

## **Section 1. Scientific Abstract**

Lung cancer kills more men and women than any other form of cancer. As the majority of lung cancer is diagnosed at a relatively late stage, only 10% of all lung cancer patients are ultimately cured. The primary treatment is surgery, followed by radiation therapy, with or without chemotherapy. However, if the patient cannot be cured by surgery at the time the cancer is found, there is a 50% chance that death will occur in less than one year. The objective of this study is to determine the safety profile of systemic intravenous non-viral hIL-2 (VLTS-587) in patients with solid tumors and the presence of metastases or primary cancer in the lungs. Specifically, the protocol is designed to identify the dose-limiting toxicity and maximum tolerated dose (MTD) of VLTS-587. In pre-clinical studies in rodent tumor models and in dogs with spontaneous tumor metastases, intravenous non-viral IL-2 gene delivery is effective in inducing anti-tumor activity against established tumors and may be superior to more conventional forms of immunotherapy. Moreover, the treatment is well tolerated by large and small animal metastatic tumor models and can be administered repeatedly without cumulative side-effects, resulting in an anti-tumor response which can lead to complete tumor regression. Lastly, we have shown that lipid-DNA complexes can be safely administered by slow IV infusion, without cumulative adverse effects, in rodents, rabbits, dogs and primates.

The proposed phase I trial is a dose escalation study designed to evaluate the safety profile, and determine any toxicities that might be associated with the intravenous administration of plasmid DNA coding for hIL-2.