



## Diabetes

### Overview

Diabetes, also known as diabetes mellitus, is a group of metabolic diseases in which a person has high blood sugar either because the body does not produce enough insulin, or because cells do not respond to the insulin that is produced.

There are two primary types of diabetes. Type 1 diabetes, also known as insulin-dependent or juvenile diabetes, is an autoimmune disorder in which the immune system attacks and destroys the insulin-producing beta cells in the pancreas. Type 2 diabetes, known as adult onset or non-insulin dependent diabetes, is caused when either there is a deficiency in the insulin being produced, or when the cells of the body become resistant to the action of insulin. Over time, the pancreas becomes unable to make enough insulin, and glucose accumulates in the bloodstream in the same manner as in type 1 diabetes.

Diabetes is a chronic condition that requires constant monitoring and creates dangerous and debilitating secondary conditions. Long-term complications include increased risk of cardiovascular problems such as coronary artery disease, heart attack and stroke. Other complications include nerve damage in the limbs, kidney failure, blindness and nerve damage in the feet and legs that can cause diabetic foot ulcers which, if not treated properly, can lead to amputation.<sup>1</sup>

Current treatments for type 1 diabetes include constant monitoring of blood glucose levels and insulin therapy which is time-consuming, costly and painful for many patients. Some type 2 patients also rely on insulin therapy, but the condition can often be managed with other diabetes medications, healthy eating and exercise.

### Diabetes and Regenerative Medicine

There are a variety of regenerative medicine technologies in preclinical and clinical development that aim to reestablish insulin production and mediate the immune system's attack on insulin producing beta cells. Some of the most innovative research is being funded by the [Juvenile Diabetes Research Foundation](#) (JDRF), the leading non-profit organization in the area of type 1 diabetes research. JDRF is working with several organizations including [Viacyte](#), [Osiris](#), researchers at the [University of Florida](#) and the [National Institutes of Health](#) among others, to develop regenerative medicine technologies for diabetes.

[Athersys, Inc.](#) is in preclinical stages of testing its MultiStem stem cell product in diabetes (as well as other autoimmune diseases). The company believes that MultiStem has the potential to regulate immune system function, and could thus work to protect the beta cells that are under attack in type 1 diabetes.

Mesoblast is using their patented human mesenchymal progenitor cells to target type 2 diabetes. In preclinical trials, the injection of a dose of MPCs into mice with diabetes resulted in a significant increase in blood insulin levels and sustained reduction in blood glucose levels during the follow-up period. Mesoblast is in the midst of a 60 patient Phase 2 clinical trial.

Osiris has completed enrollment for a Phase 2 type 1 diabetes clinical trial evaluating the efficacy and safety of their product Prochymal. Prochymal uses mesenchymal stem cells for their believed ability to delay the progression of type 1 diabetes by preserving beta cell function, and thus insulin production.

ViaCye, a San Diego, CA-based regenerative medicine company, is developing a stem cell based technology for the treatment of type 1 and type 2 diabetes. The company is developing a combination cell therapy, medical device product, VC-01, which packages and encapsulates the PEC-01 pancreatic precursor cells derived from a human embryonic stem cell line in their ENCAPTRA drug delivery system. In animal

models, the cells differentiated into insulin producing and other endocrine cells that regulated blood glucose in a manner very similar to the normal pancreas when implanted under the skin.

Researchers have also been looking at gene therapy as a means to treat diabetes. In February 2013, researchers at the **Universitat Autònoma de Barcelona** (UAB) claimed to have reversed all signs of type 1 diabetes in dogs using this approach with a single gene therapy session. The study showed promising signs of long-term control of diabetes in large animals.

## Current Regenerative Medicine Therapies for Diabetes

In addition to these significant steps towards treating the root cause of diabetes, there are several regenerative medicine therapies currently on the market to treat diabetic foot ulcers and chronic wounds that are very common and serious comorbidities of diabetes. See ARM's disease profile on non-healing wounds for more information on these therapies.

## Diabetes : Economic Impact

As of January 2011, there are over 25 million Americans that suffer from diabetes, with 90% of the patient population being afflicted with type 2.<sup>2</sup> This number is expected to increase due to a rise in obesity (obese people are more prone to develop diabetes) as well as other factors. Healthcare costs for people suffering from diabetes are 2-3 times higher than for people without the disease.



### \$174+ Billion

Total disease cost for diabetes care in the U.S. as of 2007.<sup>3</sup>



### 24 Million → 44 Million

Forecast increase in number of Americans afflicted with diabetes by 2034.<sup>4</sup>



### 200% → \$336 Billion

Forecast increase in direct economic costs for diabetes care by 2034.<sup>4</sup>

<sup>1</sup> American Diabetes Association, "Living with Diabetes: Complications," ADA website, [www.diabetes.org/living-with-diabetes/complications/](http://www.diabetes.org/living-with-diabetes/complications/)

<sup>2</sup> 2011 National Diabetes Fact Sheet: National Estimates and General Information on Diabetes and Prediabetes in the United States available at <http://www.cdc.gov/diabetes/pubs/estimates11.htm#11> (published by Centers for Disease Control and Prevention, 2011)

<sup>3</sup> 2011 National Diabetes Fact Sheet: National Estimates and General Information on Diabetes and Prediabetes in the United States available at <http://www.cdc.gov/diabetes/pubs/estimates11.htm#11> (published by Centers for Disease Control and Prevention, 2011)

<sup>4</sup> Anirban Basu, James C. Capretta, E.S. Huang, Michael O'Grady, "Projecting the Future Diabetes Population Size and Related Costs for the U.S." *Diabetes Care* Vol. 32 (12). December 2009, pp. 2225-2229. Available at [care.diabetesjournals.org/content/32/12/2225.full.pdf](http://care.diabetesjournals.org/content/32/12/2225.full.pdf)