

Lilly studies try to shed light on impact of race

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Statistics show lung cancer is the leading cause of cancer death in African-Americans, with 21,550 new cases expected to be diagnosed and 16,700 deaths expected this year. Equally devastating, lung cancer is the leading cause of cancer death in Hispanic men and the second leading cause of cancer death in Hispanic women. Researchers at Eli Lilly and Company are actively investigating the efficacy and safety of lung cancer treatments ALIMTA® (pemetrexed for injection) and GEMZAR® (gemcitabine HCl for injection) in treating non-small cell lung cancer (NSCLC) in African-Americans, Hispanics and other diverse populations.

Two retrospective Lilly studies were unveiled today at the 43rd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Ill. They offered cursory insight into how a diverse group of patients respond to treatment with Lilly chemotherapeutic options. One study analyzed data of chemo-naïve African-American patients with stage IIIB/IV NSCLC treated with GEMZAR in combination with carboplatin or paclitaxel (Taxol®) versus patients taking carboplatin in combination with paclitaxel. The second study provided data from six previous trials for non-Caucasian patients with advanced or metastatic NSCLC treated with ALIMTA.

“African-Americans are often underrepresented in clinical trials and, therefore, little is known about the possible impact of race on the utility of many medications,” said Coleman Obasaju, M.D., Ph.D., United States oncology medical director of Lilly and the principal investigator

of these two studies. “Because lung cancer is a particularly devastating disease, and a growing concern in the African-American population, it was a logical starting point for our analysis.”

The GEMZAR study released at ASCO analyzed overall survival data from a previous randomized Phase III trial in the treatment of NSCLC, viewing data outcomes and toxicity data of 128 African-Americans compared with 906 Caucasians. The trial was designed to compare the efficacy of GEMZAR plus carboplatin with GEMZAR plus paclitaxel and a reference regimen of carboplatin plus paclitaxel. Data from all three arms were pooled for this analysis. Overall survival, the primary endpoint, on the African-American arm was 8.7 months compared to 8.1 months in the Caucasian arm, which was not significantly different. African-Americans demonstrated slightly lower incidences of grade 3/4 toxicities (constitutional, hemorrhagic and metabolic).

The ALIMTA study reviewed a post-hoc analysis of pooled data from six previous trials, including one Phase III in a second-line setting and five Phase II trials in a first-line setting. Patients with Stage IIIB/IV NSCLC were given at least one dose of ALIMTA (single-agent or in combination with other treatments) every 21 days. The trial evaluated results from 411 Caucasian patients compared with 117 non-Caucasian (African-American, Asian and Hispanic) patients. Based on this analysis, race did not have a statistically significant impact on efficacy parameters (response rate, survival and disease control rate). Non-Caucasian patients had lower grade 3/4 toxicities, including neutropenia (a decrease in white blood cells); anemia (a decrease in red blood cells); fatigue; and nausea.

“At the very least, the data unveiled today suggests that we should continue actively studying the impact of our medications on a diverse number of populations,” said Dr. Obasaju.

To that end, Lilly recently began enrollment into what may be the largest and most diverse Phase III study in NSCLC. The study will evaluate ALIMTA in 1,000 patients with NSCLC. Enrollment will include 200 African-Americans, 200 Asians, 200 Hispanics and 400 Caucasians. For more information on this trial visit www.lillytrials.com or www.clinicaltrials.gov.

“Scientific reasoning tells us that because of genetic differences, patients with similar tumors may respond differently to specific treatment regimens,” said Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader at Lilly. “Ultimately, our goal is to ensure that we offer the optimal outcome to each and every patient.”

Source: CPR Worldwide

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