Scientific abstract:

The current study proposed to generate a vaccine that contains separate elements of both autologous lymphoma cells and GM-K562 cells. We hope to overcome some of the technical difficulties limiting the feasibility of virally transduced GM-CSF secreting autologous tumor cells. We postulate that GM-K562 cells will make GM-CSF secretion more reliable and less susceptible to variables associated with virus production. We will test the hypothesis that co-administration of autologous follicular lymphoma cells and GM-K562 cells can safely and predictably induce a bystander immune effect against follicular lymphoma.

GM-K562 cells will be administered according to a standard dose escalation schema. The GM-K562 doses are $5x10^6$, $1x10^7$ and $5x10^7$. Individual irradiated lymphoma tumor cell doses will range from $1x10^5$ to $5x10^7$ depending on the final cell yield from tumor procurement and processing. Patients will continue receiving vaccine until removal from study or until the supply of vaccine has been exhausted.

A number of clinical trials to augment anti-tumor immunity against lymphoma cells or idiotype protein have included GM-CSF (12). GM-CSF is a hematopoietic growth factor that augments cellular immunity by promoting T cell proliferation, increasing the expression of adhesion molecules on granulocytes and monocytes, and recruiting dendritic cells for antigen presentation. The ability of GM-CSF to increase anti-idiotype immunity has been demonstrated in pre-clinical models as well as human trials.

The study is designed with several tiers and dose levels:

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Dose level/Tier	Number of patients	GM-K562 cells per vaccination
1	4 (minimum of 3 evaluable)	5×10^6
2	4 (minimum of 3 evaluable)	1×10^7
3	4 (minimum of 3 evaluable)	5×10^7

Tier I:

Dose escalation may proceed only after 3 patients have been evaluated at the preceding dose level. Once the MTD is identified an additional 12 patients will be added at the MTD. Of note, regardless of side effects, dose escalation will not occur beyond dose level 3.

Tier II:

When 3 patients in Tier I have been evaluated at the MTD, then enrollment of Tier II patients may begin at Dose Level 1 and follow the dose escalation schema as noted above. 12 patients will be enrolled on Tier II.

Dose modifications are built into the study based on adverse events, which will be reported as per the guidelines in the protocol.