Studies suggest key correlation between lung cancer subtype and treatment outcomes

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In clinical research, patients with advanced non-small cell lung cancer (NSCLC) that are classified as having a non-squamous histology achieve statistically significant higher survival when treated in the second-line setting with ALIMTA® (pemetrexed for injection) when compared to histologically-similar patients treated with docetaxel. The data were presented at the 14th European Cancer Conference (ECCO) in Barcelona. ALIMTA, manufactured and marketed by Eli Lilly and Company, is currently indicated for the second-line treatment of advanced NSCLC in more than 85 countries.

The retrospective analysis of Phase III data consisted of 571 patients. The analysis showed that non-squamous patients treated with ALIMTA achieved a statistically higher overall survival compared to those treated with docetaxel (9.3 months and 8.0 months, respectively; hazard ratio 0.778 [95% CI 0.607-0.997]). Conversely, the analysis suggested that patients with a squamous histology and treated with docetaxel had a statistically higher overall survival compared to those treated with ALIMTA (7.4 months and 6.2 months respectively; hazard ratio 1.563 [95% CI 1.079, 2.264]). Patients with a non-squamous histology represented the majority of the patients on the trial.

The retrospective analysis was driven by preclinical data that suggested patients with a lower expression of thymidylate synthase (TS) enzyme show an increased efficacy when treated with ALIMTA. , The histological type of NSCLC is determined by how the cancerous cells appear under a microscope. Two of the most common histological types

of NSCLC are adenocarcinoma and large cell carcinoma and constitute approximately 55 percent of all NSCLC diagnoses. These two subgroups, and any other types not identified as squamous, were considered non-squamous for this analysis.

“This particular analysis suggests that histology may play an important role in determining patients who are most likely to receive a larger treatment result from ALIMTA,” said Patrick Peterson, Ph.D., principal research scientist at Lilly and principal author of the analysis.

Patients on the ALIMTA arm were treated with ALIMTA (500 mg/m^2) supplemented with vitamin B12 and folic acid. Patients on the docetaxel arm were treated with docetaxel (75 mg/m^2).

Data from a second trial (ECCO Abstract # 6560) detailed additional predictive factors for a patient’s potential benefit from treatment with ALIMTA. In a Phase II prospective study, researchers in Japan evaluated the survival outcomes of 216 patients with locally advanced or metastatic NSCLC who were treated with ALIMTA in the second-line setting. The data suggested that favorable predictive factors for ALIMTA treatment in the second-line NSCLC setting could include the following: female patients; patients with adenocarcinoma histology; patients with a longer interval since their previous chemotherapy treatment; patients with good performance status, and; those diagnosed in the early clinical stage.

“Cancer treatment continues to move in the direction of tailoring therapies to meet the needs of the specific types of cancers and patients,” said Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader for Lilly. “Our goal is to further explore the biologic rationale for this observation in non-squamous histology and work toward developing a biomarker approach to determine when ALIMTA is the right drug for the right patient.”

ALIMTA, as a single agent, was approved by both the European Medicines Agency (EMEA) and the U.S. Food and Drug Administration (FDA) in 2004 for the treatment of patients with locally advanced or metastatic NSCLC after prior chemotherapy. The effectiveness of ALIMTA in second-line NSCLC was based on the surrogate endpoint, response rate. There are no controlled trials demonstrating a clinical benefit, such as a favorable survival effect or improvement of disease related symptoms.

Source: CPR Worldwide