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In Clinical Trails in the US, Australia and New Zealand for their Nexvax2® Therapeutic Vaccine for Celiac Disease and companion Diagnostic and Monitoring Tool, ImmusanT is offering hope to Patients looking to resume a Normal Healthy Diet Containing Gluten

Healthcare
Biotechnology
Vaccines

ImmusanT, Inc.
One Kendall Square
Suite B2004
Cambridge, MA 02139
www.ImmusanT.com

Leslie J Williams
CEO

BIO:
Leslie Williams has more than 20 years of industry experience in healthcare, management, commercial product development and marketing. In 2010 she founded ImmusanT, Inc. which subsequently acquired the assets of Melbourne, Australia based Nexpep after advising the company for a year. Ms. Williams serves as Director, President & CEO of ImmusanT. Prior to that she was President & CEO of Ventaira Pharmaceuticals and under her leadership the company became a significant player in the pulmonary –drug-delivery market. The company was sold the end of 2007. While President and CEO of Ventaira Pharmaceuticals, she was recognized as one of the top 100 leaders in life sciences by PharmaVOICE magazine.

Prior to Ventaira, Ms. Williams was director of marketing for INO Therapeutics, Inc., where she played a significant role in the NDA submission for INOmax (nitric oxide). Responsible for the commercial aspects of INOmax's U.S. market introduction, Williams also assisted with expansion of the INO-therapy platform into the European marketplace. (The company was acquired by Ikaria Holdings in 2007 for some $670 million.) Ms. Williams' prior pharmaceutical industry experience includes commercial positions at Merck and GSK, and drug-delivery and -monitoring experience at Datex-Ohmeda (formerly Ohmeda, Inc.). She was a venture partner at Battelle Ventures where she sourced and evaluated deals and assisted early-stage technology companies with strategy, management, business development and M&A. She currently serves on the Boards of Hepregen Corporation, CDI Bioscience and The Capital Network (TCN) and is on the Editorial Advisory Board of Life Science Leader. She serves as a mentor in the Boston University Kindle Program and Propel Careers. Ms. Williams holds an MBA from Washington University, John Olin School of Business, and a B.S. degree with honors in nursing from the University of Iowa. Before entering industry, she was a critical-care nurse at Duke University, Medical College of Virginia and at the University of Iowa.

About ImmusanT:
ImmusanT is a privately-held biotechnology company focused on restoring tolerance to gluten in celiac disease by harnessing new discoveries in immunology that aim to improve diagnosis and treatment and return patients to a normal diet, good health and improved quality of life. The company is developing Nexvax2®, a therapeutic vaccine for celiac disease, and a companion diagnostic and monitoring tool to improve celiac disease management. ImmusanT's targeted immunotherapy discovery platform can be applied to a variety of epitope-specific autoimmune diseases. Founded in 2010, ImmusanT is backed by Vatera Healthcare Partners. More information can be found at www.ImmusanT.com.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Ms. Williams, what was the vision when you founded the company? Where are you today?
Ms. Williams: Our vision is to improve the diagnosis and treatment for patients with celiac disease and allow them to return to a normal diet, good health and improved quality of life. We are focused on happy and healthy patients and families. Our companion diagnostic will allow us to select and monitor celiac patients who will respond to our treatment and our therapeutic is designed to restore immune tolerance to gluten in patients with the disease. Our initial focus will be with celiac patients with the genetic subtype, HLA-DQ2. We then intend to leverage our understanding in diag-

nosing and treating celiac disease to genetically related autoimmune diseases such as Type 1 Diabetes.

Today we are focused on executing a plan driven towards realizing our vision. There is significant need for proper diagnosis of the disease and for treatment options to a strict gluten free diet which is difficult to follow in day to day life. We are currently conducting clinical trials in the US and Australia and New Zealand of Nexvax2 and are utilizing our companion diagnostic to screen patients. The average time to formal diagnosis has been reported to be 9 years so by providing improved diagnostics and treatment options we also hope to improve the awareness so patients are diagnosed sooner.

CEOCFO: How big of a percentage of the people with celiac disease have the subtype that would benefit from your vaccine?

Ms. Williams: Eighty to ninety percent of all celiac patients have the immune recognition gene, HLA-DQ2. The other 10% have the genetic subtype HLA-DQ8. The presence of HLA DQ2 or DQ8 is necessary but not sufficient for the development of celiac disease. Over half of most Caucasians are genetically susceptible but only 1-2% have Celiac Disease. Gene tests for HLA DQ2 and DQ8 can be useful to rule out celiac disease, but are not helpful to positively diagnose celiac disease. Our therapeutic is focused on capturing the eighty to ninety percent of celiac patients with the HLA-DQ2 gene.

CEOCFO: Has there been much research into a potential vaccine for celiac disease?

