

Development and Commercial Licensing of a Potential Universal Immune-Inducing Vaccination Type Therapy for Advanced Cancers

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Introduction

Oncologists and medical scientists have longed to discover a universal “vaccination” procedure and a method for monitoring and predicting therapy outcomes in patients with all types of human cancer. Once these objectives are achieved, it is generally accepted that the critical mechanisms by which cancers develop and spread will be revealed. It is well known that the presence of early cancer cells in the patient triggers anti-cancer immune responses in the patient which could, but do not always function correctly to kill these malignant cells in human and animal carcinogenesis. The emerging technology licensed recently to Investors Medical Fund, LLC [IMF] of Tampa, FL by South Alabama Medical Sciences Foundation (SAMSF) contains theoretical and immunological scientific content, which opens a potential avenue to achieve these long-sought anti-cancer objective.

We have developed a unifying theory regarding the immunogenic properties of all malignant cancer cell types linking this concept to cancer cell invasiveness. This technology centers on an immunogenic, cancer specific protein named OncoFetal Antigen/Immature Laminin Receptor Protein [OFA/iLRP]. The following article summarizes the background and potential for using this immune stimulating tumor-specific protein in cancer control and anti-cancer immune therapy and monitoring applications against all cancer types.

Article

This novel cancer-specific protein is the highly immunogenic OFA/iLRP [an antigen-inducing immune stimulating] component of the cancer cell. It has been detected on the surface of all human and animal cancers tested by SAMSF scientists. It has been shown to stimulate strong host cellular immunity. This immune response is mediated by the T-cell component of the human and animal immune response repertoire, which can successfully kill cancer cells. Remarkably, the OFA/iLRP component is not expressed on the surface of normal mammalian cells as an immune response-inducing antigen or immunogen

These critical observations have resulted in studies by SAMSF scientists funded largely by the NIH’s National Cancer Institute over the last 20 years. These studies not only produced a pure form of the recombinant OFA/iLRP immunogen made in bacteria, but identified several novel immune mechanisms which can explain the long-standing mystery of the why the cancer-bearing host’s immune responses do not result in destruction of emerging cancer cells when the patient develops primary cancers. All this technology and its potential applications in cancer detection, vaccine therapy and

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monitoring of the patient's cellular or T-cell responses needed to attack and destroy cancer cells have been successfully patented by SAMSF as a part of the License sale.

Collaborative human clinical as well as animal cancer studies using OFA/iLRP for immunotherapy [vaccine-type treatment] against renal and breast carcinomas, various leukemia types and sarcomas have indicated that these tumors consistently express the OFA/iLRP immunogen at their cell surface. Normal cells and tissues of these species do not express the OFA/iLRP. These investigations also illustrated that the host's immune system responded to this immunogen with both OFA-specific antibody and immune T-cells. It is now accepted that a subclass of activated T-lymphocytes or T-cells play the major role in the successful destruction of established tumors of mammals. A significant reduction and stabilization of these and other cancers in animal models and in renal cancer patients following the therapeutic use of a new "vaccine" technology, called Dendritic Cell [DC] immunotherapy resulted in a high frequency of long-term remissions from malignant spread of renal carcinomas. Preliminary studies recently conducted in breast cancer, small cell lung cancer, and leukemia patients showed that similar protection can be anticipated in recently initiated in human clinical trials.

