

Adding bavituximab to second-line chemotherapy doubles response rate

September 6 2012

Adding the monoclonal antibody bavituximab to docetaxel chemotherapy doubles overall response rate and improves progression-free survival and overall survival in late-stage non-squamous, non-small cell lung cancer (NS-NSCLC) patients who have already received one prior chemotherapy regimen, according to research presented at the 2012 Chicago Multidisciplinary Symposium in Thoracic Oncology. This symposium is sponsored by the American Society of Clinical Oncology (ASCO), the American Society for Radiation Oncology (ASTRO), the International Association for the Study of Lung Cancer (IASLC) and The University of Chicago.

Docetaxel is the standard second-line treatment for stage IIIB and stage IV NS-NSCLC patients. Researchers in this phase II, nine center, double-blind, randomized study evaluated the efficacy and safety of docetaxel plus a placebo (control arm) versus docetaxel plus either 1 mg or 3 mg bavituximab. The 117 evaluable patients were randomized to receive one of the three regimens every 21 days for up to six cycles. Patients received the same regimen for each cycle.

The overall response rate for the 1 mg bavituximab arm was 15 percent and 17.9 percent in the 3 mg arm, approximately double the control arm rate of 7.9 percent. Median progression-free survival was 4.2 and 4.5 months for the bavituximab arms, respectively, compared to three months for the control arm.

The trial was unblinded after 18 months, at which point the median

overall survival had been reached in the control arm at 5.4 months (61 percent of patients died); however, neither bavituximab arms had reached median overall survival (fewer than 35 percent of patients died).

"This rigorous phase II trial demonstrates that not only is bavituximab well tolerated when given with [docetaxel](#) but it improves response rates, progression free survival and overall survival of second-line chemotherapy in patients with advanced NSCLC," said David Gerber, MD, lead author of the study and an assistant professor of internal medicine at University of Texas Southwestern Medical Center in Dallas who specializes in lung cancer treatment. "If a phase III trial confirms these findings, bavituximab could become a major component of standard treatment for patients with this challenging disease."

More information: The abstract, "Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial of Bavituximab Plus Docetaxel in Patients with Previously Treated Locally Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer (Top-line Results)," will be presented during the Plenary Session at 12:30 p.m., Central time on September 7, 2012.

Provided by American Society for Radiation Oncology

Citation: Adding bavituximab to second-line chemotherapy doubles response rate (2012, September 6) retrieved 3 May 2024 from <https://medicalxpress.com/news/2012-09-adding-bavituximab-second-line-chemotherapy-response.html>

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