



SARCOMA FOUNDATION OF AMERICA
FINAL REPORT

Project Title: Immunologic Monitoring of Patients with
Alveolar Soft Part Sarcoma Receiving a Long
Translocation-Specific Peptide Vaccine with
GM-CSF Adjuvant

Project Number: SFA05-H

1. Date project was initiated: __vaccine design initiated Jan 2005, but the immunologic monitoring of patients is pending awaiting opening of clinical trial_____
2. Period covered by this report: From __ June 2005 _____
To _____ June 2006 _____
3. Publications, Abstracts, and Presentations:
 - a. List all manuscripts submitted for publication during the period covered by this report resulting from this project. Include those in the categories of lay press, peer-reviewed scientific journals, invited articles, and abstracts. Each entry must include the author(s), article title, journal [book, editors(s), publisher, volume number, page number(s), and date.]

(1) Lay Press:

Reviewer for
Electronic Sarcoma Update Newsletter (ESUN) August 2005
"Clear Cell Sarcoma and Alveolar Soft Part Sarcoma"
John M. Goldberg, MD and Karen Albritton, MD
Dana-Farber Cancer Institute

(2) Peer-Reviewed Scientific Journals:

Ferrone CR, Perales MA, Goldberg SM, Somberg CJ, Hirschhorn-Cymerman D, Gregor PD, Turk MJ, Ramirez-Montagut T, Gold JS, Houghton AN, Wolchok JD. Adjuvanticity of plasmid DNA encoding cytokines fused to immunoglobulin Fc domains. *Clinical Cancer Research* (in press)

Goldberg SM, Bartido SM, Gardner JP, Guevara-Patino JA, Montgomery SC, Perales MA, Maughan MF, Dempsey J, Donovan GP, Olson WC, Houghton AN, Wolchok JD. (2005) Comparison of two cancer vaccines targeting tyrosinase: plasmid DNA and recombinant alphavirus replicon particles. *Clinical Cancer Research*, **11**(22) 8114-8121.

(3) Invited Articles:

Chapter:

Uchi H, Stan R, Turk MJ, Engelhorn ME, Rizzuto GA, Goldberg SM, Wolchok JD, Houghton AN.
Unraveling the complex relationship between cancer immunity and autoimmunity: lessons from melanoma and vitiligo. Adv. Immunol. , vol 90. 2006

(4) Abstracts:

- b. List presentations made during the last year (international, national, local societies, etc.). Use an asterisk (*) if presentation produced a manuscript.
4. Provide a brief list of keywords: (limit to 20 words)

 5. Summarize the progress during the period of this report and its impact on your plans for the remainder of the project. Include a summary of the progress toward the achievement of the originally stated aims and list the significant results:

Please Note: The SFA guidelines specifically prohibit use of funds for the purpose of clinical trial. The proposal was written, therefore, with the aim of monitoring immunologic responses to patients receiving the ASPS vaccine rather than for the construction of the trial itself. However, the institutional and IND processes are still under way. As such, the trial has not yet opened and, therefore, the monitoring of patient responses is still pending trial opening and patient accrual. The funds from the SFA will be spent and responses measured once patients have completed the vaccine trial and their responses at various timepoints can be analyzed and compared. In the meantime, a brief summary of vaccine and trial design are included in the separate attachment.

6. In layperson's terms, summarize the progress during the period of this report. Explain any medical significance or implications of your results to date:

Principal Investigator (signature)

Date

Department Chair (signature)

Date

Layperson's Summary

The purpose of this study is to find out if people with alveolar soft part sarcoma (ASPS) can develop an immune response against proteins found in their tumor cells.

To do this, we will compare the effects of a vaccine made with parts of proteins found in ASPS given in two different schedules. These vaccines are made more potent by the addition of substances called adjuvants (Montanide ISA and GM-CSF) which should help make the immune response stronger and last longer. Patients with alveolar soft part sarcoma will get either 1) a weekly vaccine or 2) clusters of vaccines given several days in a row. In each group, patients will receive a total of 22 vaccinations given over a twelve month period. Blood will be drawn from patients before, during, and after, the 12 month vaccinations so that patient immune response can be measured and compared between the two different groups. We will use these blood test results to see 1) if it is possible to create an immune response to a patient's ASPS cancer and 2) if one vaccination schedule is better than the other at giving an immune response. The long term goal is to see if these immune responses can help destroy the tumor in patients with ASPS.