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## Advanced NSCLC

*A Multicenter Randomized Phase III Study of Docetaxel/Cisplatin and Docetaxel/Carboplatin versus Vinorelbine/Cisplatin in Chemotherapy-Naïve Patients with Advanced and Metastatic NSCLC*

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Chemotherapy with docetaxel plus cisplatin achieved significantly better survival compared with vinorelbine plus cisplatin in treatment-naïve patients with advanced non-small cell lung cancer (NSCLC). Chandra P. Belani, MD, Professor of Medicine, University of Pittsburgh Cancer Institute, Pittsburgh, Pennsylvania, presented the first results of the multicenter Phase III study. This study compared docetaxel/cisplatin to standard chemotherapy with vinorelbine/cisplatin. In addition the study compared carboplatin/docetaxel to the standard chemotherapy of vinorelbine/cisplatin.

Patients treated with docetaxel/cisplatin had a one-year survival rate of 46%, with a median survival of 10.9 months. Overall, toxicities were acceptable, said Dr. Belani.

"Results of this trial were comparable with those seen by other investigators using docetaxel/cisplatin. The median survival and one-year survival represent a modest improvement in the treatment of advanced NSCLC," Dr. Belani told listeners.

### **The Largest Trial Conducted in NSCLC**

"This trial was conducted at 139 sites in 28 countries," Dr. Belani told the ASCO audience. "It is the largest trial that has been conducted in NSCLC."

The study included more than 1200 men and women 18 years or older with pathologically confirmed, unresectable, locally advanced and/or recurrent or metastatic NSCLC.

Karnofsky performance status was at least 70%. Median age of the study population was 60 years, and most of the patients were men. About two thirds of patients had Stage IV disease. Some one third of those with metastatic disease had involvement of at least three other organs.

Patients were randomized to one of three treatment groups. Group 1 received docetaxel 75 mg/m<sup>2</sup> plus cisplatin 75 mg/m<sup>2</sup> every 21 days. Group 2 received docetaxel 75 mg/m<sup>2</sup> plus carboplatin AUC=6 every 21 days. Group 3 received vinorelbine 25 mg/m<sup>2</sup>/week plus cisplatin 100 mg/m<sup>2</sup> repeated every 28 days. Treatment was continued for six cycles or until evidence of disease progression or unacceptable toxicity. There were 406 patients in the docetaxel/cisplatin arm, 401 in the docetaxel/carboplatin arm, and 396 in the vinorelbine/cisplatin arm.

"The study was designed to compare each of the docetaxel regimens with the reference standard of vinorelbine/cisplatin. It was not designed to compare docetaxel/cisplatin with docetaxel/carboplatin," emphasized Dr. Belani.

Dr. Belani and coinvestigators were hoping to achieve a 2-month improvement in survival in the present study from 8 months to 10 months. The median survival achieved with vinorelbine/cisplatin is 10 months compared to 10.9 months for doc-