

Title: A Phase I Trial of Monoclonal Antibody HGS-ETR2 (Lexatumumab) With or Without Interferon Gamma in Patients with Refractory Pediatric Solid Tumors (P6981)

IRB# 2009-071

Principal Investigator: Bindu Kanathezhath, MD

Synopsis:

Pediatric solid tumors represent approximately one fourth of cancer diagnoses in children. Despite intensive regimens, patients with metastatic or recurrent tumors have unsatisfactory survival rates. Therefore new therapies are needed to improve outcomes. Members of the TNF ligand superfamily induce death in tumor cells through direct ligation of death receptors and apoptosis induction.

TRAIL (TNF-related apoptosis inducing ligand) has been shown to have specific antitumor activity against a wide range of tumor cells without inducing death in normal cells. Many pediatric solid tumors are sensitive to TRAIL induced apoptosis therefore it may cause cell death in tumors that have been resistant to chemotherapy without the standard toxicities associated with chemotherapy.

The goal of the study is to determine the MTD and tumor response of Lexatumumab in patients with refractory pediatric solid tumors as a single agent and in combination therapy with a fixed dose of interferon gamma 1b.