

## **I. SCIENTIFIC ABSTRACT**

This study will evaluate the efficacy and safety of *in vivo* gene transfer of the Herpes Simplex-thymidine kinase (HSVtk) gene using LTKOSN.1 vector producer cells (VPC) in patients with recurrent or refractory ovarian cancer. Insertion of the HSVtk gene into tumor cells confers a sensitivity to the anti-herpes drug ganciclovir (GCV). The HSVtk/GCV system induces an anti-tumor response in some patients. HSVtk VPC delivery system and GCV administration have destroyed intraperitoneal tumors growing in animals. This procedure was found to be safe in patients with ovarian cancer and some anti-tumor responses were observed. Therefore, we propose a Phase II trial of this approach.

Adult women ( $\geq 18$  years) with recurrent or refractory ovarian, fallopian, or peritoneal carcinoma, will be evaluated for the extent and location(s) of their disease before being entered into the study. Patients will have a CT scan and laparotomy or laparoscopy with biopsy to confirm the diagnosis. During laparoscopy, eligible patients will have a peritoneal dialysis catheter placed. HSVtk VPC will be infused into the peritoneal space. Four weeks later, GCV will be administered at 5 mg/kg/dose IV b.i.d. for 14 days. Patients may receive up to three cycles of therapy if no tumor progression is observed. After the completion of therapy, patients who continue to show evidence of response will be followed every three months for the first year.