IMF manages the license to this patented technology and is funding a study of OFA/iLRP DC immunotherapy in patients with advanced breast cancer after consummating a multimillion dollar transaction protected as proprietary by several patents in the U.S., EU and other countries. Previous studies have shown the DC vaccine-type immunotherapy has no significant toxicity since the patient's own monocytes are used to prepare the OFA/iLRP loaded DC cells which are subsequently used to arouse the cancer patient's host immune T cells essential to kill advanced tumor cell metastasis. The preparation of these DC cells is done in a closed bag system in the lab over a week of differentiation of the patient's blood monocytes collected by cytophoresis. These monocytes can be cultured in the lab to prepare OFA/iLRP loaded DC cells derived from each patient. The recombinant purified OFA/iLRP is added to "load" the maturing DC cells, which are then returned to the patient in immunotherapy. More than half the patients with advanced renal carcinomas who had failed to respond to conventional surgery, chemotherapy and/or other experimental therapies obtained a remission which has lasted for >40 months to date. Most of the patients who did not achieve a remission from the first round of DC immunotherapy have sufficient life extension to potentially undergo additional rounds of the immunotherapy since the vaccine does not show significant toxicity or compromise the patient's remaining immune competence as observed in patients receiving "conventional" chemo and radiation therapy.

If this clinical trial in Mobile, AL extends the safety and efficacy of OFA/iLRP to treat advanced breast cancer as has been obtained in renal cancer studies, it is anticipated that the immunotherapy procedure might be approved by the FDA for testing against all forms of human cancer. It would be also feasible to use the OFA/iLRP immunotherapy earlier before the cancers become so advanced since it causes no significant toxicity to date and could conceivably used in combination with conventional chemo- and radiation therapy.

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A new automated T-cell monitoring clinical instrument and lymphocyte T-cell subclass enumeration procedure employing OFA/iLRP and various “tagging” antibodies along with commercially available lymphocyte typing antibodies is covered in the technology license. This clinical lab procedure is quantitative and highly reproducible. The instrument is used to monitor the OFA/iLRP T-cell subclasses, which are stimulated in the patient receiving this DC immunotherapy to determine the increase in the desired cytotoxic anti-tumor T-cell population aroused by the administration of the autologous DC cells derived from the treated cancer patient.

All supporting data related to this technology are published in some 100+ peer-reviewed cancer and immunology-based international scientific journals. SAMSF holds the patents licensed to the IMF, LLC and VRI, Inc. Additional patents are pending in the U.S. and recently allowed in the EU concerning the potential applications of these peptide components or “peptides” in anti-cancer therapy of the OFA/iLRP protein responsible for stimulating the needed T-cell subclass. Innovative methods for using “peptide cocktails” of the protein which stimulate OFA/iLRP specific T cell mediated immunity to use the novel immunogen for direct immunotherapy are planned in the license agreement. The automated, quantitative laboratory technology needed to monitor conventional anti-cancer therapies effectiveness as well as the OFA/iLRP immunotherapy to stimulate the protective T-cell subpopulation in cancer patients may prove useful for predicting therapy efficacy against all types of human cancer since the OFA/iLRP is universally expressed on all types of human cancer tested to date.

In addition, the sum of the new information discovered about the expression of the OFA/iLRP immunogen described in SAMSF’s literature reports concerning the role of this universally expressed immunogen in cancer cell transformation and its association with the development of malignancy and cancer cell invasiveness may open new avenues for understanding of cancer immunobiology. These discoveries may provide a new understanding of how cancer cells are induced and how to use the OFA/iLRP immunogen to potentially interrupt cancer development before cancers emerge.

Dr. Joseph H. Coggin, Jr. Ph.D. received his B.A. degree from Vanderbilt University, his M.S. degree from the U. of Tennessee and his Ph.D. from The U. of Chicago. He completed his post-doctoral training at the Merck Institute under Dr. Maurice Hilleman. He was director of the MAN NCI cancer research program at Oak Ridge National Laboratory, Professor of Microbiology at the University of Tennessee for 12 years and, for 33 years, served as Chairman and Professor of Microbiology and Immunology in the College of Medicine at the U. of South Alabama until 2006. He continues there as Emeritus Professor working with the co-inventors on the SAMSF patents, Dr. James Rohrer and Dr. Adel Barsoum. For more information on the SAMSF patents, contact Dr. Coggin at: jcoggin@jaguar1.usouthal.edu