# 3. NON-TECHNICAL ABSTRACT

In women, ovarian cancer is the fifth most common form of cancer, and the fourth most common cause of cancer death, with a prevalence of 167,002 women in the USA. The most common type of ovarian cancer is epithelial ovarian cancer, which starts from the cells that cover the outer surface of the ovary.

Symptoms of ovarian cancer do not usually appear until the cancer has spread into the pelvic area or abdomen. There is no available early detection screening test, like pap smears and mammograms for cervical and breast cancers, respectively. As a result, more than 75% of cases of ovarian cancer are at advanced stages, causing swelling and pain when diagnosed. Chemotherapy has about an 80% success rate in shrinking the ovarian cancer, but in 55-70% of treated women the ovarian cancer will return within two years. For women diagnosed with advanced ovarian cancer, five-year survival rates are 23-41% for tumors that have spread to the abdomen, and 11% for tumors that have spread to the other organs outside the abdomen.

Interleukin-12 (IL-12) is a type of protein called a cytokine that stimulates an immune response within the body. This immune response allows the body to fight disease; however, most cancerous cells stop the production of IL-12, resulting in an inability of the immune system to become active. Research has shown that IL-12 protein can be given to cancer patients and will lead to the activation of the immune system. Unfortunately, early studies of high doses of IL-12 given as a protein drug resulted in serious side effects, including death. However, more recent studies have shown that IL-12 can be safely given directly into the tumor via gene therapy, which lowers the dose and toxicity of the treatment.

The study medicine, EGEN-001, contains the gene for human IL-12 in a non-viral lipopolymer gene delivery system, which can be transferred directly into the cancer cells or cells of the immune system to achieve long-term expression of IL-12 locally in tumor environment. Studies have shown that the use of similar gene delivery systems can successfully stimulate the immune response while reducing toxicity of the gene product.

The purpose of this research study is to test the safety and tolerance of the study medicine, EGEN-001, a new form of human IL-12 gene therapy in the treatment of recurrent epithelial ovarian cancer. Patients will be closely monitored for any side effects, and also for any shrinkage of ovarian tumors. In the absence of worsening of ovarian cancer or serious side effects, all patients will have a total of four EGEN-001 treatments given directly into the abdomen via a catheter, once per week for four weeks. In this first-in-humans research study, all patients will receive EGEN-001 only. There will be no other cancer drugs given together with EGEN-001, nor will any patient get placebo (dummy) treatment.