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Vaccination of prostate cancer patients with a therapeutic vaccine containing prostate specific antigen (PSA) and the biological adjuvants IL-2 and GM-CSF results in reduced serum PSA

Jonathan F. Head and Robert L. Elliott
OncBioMune, USA

In 1997 we initiated a phase I/II clinical trial of a therapeutic prostate cancer vaccine. We have enrolled 12 biopsy confirmed prostate cancer patients in this study and 11 finished the initial course of 6 intradermal vaccinations containing prostate specific antigen (50 μg) and biological adjuvants (IL-2, 20,000 units, and GM-CSF, 16.7 μg) at 0, 1, 2, 6, 10 and 14 weeks. During this study the prostate cancer patients received no other concurrent therapy (surgery, hormone, radiation, radioactive seeds, and chemotherapy). One of the 12 patient's PSA rose from 7.6 to 13.7 after the fourth vaccination and he (patient #8) withdrew from the study to seek other therapy. In the remaining 11 prostate cancer patients serum PSA concentrations were determined before initiating vaccination and 3-4 weeks after the 6th vaccination. There was a decrease in the PSA levels in 8 of 12 of the prostate cancer patients after 6 vaccinations. One of the patients (patient #3), whose PSA had dropped from 6.8 to 6.4 and had previously received radiotherapy (the only patient previously treated), elected to withdraw from the study and underwent radical prostatectomy. Nine of the original 12 patients have received monthly 3 intradermal IL-2 injections (11 million units) alternated with 3 further vaccinations for the 6 months following the initial vaccinations, and 8 patients have been followed from 18 to 92 months. The mean PSA values for the 8 patients still being followed without additional therapy were 5.8 initially, decreasing to 4.1 after 6 vaccines, 3.7 after 12 vaccines and is 4.7 after a mean follow-up of 49 months (median follow-up of 45.5 months). These promising results have led to the creation of the U.S. Navy Cancer Vaccine Program with a Phase I clinical trial at the Veterans Administration Medical Center San Diego/UCSD Medical School.

Biography

Jonathan F. Head has been instrumental in the development of several of our new chemotherapy and immunotherapy programs. Himself and Elliott are the co-developers and patent holders of one of the first patented autologous breast cancer vaccines in the United States. His major goal is to implement translational research-the movement of laboratory-developed technologies into the clinical setting. This is the taking of new therapies from cell culture to an accepted therapy for cancer patients. As a tumor cell biologist, his specialties include: Cell culture research Animal research Human clinical research Innovative chemotherapies Immunotherapy/cancer vaccines Oncogene and antisense research Tumor markers he is an Adjunct Associate Professor of Biochemistry at Tulane University, an Adjunct Professor of Physical and Biological Sciences at Delta State University, and an active member of the American Association for Cancer Research and the American Society of Clinical Oncology. Although patients rarely meet him, many of the new treatments we offer are the result of his work.

jhead@eehbreastca.com