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TRUST study data confirms safety and efficacy of erlotinib for advanced lung cancer

Large, global phase IV study extends therapy benefits beyond standard patient population

Featured in the October edition of the *Journal of Thoracic Oncology* (JTO), data from The Tarceva Lung Cancer Survival Treatment (TRUST) confirms the safety and efficacy profile of erlotinib, a highly potent oral active, reversible inhibitor of epidermal growth factor receptor (EGFR) tyrosine-kinase (TK) activity in a large heterogeneous non-small cell lung cancer (NSCLC) population.

Erlotinib has been shown to significantly increase survival for patients with previously treated advanced NSCLC. Certain groups of patients with NSCLC, such as those with a particular type of cancer - adenocarcinoma, women, Asian ethnicity and non (minimal) smokers are reported to be more likely to have tumor responses to EGFR TK inhibitors (TKIs) than other groups. However, results from the TRUST study suggest that erlotinib can benefit a wide range of patients, including those who have previously been thought unlikely to benefit from this treatment.

The large, global, open-labeled, phase IV trial TRUST study included the participation of 513 centers across 51 countries, culminating safety data from more than 6,500 patients. In patients with advanced NSCLC, the progression-free survival and overall survival in this study were 3.25 months and 7.9 months, respectively, and the disease control rate (defined as the sum complete response, partial response, or stable disease) was 69 percent.

As a post marketing surveillance trial (phase IV) occurring after erlotinib received permission to be sold, the study provided an opportunity to evaluate the efficacy and safety of this medication in a broad patient population in a real-life clinical setting. Furthermore, it included patients with advanced stage IIIB/IV NSCLC who had previously failed on or were considered unsuitable to receive standard chemotherapy or radiotherapy and were ineligible for other erlotinib trials.

"The criteria used for selecting the most appropriate therapy for a patient are of particular interest to physicians," explains lead investigator Martin Reck, MD, PhD. "Tumors with EGFR mutations have been shown to be highly responsive to EGFR TKIs. Although patients whose tumors have these mutations are likely to obtain a greater magnitude of benefit from EGFR TKIs such as erlotinib, it is important to note that the absence of these mutations does not necessarily result in a lack of benefit with erlotinib therapy."

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The JTO is a prized resource for medical specialists and scientists who focus on the detection, prevention, diagnosis and treatment of lung cancer. The JTO is the official monthly journal of the International Association for the Study of Lung Cancer (IASLC.org) and emphasizes a multidisciplinary approach, including original research (clinical trials and translational or basic research), reviews and opinion pieces.

