



AVM Biotechnology Awarded \$1.6 Million Phase II SBIR Grant to Study AVM0703's Potential to Reverse Type 1 Diabetes

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Seattle, WA – ([BUSINESS WIRE](#)) - AVM Biotechnology, LLC, a clinical stage company advancing AVM0703 in the treatment of Non-Hodgkin's Lymphoma (NHL)/Leukemia, today announced that it has been awarded a Phase II Small Business Innovation Research (SBIR) grant. This \$1.6 million award from the National Institute of Diabetes and Digestive Kidney Disease (NIDDK) will allow the company to pursue additional research in the use of AVM0703 as a monotherapy and combination therapy to reverse recent onset and established Type 1 Diabetes (T1D). T1D is an autoimmune disease that destroys beta cells, the insulin-making cells in the pancreas. This award provides an endorsement of AVM0703's potential in two distinct and crucial therapeutic areas, diabetes and cancer.

The company has partnered with Dr. Clive Wasserfall, University of Florida, College of Medicine for this grant. Dr. Wasserfall's research activities are focused on the immune pathogenesis of T1D. He has paved the way for both prevention and reversal efforts in T1D. Dr. Wasserfall is a respected leader in diabetes research having authored more than 170 publications and several book chapters on diabetes and immunology. He serves as a reviewer for many journals including Diabetes, Pediatric Diabetes, and the Journal of Clinical Endocrinology and Metabolism.

"My laboratory is very excited to collaborate with Dr. Deisher and AVM in testing AVM0703 in preclinical type 1 diabetes. This novel compound has great potential to safely interdict autoimmune disease, and this is greatly needed in the type 1 diabetes space," stated Dr. Wasserfall.

AVM0703 is a small molecule which triggers the production and release of endogenous bispecific gamma delta TCR+ invariant TCR+ Natural Killer T-like cells (AVM-NKT). These naturally occurring amplified immune cells have unique properties and appear rapidly in the blood following a single dose of AVM0703, which has shown efficacy in delaying T1D in murine models.

Type 1 diabetes mellitus affects approximately 20 million individuals worldwide, including 1.25 million Americans. T1D is associated with an annual economic burden in the US of \$14.4 billion. Therapeutic insulin and other treatments do not cure T1D, but simply control blood glucose levels. Even in combination, current immunotherapies can fail to guarantee restoration of insulin independence. One such therapy, autologous hematopoietic stem cell transplantation (HSCT) exposes patients to the risk of possible side effects, including short-term risk of infection, acute organ dysfunction, and long-term risks of malignancies and secondary autoimmune disease. AVM0703 may provide a safer and more sustainable treatment option.

Data suggest that a single dose of AVM0703 removes autoimmune pathophysiologic substrates present in T1D patients. The short half-life precludes prolonged immune suppression, and the non-myeloablative lymphodepletion of AVM0703 is receptor-mediated and an "immunologic reset" that can be repeated in cases of relapse. Importantly, AVM0703 has been well-tolerated in clinical studies with generally mild to moderate and self-limiting side effects.

This NIDDK grant follows an earlier 2019 Phase I grant for targeted lympho-ablation as an alternative to cure T1D. Results of that preclinical research program showed that AVM0703 significantly delayed the onset of T1D by 20-31 weeks in 55% of treated mice and prevented diabetes onset in the other 45% of mice. This Phase II funded project has been designed to further preclinical research, to expedite data acquisition to support an IND and pave the way to clinical trials. The grant will be awarded over a two year period with the second year payment subject to funds availability and satisfactory progress of the study.

A preclinical dose-finding and mechanism of action (MOA) study in three scenarios including pre-diabetic, new-onset, and established diabetes is the first aim of the program. Those results will be used to determine the targeted dose to be used in a pivotal efficacy study for reversal of new-onset and established diabetes. It is anticipated that for patients not showing remission, AVM0703 may reinforce other immunotherapies allowing a wider range of patients to achieve insulin independence.

About AVM Biotechnology

AVM Biotechnology is a clinical stage company developing AVM0703 for cancer, infectious disease syndromes, and autoimmunity diseases as a commercial product. The basis for these programs is the endogenous mobilization and activation of AVM-NKT cells by a glucocorticoid-receptor-independent mechanism with the administration of AVM0703. While the full potential of these cells continues to be explored by AVM scientists, it is clear they have the potential to play a significant role in several diseases providing the prospect of a high value pipeline.

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