

## **NON-TECHNICAL ABSTRACT**

The title study is sponsored by Hoffmann-LaRoche for the treatment of patients with chronic lymphocytic leukemia (CLL), a cancer that is still incurable. This study will be conducted at seven different research centers to confirm preliminary positive results of a novel cancer vaccine therapy. To participate in this study, male or female leukemia patients with or without previous chemotherapy for CLL should be at least 18 years of age.

Sixty leukemia patients will be enrolled in this study which has three major stages:

- I. Each patient undergoes leukapheresis which is a process that removes leukemia cells from blood and collects these cells.
2. The leukapheresed cells are infected with a genetically altered adenovirus (i.e., a form of cold virus). The altered adenovirus contains a normal gene that directs the leukemia cells to produce CD154 a protein molecule that activates the immune system and allows the body to fight the disease.
3. Each patient's modified leukemia cells that now contain the altered adenovirus are re-infused intravenously into the same patient.

The actual study treatment consists of a course of at least five intravenous infusions given at intervals of 2 weeks, with each infusion delivering a portion of the patient's own modified leukemia cells. Those patients who respond positively to the treatment will be allowed to receive additional infusions (up to a total of 10 infusions). Patients will be observed for 2 years from their first infusion.