Abstract

Drug delivery systems are widely used to reduce toxicity of drugs and enhance the quality of a patient’s life. Nanosomal docetaxel lipid suspension (NDLS) is formulated based on an aqueous lipid delivery system. Patients with breast cancer were not required to be premedicated before administration of NDLS. Docetaxel administered using this delivery system also improves the response rate compared with commercially available docetaxel drug.

Background: Nanosomal docetaxel lipid suspension formulation was developed to eliminate ethanol and polysorbate 80 from the currently used docetaxel (Taxotere) drug for treatment of cancer patients. NDLS clinical safety and efficacy was evaluated and compared with Taxotere at 75 mg/m² in metastatic breast cancer patients.

Patients and Methods: A total of 72 patients were randomized in a ratio of 2:1 (NDLS:Taxotere). Patients treated with NDLS were not premedicated with Corticosteroids as required with solvent-based Taxotere. Disease status and tumor response was assessed after every 2 cycles of treatment using Response Evaluation Criteria in Solid Tumors 1.1 guidelines through cycle 6.

Results: Overall Therapeutic response (complete + partial) rate in metastatic breast cancer patients treated with NDLS and Taxotere were 35.5% and 26.3%, respectively, indicating better response in patients treated with NDLS. Patients in the NDLS group were not premeditated but the safety results of NDLS were found to be comparable with Taxotere.

Conclusion: NDLS Formulation with no premedication provides an alternative treatment option for breast cancer patients.