

Scientific Abstract:

Imatinib has rapidly become standard therapy for CML, but >95% of patients in complete cytogenetic remission remain PCR positive for *BCR-ABL*. Additional therapy is thus needed to further reduce the level of residual disease in patients on imatinib. Vaccination is a reasonable strategy to generate an anti-leukemic response in this setting. Several lines of evidence support the use of GM-CSF based tumor vaccines to generate an immune response which could potentially eradicate residual disease. The current Phase I study therefore proposes to evaluate the safety and toxicity of using serial intradermal and subcutaneous vaccinations with irradiated K562 cells (a CML cell line) that has been engineered, by introduction of a plasmid, to secrete GM-CSF (GM-K562 cells). Patients with persistent and molecularly significant disease in the face of maximal response to a stable dose of imatinib are eligible and will be treated at one of 3 dose levels, 10 patients per dose level. The goals of the study are to determine a safe and well-tolerated dose of GM-K562 K562 vaccine that can generate a measurable immune response.