Ms. Williams: Considering how large the market is for Celiac Disease and that the disease is a lifelong disease for which the gluten free diet is the only treatment, there are not a lot of therapeutics in the pipeline. The work with our vaccine, Nexvax2, began over a decade ago when Dr. Anderson, our Chief Scientific Officer, was at Oxford University and began his work in celiac disease. He continued his work at Walter and Eliza Hall Institute in Melbourne, Australia. Dr. Anderson and his colleagues determined the components in gluten that caused the immune response. This work was done by giving celiac patients a gluten food challenge and then determining what part of gluten was responsible for the immune response elicited in blood. The "oral challenge" work along with high through put screening of thousands of components of gluten led to the selection of the immunodominant peptides that consistently trigger the response in the main genetic subgroup, DQ2, of CD patients. Over 400 patients from Australia and Europe have been orally challenged to confirm the selection of peptides. Seminal publications in Nature Medicine, 2000, and Science Translational Medicine, 2010, describe the work. Proof of concept using the peptides in Nexvax2 was demonstrated in a humanized mouse model of gluten immunity. A Phase 1 study with Nexvax2 was completed in 2010 and established safety and tolerability in Celiac patients. We are currently in two Phase 1b studies looking safety, tolerability and PK at different dose levels and regimens. Thus, over 10 years of research and development has been dedicated to advancing our antigen specific immunotherapy, Nexvax2.

"Our vision is to improve the diagnosis and treatment for patients with celiac disease and allow them to return to a normal diet, good health and improved quality of life. We are focused on happy and healthy patients and families. The average time to formal diagnosis has been reported to be 9 years so by providing improved diagnostics and treatment options we also hope to improve the awareness so patients are diagnosed sooner. Nexvax2 is a disease modifying T-cell epitope derived peptide immunotherapy that will restore antigen-specific immunological tolerance in DQ2 celiac disease. It is the only treatment designed to allow patients to resume a normal healthy diet containing gluten." - Leslie J Williams

CEOCFO: What have you realized at ImmusanT as far as the potential vaccine that others have not understood?

Ms. Williams: It is understood by most that a strict gluten free diet is challenging to maintain, nutritionally deficient and can be socially isolating. These shortcomings may be the reason why the small intestine remains inflamed in many patients who think they maintain a gluten free diet; such patients are increased risk of long-term complications. The need for a therapeutic option beyond a dietary supplement is needed. We were the first to recognize the importance and value of measuring the specific immune response to gluten in blood after oral gluten challenge. This enabled the immune response to particular gluten peptides to be used to design our therapy and in diagnostics. Celiac Disease is an autoimmune disease triggered by the ingestion of gluten in genetically susceptible people. Nexvax2 utilizes the most important fragments of gluten that are the immunological trigger for the disease. Dr. Anderson identified the sections of the dominant peptides that trigger the immune response. Our vaccine is designed to reprogram the immune response so gluten is tolerated. Nexvax2 is a disease modifying T-cell epitope derived peptide immunotherapy that will restore antigen-specific immunological tolerance in DQ2 celiac disease. It is the only treatment designed to allow patients to resume a normal healthy diet containing gluten. Thus, our approach is differentiated from other treatments in development that would be used in conjunction with a GFD.

CEOCFO: You are conducting trials in New Zealand, Australia and the US. Why New Zealand and Australia?

Ms. Williams: The Phase 1b US trial and the Phase 1b Australia/New Zealand trial are safety and tolerability studies using different approaches to dosing. The earlier Phase 1 clinical

trial was completed in Australia in 2010 and our Phase 1b Australian/New Zealand trial is a continuation of that. Also, Dr Bob Anderson, our chief scientific officer, was a gastroenterologist in Melbourne, Australia, and worked with support groups, primary care physicians and gastroenterologists throughout the country to improve standards of care with accurate diagnosis.

CEOCFO: Have you identified any potential side effects so far?
Ms. Williams: Immunization in the completed Phase I study on HLA DQ2 volunteers with celiac disease was shown to be well tolerated and safe without any serious adverse events. In our current Phase 1b trials we are looking at safety and tolerability at different dose levels and durations. The formulation is straightforward consisting of the 3 peptides in normal saline with no adjuvant. Also, the peptides are small, 15-16 amino acids in length, so there is minimal risk for crosslinking IgE, thereby avoiding potential anaphylaxis which can occur in allergy treatments.

CEOCFO: What is the prevalence of celiac disease today? What is the potential market for ImmusanT?
Ms. Williams: Approximately 1-2% of the entire US and European population have celiac disease. Medical awareness and diagnosis rates vary widely between countries, but in the US only 5-10% of the cases have been formally diagnosed compared to other parts of the world such as Finland and the UK which have diagnosis rates > 25%. Among adults diagnosed with celiac disease, 30% have autoimmune diabetes and/or thyroid disease. The typical time from onset of symptoms to a diagnosis of celiac disease can be prolonged, in the US this delay has been reported to be as long as 10 years. Undiagnosed patients are at risk for a variety of systemic issues such as osteoporosis, fatigue and depression, infertility, lymphoma's and others, and are at increased risk of all-cause mortality. This represents significant unmet medical need. ImmusanT's market is celiac patients who carry the HLA-DQ2 gene which is the majority, 80-90%, of celiac patients.

