



# REGiMMUNE Announces Collaboration with JDRF and Pfizer Inc. for Type 1 Diabetes Prevention and Treatment Promoting Regulatory T-Cells

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- Antigen-Specific Immunotherapy to Potentially Prevent or Delay Diabetes in Preclinical Model -

Tokyo, Japan - April 14 - REGiMMUNE Corporation (RGI) and JDRF today announced a partnership, along with financial assistance and scientific expertise from Pfizer Inc., for a research collaboration to develop an antigen-specific immunotherapy utilizing RGI's proprietary  $\alpha$ GalCer/liposome platform for immunological tolerance for the treatment of type 1 diabetes (T1D). Under the terms of the collaboration, REGiMMUNE will develop an antigen-specific therapeutic liposome that potentially prevents or delays the onset of T1D and induces immunologic tolerance.

"JDRF's mission is to create a world without type 1 diabetes and to ultimately find a cure. We collaborate and work with many organizations in our efforts to enable this goal. We are pleased to enter a new partnership with REGiMMUNE to develop an antigen-specific immunotherapy that might result in a new treatment for T1D based on their unique liposome platform," said Richard A. Insel, MD, chief scientific officer for JDRF. "We look forward to a very productive collaboration."

Key defects in the human immune system are believed to be an underlying cause of T1D. The regulatory T cells (Tregs) in the immune system help turn off the immune response

when no longer needed to respond to an infection or foreign substance, essentially acting as the master police of the immune system. In T1D, islet-reactive CD8+ T cells play a central role by infiltrating the pancreas and destroying the insulin producing beta cells. The joint research collaboration is investigating a therapy designed to potentially restore the normal balance within the immune system and therefore help prevent T1D or delay the need for insulin therapy. The candidate therapy will be derived from the RGI  $\alpha$ GalCer/liposome platform containing an encapsulated T1D target antigen (RGI-3100). This approach is unique in that it combines an antigen specific therapy with an immune modulatory component which may lead to the induction of tolerance to multiple T1D-related antigenic specificities.

RGI's  $\alpha$ GalCer/liposome platform, when utilized with T1D autoantigens, may be effective in inducing T1D-specific Tregs and specific immune tolerance for T1D patients without promoting broad immunosuppression associated side-effects as typically seen with other therapeutics. With the support of three partners, a preclinical mouse study will assess the therapy for efficacy in delaying the onset of T1D.

REGiMMUNE chief executive officer Yasuyuki Ishii, PhD, commented, "It is an honor to partner with JDRF for our diabetes research collaboration. We are hopeful that this partnership program will garner valuable data that will lead to further development in human studies and ultimately, to a new approach to treating or even preventing type 1 diabetes."

**About JDRF** JDRF is the leading global organization focused on type 1 diabetes (T1D) research. JDRF's goal is to progressively remove the impact of T1D from people's lives until we achieve a world without T1D. JDRF collaborates with a wide spectrum of partners and is the only organization with the scientific resources, policy influence and a working plan to bring life-changing therapies from the lab to the community. As the largest charitable supporter of T1D research, JDRF has invested nearly \$2B in research over the past 45 years and is sponsoring scientific research in 17 countries worldwide. For more information, please visit [jdrf.org](http://jdrf.org)

**About REGiMMUNE** REGiMMUNE Corporation is a biotechnology company focused on the discovery, development and commercialization of immune regulatory therapeutics to treat life-threatening and debilitating conditions, including allergies, autoimmune diseases and transplantation. The company's proprietary platform technology, reVax, induces immune tolerance in an antigenspecific manner through pharmacological induction of regulatory T (Treg) cells. Using its reVax technology, REGiMMUNE is developing RGI-2001, which may be the first drug in the class of Treg-inducing agents.

The company is also applying its reVax technology to develop a range of pipeline products, including its RGI-1000 series for allergy and its RGI-3100 series for type 1 diabetes. Additionally REGiMMUNE is developing products for preventing inhibitor formation in enzyme replacement therapies (ERT) and for celiac disease with undisclosed partners. The company is seeking pharmaceutical partnership opportunities for its products worldwide, exclusive of Japan. REGiMMUNE is headquartered in Tokyo, Japan and has a US operation in Berkeley, California. For more information, visit [www.regimmune.com](http://www.regimmune.com).

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