

NON-TECHNICAL ABSTRACT

The abnormal proliferation of cells involved in the formation and growth of cancers is under the control of abnormal genes called oncogenes. The presence of the oncogene called *HER-2/neu* in increased amounts in breast cancer, certain lung cancers, and head and neck cancers results in a more aggressive (malignant) tumor which appears more resistant to therapy. Another gene called E1A which was obtained from a small part of the DNA of a common virus was introduced with a non-viral gene delivery system composed of lipids (or fats) into cancer cells maintained in culture. This resulted in the decreased production of the *HER-2/neu* oncogene and the loss of the malignant characteristics of the cancer cells. When administered in the tumor in an animal model for breast cancer, the E1A gene combined with the lipid gene delivery system produced long-term tumor-free survival of treated mice compared to untreated control mice.

The same treatment will be applied in the proposed study to patients with advanced metastatic or surgically unresectable tumors whose tumors express increased amounts of the *HER-2/neu* oncogene in the hope that the suppression of the oncogene activity may result in tumor response. In this study we will determine the tolerance of the E1A Lipid Complex and the nature of possible side effects that may be related to the gene therapy. The evaluation of tumor response is also one of the objectives of the study.