Novel paclitaxel formulation encouraging for treating advanced lung cancer

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The June edition of the *Journal of Thoracic Oncology* features a study aimed at determining the optimal dose of the chemotherapy drug nab-paclitaxel with carboplatin as a first-line therapy in patients with non-small cell lung cancer (NSCLC). Results will provide researchers with a data needed to guide a phase 3 trial.

The most commonly used combination treatment for patients with NSCLC is carboplatin plus solvent-based paclitaxel. However, this current treatment has major safety and efficacy concerns, such as severe toxicities, nerve damage. As lung cancer is the leading cause of lung cancer death worldwide, there is a critical need for safe chemotherapy treatments to curb this disease.

In this multi-center study, researchers sought to determine the optimal dose of a chemotherapy treatment using a novel paclitaxel formulation, nanoparticle albuminbound (nab-), which can be administered safely at higher doses than the solvent-based paclitaxel and has performed well when treating breast cancer patients. One hundred seventy-five previously untreated patients were enrolled in the study and received treatment with nab-paclitaxel either on a weekly or every-three-week basis. Dosing levels were also investigated.

Overall results showed response rate was greater in weekly doses than in every-three-week doses. Median progression-free survival was similar between both schedules and ranged from 4.8 to 6.9 months in the every-three-week cohorts and 5.6 to 6.4 months in the weekly cohorts. Overall

survival was also similar in both groups and ranged from 8.3 to 14.6 months in the every-three-week cohort and 11.3 to 15.0 in the weekly cohort. Most favorable of all the cohorts was the group receiving 100 mg/m2 weekly nab-paclitaxel. This group achieved a 48 percent response rate with 6.2 and 11.3 months of progression-free survival and overall survival, respectively.

In addition to improved anti-tumor activity, nab-paclitaxel administered weekly was associated with less serious adverse events than when administered every three weeks, with significant reductions of nerve damage and muscle and joint pain. More specifically, it was found that a 100 mg/m2 weekly nab-paclitaxel produced less serious adverse events than other doses.

	Weekly dose	**Every-three-week dose**
Response rate	47%	30%
ORR	36-56%	24-40%
Progression-free survival	5.6-6.4 months	4.8-6.9 months
Overall survival	12.0-15.0 months	8.3-14.6 months

Researchers concluded that nab-paclitaxel plus carboplatin is an effective therapy for advanced NSCLC and recommend a phase 3, randomized, multi-center study comparison 100 mg/m^2 weekly nab-paclitaxel plus carboplatin to solvent-based paclitaxel plus carboplatin.

"Given the high cumulative dose delivered and the excellent safety and efficacy profile of the patients who received 100 mg/m2 weekly nab-paclitaxel plus carboplatin, we believe this to be the optimal dosing and schedule for phase 3 comparison in patients with advanced NSCLC," confirms lead investigator Mark A. Socinski, MD of the University of North Carolina Lineberger Comprehensive Cancer Center.

Provided by International Association for the Study of Lung Cancer