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Meeting abstract

A phase I study assessing the feasibility and safety of intraductal pegylated liposomal doxorubicin (PLD) in women awaiting mastectomy

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Background

Our preclinical data have demonstrated that intraductal administration of PLD decreases tumor volume, prevents the development of new lesions, and eradicates pre-malignant disease. We initiated a phase I study to determine the feasibility, safety, and maximum tolerated dose of PLD administered to women awaiting mastectomy.

Methods

Women 18 or older with a known breast cancer awaiting a mastectomy were eligible. Neoadjuvant chemotherapy was allowed. Women with T4 features, prior breast irradiation, or procedures that in the opinion of the investigator may have altered the breast ductal system were excluded. Participants underwent nipple aspiration and ductal cannulation using a dose escalation schema. The first 3 women received 5 mL intraductal dextrose only. We determined serial doxorubicin and doxorubicinol concentrations in plasma and nipple aspirate fluid using LC/MS/MS. We injected blue dye into the treated duct just prior to mastectomy and obtained tissue for pharmacokinetic and biomarker analysis.

Results

From 02/06 to 09/08, 14 women entered the study, and 12 underwent study procedures successfully. We completed all dose levels up to 10 mg PLD per one duct without serious adverse events or surgical delays. Pharmacokinetic and representative histopathological data will be presented.

Conclusion

Intraductal administration of PLD is feasible and can be safely administered both in women with and without prior chemotherapy awaiting mastectomy. Studies to evaluate other agents administered to one or more ducts are required.