Neoadjuvant therapy with gemcitabine in breast cancer

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Primary systemic therapy (ie, preoperative or neoadjuvant) increases the possibility for breast-conserving surgery in patients with primary breast cancer. Patients with pathologic complete response to primary systemic therapy have improved survival compared with those with persistent tumors. Several phase II trials have evaluated gemcitabine-containing doublet or triplet regimens as primary systemic therapy for breast cancer, results of which have shown promising clinical and pathologic response rates with manageable toxicity. Results of a phase I/II study of gemcitabine (Gemzar)/epirubicin (Ellence)/docetaxel (Taxotere), or GEDoc, with prophylactic filgrastim (Neupogen), as primary systemic therapy in 77 evaluable patients with primary breast cancer are reported herein. Dose-limiting toxicities were grade 3 febrile neutropenia (n = 1) and grade 3 diarrhea (n = 2) at the fourth dose level of GEDoc tested (gemcitabine at 800 mg/m2 days 1 and 8, epirubicin at 90 mg/m2 day 1, and docetaxel at 75 mg/m2 day 1). As assessed by ultrasound, 92% of patients responded overall (22% complete response), and 79% of patients could undergo breast-conserving surgery. The pathologic complete response rate in resected breast tissue was 26%.