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Antibody based treatment for Type 1 Diabetes

A humanized monoclonal antibody against Serpin B13 to treat Type 1 Diabetes.

Technology No. 20180340

IP Status: Provisional Patent Application Filed; **Application #:** 63/040,356

Serpin B13 offers potential treatment for type 1 diabetes

Type 1 diabetes (T1D) is a chronic, incurable disease affecting 1.5 million Americans with an estimated 40,000 new cases each year. Healthcare associated expenses and lost income due to T1D is estimated at \$14 billion annually. T1D is treated with regular administration of insulin, however the rising cost of insulin has led patients to ration treatment with devastating effects. 1 in 4 patients have reported cost-related insulin underuse resulting in poor glycemic control. Consequently, premature deaths related to such non-adherence are on the rise. T1D results from an autoimmune response in which the body attacks its own insulin-producing pancreatic beta-cells. As a result, the pancreas cannot produce enough insulin to regulate blood sugar levels. This can cause complications ranging from blindness, kidney failure to early death.

Researchers at the University of Minnesota seeking to find new interventions for diabetes identified serpin B13 proteinase inhibitor as a potential target for diabetes treatment. The scientists developed a monoclonal antibody (mAb) targeting serpin B13 (clone B29) that shows promise as a novel treatment strategy for T1D. When administered to diabetes prone mice, the antibody reduces the number of inflammatory cells (associated with an auto-immune response) and leads to increased proliferation of beta cells in the animals. This approach is particularly promising as a human therapeutic since studies in humans have shown that natural serpin B13 autoantibodies are associated with positive outcomes in T1D. Instructively, high levels of serpin B13 autoantibodies were correlated with lower risk for T1D. Building on the efficacy observed with the mouse mAb, it is anticipated that a humanized version of the antibody will prevent immunogenic effects while offering therapeutic relief.

May also treat inflammatory and/or central nervous system diseases

Due to its ability to reduce inflammation and induce tissue regeneration, this novel humanized mouse monoclonal antibody (mAb) targeting serpin B13 may also prove therapeutic for inflammatory and/or central nervous system diseases (e.g., bone fractures, ulcerated skin lesions/wounds, multiple sclerosis, lupus, hair loss, etc.).

Phase of Development

- In vivo animal studies have shown that the antibody is capable of reducing inflammation and induces beta-cell regeneration.

Features & Benefits

- **Treats Type 1 Diabetes:** Administration of antibodies to Serpin B13 in mouse models of disease results in reduced inflammation, increased beta-cell proliferation and decreased blood sugar.
- **Based on identified human biomarkers:** Natural autoantibodies to Serpin B13 are associated with positive outcomes in Type 1 Diabetes in humans.
- **Reduced host immune reactivity:** The creation of a humanized version of the antibody helps mitigate immunogenic effects in humans.

Applications

- Treatment for Type 1 diabetes
- Treatment for tissue regeneration: bone fractures, skin ulcerations/wound healing, hair loss, diabetic foot, etc.
- Treatment for other inflammatory and central nervous system diseases: multiple sclerosis, lupus, encephalomyelitis, etc.
- Endocrinology

Researchers

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Associate Professor, Department of Laboratory Medicine and Pathology

[External Link](http://www.med.umn.edu) (www.med.umn.edu)

Publications

[Antibody response to Serpin B13 induces adaptive changes in mouse pancreatic islets and slows down the decline in the residual beta cell function in children with recent onset of Type 1 Diabetes Mellitus](#)

Journal of Biological Chemistry, 2016, Jan 1; 291(1): 266-278

[Cellular proliferation in mouse and human pancreatic islets is regulated by serpin B13 inhibition and downstream targeting of E-cadherin by cathepsin L](#)

Diabetologia, 2019, Jan 1; 62(5): 822-834

[Enhanced anti-serpin antibody activity inhibits autoimmune inflammation in type 1 diabetes](#)

Journal of Immunology, 2012; 188:6319-6327

[Anti-serpin antibody-mediated regulation of proteases in autoimmune diabetes](#)

The Journal of Biological Chemistry, 2013; 288:1612-1619

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