the University of Colorado Cancer Center and School of Medicine and CEO of the IASLC. "Targeting this EGFR resistance mutation represents a great opportunity for many patients for improving treatment outcomes and life perspectives."

Lung cancer is the leading cause of cancer deaths worldwide, causing more than 1.6 million deaths each year. That represents more than breast, colon and prostate cancers combined. However, precision medicines, like osimertinib, gives physicians more options to make a difference.

"By targeting an individual's specific lung cancer based on its molecular characteristics, we move ever closer to the goal of making lung cancer a manageable, chronic or curable condition," Dr. Hirsch said.

The path to accelerated approval was aided by two studies initially presented at the 16th IASLC World Conference on Lung Cancer in Denver in September. Both studies showed the ability of osimertinib to significantly decrease tumor size, 57 percent of lung cancer patients in one study and 61 percent in the other.

In addition to granting accelerated approval for osimertinib, the FDA also approved a new test (cobas EGFR Mutation Test v2) to detect the T790M EGFR resistance mutation. The new version of the test means the therapy will be able to help many more patients in the future.

More information: www.fda.gov/NewsEvents/Newsroo … ements/ucm472525.htm

Provided by International Association for the Study of Lung Cancer