ImmunoMolecular Therapeutics Awarded SBIR Grant and Receives Rare Pediatric Disease Designation from FDA for IMT-002

-- SBIR grant awarded to develop D-MDOPA for the preservation of residual beta cell function in type 1 diabetes --

-- Rare Pediatric Disease designation granted to IMT-002 for type 1 diabetes--

BROOMFIELD, Colo. – November 14, 2018 – ImmunoMolecular Therapeutics (IM Therapeutics), a company developing personalized small molecule therapies for the treatment of genetically defined autoimmune diseases, today announced that it has been awarded a grant from the Small Business Innovation Research (SBIR) program to develop the D enantiomer of methyldopa (D-MDOPA) into an oral small molecule drug for the preservation of residual beta cell function in type 1 diabetes (T1D). IM Therapeutics is developing D-MDOPA as lead candidate, IMT-002, which was granted Rare Pediatric Disease designation from the United States Food and Drug Administration (FDA).

"The Rare Pediatric Disease designation and SBIR grant awarded to IM Therapeutics for D-MDOPA show the need for new treatment options for type 1 diabetes, a lifelong disease for which there are no approved therapies to treat the underlying autoimmunity," said Aaron Michels, M.D., Chief Scientific Officer, IM Therapeutics. "We are developing D-MDOPA as IMT-002, to inhibit the autoimmune cascade in recent onset T1D patients with the human leukocyte antigen (HLA)- DQ8 gene with the intent to preserve beta cell function and maintain normal insulin production."

"The SBIR grant will help support the development of IMT-002 to IND filing in 2019 and into Phase 1 studies," said Peter Gottlieb, M.D., Interim Chief Executive Officer and Chief Medical Officer, IM Therapeutics. "We look forward to evaluating IMT-002 in T1D patients and to extending our platform for identifying HLA-specific drugs to celiac disease."

IM Therapeutics has conducted a series of studies to evaluate the initial toxicity, pharmacology and metabolic properties of D-MDOPA to establish initial safety parameters, inform future dosing strategies, and further differentiate L-MDOPA from D-MDOPA in terms of in vitro metabolism to support development of a clinical program. To advance D-MDOPA to filing an IND in 2019 and further delineate the drug target effect, the SBIR grant will allow IM Therapeutics to evaluate the direct drug target effect for D-MDOPA both in vitro and in vivo.

The FDA grants Rare Pediatric Disease designation for diseases that primarily affect people aged from birth to 18 years, and that affect fewer than 200,000 people in the U.S. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.

About Type 1 Diabetes

Type 1 diabetes (T1D) is a polygenetic disorder that affects the insulin producing beta-cells in the pancreas, categorized by a lack of sufficient insulin production, which prevents tissues from utilizing glucose, leading to high blood sugar. Insulin production is slowed when T and B cells react to self-antigens in the islets of the pancreas where the body's insulin-producing beta-cells reside. The human HLA-DQ8 gene is the most significant factor in predisposing an individual to acquire T1D. The DQ8 gene is present in 50-60% of T1D patients and its protein product (a major histocompatibility class II molecule) is known to abnormally bind and present particular self-peptides to autoreactive T cells.

About IMT-002

IMT-002 (D-MDOPA) is an oral small molecule drug being developed to treat T1D in patients with the HLA-DQ8 gene. IMT-002 occupies the peptide binding groove of DQ8 present on the surface of antigen presenting cells where diabetogenic peptides such as insulin are presented to CD4 T-lymphocytes to initiate the autoimmune cascade. When HLA-DQ8 function is inhibited, the immune system will no longer attack insulin producing beta-cells, thus creating the potential for at risk or early stage patients to maintain normal insulin production. IMT-002 has been granted Orphan Drug status by the U.S. FDA.

About IM Therapeutics

IM Therapeutics is developing personalized immuno-therapeutic drugs for autoimmune diseases based on the genetic risk attributed by human leukocyte antigen (HLA) genes. The lead candidate drug is an oral small molecule that starves the autoimmune process in type 1 diabetes (T1D) by blocking DQ8 on specific immune cells. Our goal is to preserve pancreatic beta-cell function and maintain normal insulin production in at-risk and early-stage patients with type 1 diabetes. We are leveraging our platform for identifying HLA-specific drugs to expand our pipeline beyond T1D, to include celiac disease as well as potential additional autoimmune diseases.
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