CEOCFO: Has the portion of the medical community that should pay attention to ImmusanT aware of your progress?
Ms. Williams: Physicians, nutritionists and nurses specializing in celiac disease as well as celiac patients are extremely interested in what we are doing and following our progress. However, there is a lack of awareness and understanding the necessary steps for diagnosis of the disease more broadly especially amongst primary care physicians. We believe that improved diagnosis and providing treatment options to a gluten free diet will increase awareness of the celiac disease and the companies developing the treatments such as Nexvax2 at ImmusanT.

CEOCFO: Are they aware of ImmusanT and what you are working on?
Ms. Williams: Healthcare providers who treat patients with celiac disease or touched by the disease are aware of what we are doing at ImmusanT. There has been tremendous interest in Nexvax2. In fact, vaccination was chosen as the preferred option among emerging treatments to GFD by patients with celiac disease. The unmet need for celiac patients is significant, the interest is high and we are compelled and motivated to providing these patients with treatment options that improve their health and quality of life.

CEOCFO: Development is certainly a costly endeavor. How far will your current funding take ImmusanT?
Ms. Williams: Yes, clinical development is costly. Our funding will allow us to finalize our current trials and beyond. We are fortunate to be backed by Vatera Healthcare Partners. There has also been interest from various pharmaceutical companies which we are exploring as we advance the development of Nexvax2 and our companion diagnostic.

CEOCFO: Would you tell us about your background and the background of your team, which enables a smooth transition to commercialization?
Ms. Williams: We have an incredible team with extensive experience in transitioning from the lab to the market. I have been in the industry for more than 20 years with experience in healthcare, management, commercial product development and marketing. I founded ImmusanT in 2010 and acquired the assets from Nexpep based in Melbourne, Australia. I had worked with Dr. Anderson and advised Nexpep for over a year prior to acquiring the asset. Before this I was a Venture Partner at a venture firm and worked with companies on strategy, business development and M&A in addition to assessing and sourcing companies for investment. Before that I was President & CEO of Ventaira Pharmaceuticals which developed a proprietary pulmonary drug delivery technology. The company was sold the end of 2007. Prior to this I was Director of Marketing and held a variety of commercial positions at INO Therapeutics which included lobbying for reimbursement. INO Therapeutics was sold to Ikaria for $670M. Previous experience also includes commercial positions at GlaxoSmithKline and Merck where I was involved with a variety of product launches.

Dr. Bob Anderson is the inventor of the immunodominant peptides and is our Chief Scientific Officer. Bob moved to the US from Australia this year. Formerly, he was a gastroenterologist focused on T-cell epitope discovery in celiac disease in Melbourne, Australia and Oxford, UK. Over the last 13 years, his academic research identified immunoreactive peptides in gluten responsible for celiac disease. He pioneered the in vivo antigen challenge and high throughput peptide screening to provide accurate, personalized T-cell epitope profiling. Since 2002, he worked closely with Australian support groups, primary care physicians and gastroenterologists to improve medical and public awareness of celiac disease.

Dr. Patrick Griffin joined ImmusanT in 2012 as Chief Medical Officer and Senior VP of Development. He has

over 25 years experience in drug development. Patrick is a board-certified physician in both internal medicine and gastroenterology and most recently held the position as Head of External Innovation for Sanofi's immuno-inflammation therapeutic strategy unit, where he had a particular focus on therapeutic approaches to autoimmunity through immune system modulation. He originally joined Sanofi in 2005 as a Senior Director, Clinical Development in the area of internal medicine. Previously he was responsible for clinical development at Forest Laboratories. Prior to industry he held a faculty position at Columbia and had a solo internal medicine and gastroenterology practice in NYC. He brings exceptional expertise as a gastroenterologist, drug developer and evaluator of numerous drug candidates for immune and inflammatory diseases.

CEOCFO: Why should investors and people in the drug development community pay attention to ImmusanT?

Ms. Williams: There is significant need for a therapeutic treatment for patients with Celiac Disease which affects 1-2% of the population and there is currently no pharmacologic option. Gluten free diet is the only treatment available. Nexvax2 will be the first of a new class of antigen specific immunotherapies being developed in conjunction with diagnostics for autoimmune diseases. Nexvax2 is designed to modify celiac disease and allow patients to resume a normal diet containing gluten. We are currently in Phase 1b of our clinical development program and are leveraging our companion diagnostic to screen responders. In addition the fact that Celiac Disease has a genetic component, the affected organ, the small intestine, can be accessed and the tissue damage is reversible and we know the specific exogenous antigens that trigger the immune response make Celiac Disease is an ideal model for autoimmune disease. Nexvax2 is the first treatment in our proprietary discovery platform for targeted therapies and diagnostics. We are also expanding our development program and leveraging our understanding to other autoimmune diseases beginning with Type I diabetes. Finally our robust patent portfolio is blocking.

So our technology is game changing for Celiac Disease but also more broadly for a new class of therapeutics and linked diagnostics.

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