
Study supports weekly *nab*-paclitaxel for MBC

Patients with metastatic breast cancer are more likely to have a response when treated with weekly *nab*-paclitaxel (Abraxane) than when treated with docetaxel (Taxotere) or with *nab*-paclitaxel given every 3 weeks (Q3W), reported William J. Gradishar, MD. In addition, adverse-event profiles favored the weekly *nab*-paclitaxel.

“The intention of this trial at the outset was clearly to inform the design of future trials involving *nab*-paclitaxel,” said Dr. Gradishar, Professor of Medicine at the Northwestern University Feinberg School of Medicine in Chicago.

The randomized phase II trial undertook three overarching com-

parisons: *nab*-paclitaxel given weekly versus Q3W, high- versus low-dose weekly *nab*-paclitaxel, and *nab*-paclitaxel versus docetaxel. Women with stage IV adenocarcinoma of the breast who had not received chemotherapy for metastases were assigned to four arms:

- Arm A: *nab*-paclitaxel 300 mg/m² Q3W
- Arm B: *nab*-paclitaxel 100 mg/m² weekly (3 of 4 weeks)
- Arm C: *nab*-paclitaxel 150 mg/m² weekly (3 of 4 weeks)
- Arm D: docetaxel 100 mg/m² Q3W.

The interim analysis was based on 302 women. About 40% had received

neoadjuvant or adjuvant chemotherapy, most commonly alkylating agents and antimetabolites. No patient on any treatment arm had received prior taxane therapy.

Response rate nearly doubled

Antitumor response (the primary efficacy outcome) was assessed every 8 weeks using RECIST criteria. The objective response rate was 33% in arm A, 58% in arm B, 62% in arm C, and 36% in arm D. "The two weekly schedules of *nab*-paclitaxel were superior statistically to both *nab*-paclitaxel and docetaxel administered Q3W," Dr. Gradishar noted. "With 33% of all possible events now being reported, the progression-free survival for the *nab*-paclitaxel-containing treatment

arms is statistically superior to that of patients who received docetaxel."

Analyses of treatment-related adverse events generally favored weekly *nab*-paclitaxel. All *nab*-paclitaxel-containing treatment arms had statistically less neutropenia than did the docetaxel treatment arm. Within the *nab*-paclitaxel-containing treatment arms, *nab*-paclitaxel at 100 mg/m² weekly was associated with less neutropenia than the other *nab*-paclitaxel-containing arms.

In terms of peripheral neuropathy, none of the *nab*-paclitaxel groups differed from the docetaxel group; however, among the *nab*-paclitaxel groups, the rate was significantly lower with the 100 mg/m² weekly regimen than with the others. Stomatitis and mucositis occurred significantly more often in the docetaxel group than in any

nab-paclitaxel group but did not differ among the *nab*-paclitaxel groups. Fatigue was significantly less common with *nab*-paclitaxel 100 mg/m² weekly than with docetaxel and the other *nab*-paclitaxel regimens. On the other hand, arthralgia occurred significantly more often with two *nab*-paclitaxel regimens (300 mg/m² Q3W and 150 mg/m² weekly) than with docetaxel; among the *nab*-paclitaxel groups, arthralgia occurred less often with the 100 mg/m² weekly regimen.

Gradishar W, Krasnojon D, Cheporov S, Makhson A, Manikhas G, Hawkins MJ. A randomized phase 2 trial of qw or q3w ABI-007 (ABX) vs q3w solvent-based docetaxel (TXT) as first-line therapy in metastatic breast cancer. Paper presented at the 29th Annual Meeting of the San Antonio Breast Cancer Symposium; December 14-17, 2006; San Antonio, Tex. Abstract 46.