

## **ONCOLOGY**

not appear to affect the safety profile of aflibercept. Although analysis of a prespecified subgroup, this study was not powered to show a treatment difference between arms; therefore, no definitive conclusions can be drawn concerning the benefit of aflibercept in the prior BEV-treated subgroup.

## Docetaxel Is Widely Used In Treatment of Breast Cancer in China

Findings from "Patterns of docetaxel application in breast cancer patients from China: Experience in 42 cancer centers" show that docetaxel is widely used for treating breast cancer, especially as adjuvant and/or neoadjuvant therapy. Binghe Xu, MD, PhD, Chinese Academy of Medical Sciences, Beijing, China, presented results from the study.

This retrospective review was carried out in China from 2009 to 2011 [XuBetal. J Clin Oncol 2012 (suppl; abstre115637)]. The aim of the study was to investigate how patients with breast cancer are treated with docetaxel. It included all patients diagnosed with invasive breast cancer and treated with docetaxel-containing regimens in 42 cancer centers from 12 provinces in China. Regimens were compared in different subgroups based on stage, subtype, and lymph node (LN) status. Patterns of chemotherapy were also compared with published guidelines.

Among 2188 breast cancer patients (mean age, 48.7 years; range, 14 to 82 years) treated with docetaxel, 1881 (86.0%) were in an adjuvant and/or neoadjuvant setting (including

91 in both settings). Only 288 (13.2%) patients received docetaxel as a single agent; 1900 (86.8%) received docetaxel-containing combination regimens. The mean cycle administered was 4.8, and the dose for every cycle was 73.0 mg/m2. Dose reduction and delay occurred in 409 (19.0%) patients, caused mainly by nonmedical factors (10.9%) and hematologic toxicity (5.9%).

Docetaxel, doxorubicin, and cyclophosphamide (TAC), docetaxel/doxorubicin (TA), docetaxel and cyclophosphamide (TC), docetaxel (TX), and doxorubicin and cyclophosphamide followed by docetaxel (AC-T) regimens were given in 34.8%, 19.7%, 17.4%, 5.3%, and 2.2% of patients, respectively. TAC was used more frequently in triple-negative breast cancer (TNBC) cases than in other types (43.0% vs 32.7%; p=0.004). In the (neo)adjuvant setting, TAC was used more frequently in LN-positive than LN-negative patients (44.2% versus 30.0%; p<0.001). Of 1682 patients in the adjuvant setting, 729 (43.3%) were treated with triplet (TAC or AC-T) regimens. Of 290 patients who received neoadjuvant chemotherapy, 94 (32.4%) received TAC and none received AC-T (p=0.013)

Although most guidelines recommend AC-T in adjuvant settings, investigators found that the TAC regimen was used most frequently in China, especially in patients with TNBC or LN-positive breast cancer.

## Compassionate Use With CbzP Plus Prednisone for mCRPC: Interim Results

The XRP6258 Plus Prednisone Compared to Mitoxantrone Plus Prednisone in Hormone Refractory Metastatic Prostate Cancer [TROPIC; NCT00417079] trial showed that treatment with cabazitaxel (CbzP) produced statistically significant improvement in overall survival versus mitoxantrone plus prednisone in patients with metastatic, castration-resistant prostate cancer (mCRPC) previously treated with a docetaxel-containing regimen (HR, 0.70; p<0.0001). Sevil E. Bavbek, MD, Istanbul University Oncology Institute, Istanbul, Turkey, presented interim results from a cohort compassionate-use program (CUP) with CbzP plus prednisone for patients with mCRPC [EAP; NCT01254279; Bavbek SE et al. *J Clin Oncol* (suppl; asbtr e15112) 2012].

Results from the TROPIC trial supported the establishment of a CUP and an early access program (EAP). The aims of this Phase 3, single-arm, open-label trial are to provide access to CbzP prior to commercial availability to mCRPC patients who may benefit from it, and to further assess the agent's safety profile. Estimated enrollment is 1600 patients from 250 centers globally. Eligible patients received CbzP in combination with oral prednisone until disease progression, death, unacceptable toxicity, or physician/patient decision.

Baseline characteristics and safety data are available for the first 399 patients. The median age is 68 years (range, 43 to 89); 90.2% of patients had ECOG Performance Status scale 0 to 1. The median cumulative dose of prior docetaxel was 675  $\,$  mg/m²; previous therapy with mitoxantrone plus prednisone was allowed.

The median time from the last dose of docetaxel to progression was 4 months; 53.3% of patients experienced disease progression either during or <3 months after docetaxel therapy; 61% had  $\geq 2$  metastatic sites, most commonly bone (93.2%) and regional lymph nodes (34.4%). At the time of analysis, a median of four cycles of CbzP had been administered; four patients received  $\geq 10$  cycles.

Median relative dose intensity was 99.2% (range, 80.1 to 104.9). Granulocyte colony-stimulating factor was administered to 34.3% of patients in Cycle 1 (6.3% therapeutic, 26.6% prophylactic). Overall, 71.4% of patients had adverse events