

UM Partners with Seed-One Ventures to Form New Company to Develop and Market Broad-Based Therapies for Cancer and Other Diseases

The University of Miami Miller School of Medicine and Seed-One Ventures announce the formation of Heat Biologics Inc. to develop two related platform technologies which introduce a novel lung cancer vaccine and asthma therapy, with potential applications in the treatment of a number of other inflammatory diseases. The two treatments were developed by Eckhard Podack, M.D., Ph.D., Sylvester Distinguished Professor of Medicine and chairman of the Department of Microbiology and Immunology.

Seed-One Ventures forms new companies based on cutting-edge technologies and breakthrough medical therapies.

This collaboration is the work of UM Innovation, the University of Miami's home of technology advancement which develops university-generated treatments or devices, and works with businesses to take that technology into the marketplace. Under the umbrella of UM Innovation, the Wallace H. Coulter Center for Translational Research produced the lung cancer vaccine, which is currently in Phase 1 clinical trials, and subsequently matched both groundbreaking treatments with Seed-One Ventures.

"Seed-One Ventures evaluates hundreds of technologies every year, and the treatments developed by Dr. Podack are among the best we've seen," said Jeffrey Wolf, managing partner, Seed-One Ventures. "His approach represents a paradigm shift, a non-traditional view of certain prevailing ideas about immunology. The decision to form Heat Biologics around Dr. Podack's breakthrough work was an easy one."

Bart Chernow, MD, vice provost for technology advancement at the Miller School, indicated how pleased he was that Mr. Wolf and his colleagues at Heat Biologics would be helping in the research and development of this important therapeutic approach. "The formation of this spin off company will hopefully enable Dr. Podack's discovery to reach its full potential, and if it is found to be safe and efficacious, it will help many people suffering from lung cancer."

Dr. Podack's novel lung cancer vaccine, gp-96, was developed to treat non-small cell lung cancer (NSCLC), which accounts for 85 percent of all lung cancers. For NSCLC patients, surgery and chemotherapy are often the only options, so this treatment will fill a substantial need.

While conventional vaccines are used to prevent infectious diseases, Dr. Podack's treatment is meant to stimulate the immune system to fight the disease once it is diagnosed. The body's immune system does not recognize NSCLC as dangerous, so it does not attack those cells. To trigger the immune system, Dr. Podack began working with gp-96, a heat shock protein. Normally, this heat shock protein remains in the cell and is protected from the immune system. Dr. Podack genetically engineered a NSCLC cell to secrete this protein, which "induces tumor-antigen specific cytotoxic T cells and natural killer cells," he explains.

This is where the second of the two complementary technologies comes into play. Vaccines against cancer have been limited in effectiveness by regulatory T cells, which block the immune response system. Dr. Podack has developed tumor necrosis factor receptor (TNFR) 25 agonists and antagonists, which can be used to benefit patients in two ways. TNFR25 agonists have the ability to block the production of regulatory T cells, allowing the immune system to work uninhibited. By applying this therapy in conjunction with the gp-96 vaccine, the anti-tumor treatment can be much more effective. Dr. Podack notes that it is five to ten times more effective in mice. He sees a lot of hope with this new therapy. "The gp96-vaccine in combination with TNFR25 agonists offers the best hope to conquer cancer and other intractable diseases."

TNFR25 antagonists offer hope to those with asthma and other inflammatory diseases. As the opposite of TNFR25 agonists, this antibody works as an anti-inflammatory agent, easing the symptoms of asthma and several other auto-immune diseases.

Heat Biologics and the University of Miami are currently enrolling patients in a Phase I clinical trial of gp-96, under the direction of Luis E. Raez, M.D., associate professor of medicine and co-leader of the Lung Cancer Site Disease Group at UM/Sylvester Comprehensive Cancer Center. A Phase I trial is meant to determine the safety of a treatment. Dr. Podack believes this vaccine could get a fast track for review by the U.S. Food and Drug Administration because there are so few effective treatments for NSCLC. A fast-track designation would mean a six-month review following a Phase III trial involving hundreds of patients.

Heat Biologics is one of several cutting-edge healthcare technology and biotechnology companies founded in Florida by Seed-One in recent years, making it one of the region's more active seed-stage venture firms. Seed-One builds its portfolio companies from the ground up and actively manages each. Mr. Wolf will serve as CEO of Heat Biologics and oversee the development and commercialization of the company's platform technologies.

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About UM Innovation

UM Innovation is the home of technology advancement at the University of Miami and serves to nurture and integrate UM's vibrant and comprehensive research initiatives. UM Innovation incorporates the Office of Technology Transfer, the Wallace H. Coulter Center for Translational Research and the new Life Science Park and

serves as a bridge between faculty scientists seeking to commercially transfer their research efforts and corporate entities interested in accessing and advancing innovative technologies.

About Seed-One Ventures

Seed-One Ventures, LLC, is focused on forming new companies from the ground up based upon breakthrough technologies with significant commercial applications. Seed-One actively manages each new venture it creates.

Seed-One's target areas for new venture creation include biotechnology, pharmaceuticals, information systems, and hardware and software technologies.

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