

**2009 North American Diabetes Mellitus Therapeutics
Excellence in Healthcare Product Innovation of the Year Award**

CureDM, Inc.

Frost & Sullivan's 2009 North American Excellence in Healthcare Product Innovation of the Year Award for diabetes mellitus therapeutics is presented to CureDM, Inc. to recognize the development of Human proIslet Peptide, Pancreate™. This technology is unique in that it opens up the possibility of a treatment option that repopulates the pancreas with new islets, thereby offering a distinctive and potentially curative method to treat type-1 diabetes, Latent Autoimmune Diabetes in Adults (LADA), type-2 diabetes, and pre-diabetes.

Company Background

CureDM is a biotherapeutics company that focuses on diseases associated with metabolism. CureDM's core focus has been the development of peptide therapeutics through an amalgamation of capabilities involving bioinformatics, proteomics, and Human Genome sequence data. Under the visionary leadership of its three founders, CureDM has worked toward developing new therapeutic approaches for the treatment of diabetes and its reversal that will enable discontinuation of insulin therapy and reduce or eliminate clinical complications. Therein, CureDM has developed proprietary platform technologies based on human genomics and proteomics data to identify bioactive components of gene products that are essential to meet such medical needs.

Relevance in the Market Place

About twenty-one million people living in the US are estimated to be affected with diabetes. Of these, 10% of the patients with diabetes have autoimmune type-1 diabetes. Increasingly, patients are being diagnosed with type-1 diabetes at the rate of 4% per year. The incidence of diabetes is growing at a two-digit rate worldwide and about 300 million patients are deemed to be diabetic by 2030. In 2002, the US spent around \$132 billion treating diabetes and related problems. Diagnosis of diabetes reveals that in most cases, the islet mass is reduced by 80% in type-1 patients and by 50% in type-2 patients, which highlight the importance of targeting and restoring the islet population to reverse this disease. The therapeutic portfolio for diabetes is

currently challenged by the lack of sufficient technologies and alternatives that could be effective in treating the core disease pathology associated with type-1 and type-2 diabetes or conditions of impaired insulin production and glucose metabolism. As a consequence, there is a need to develop restorative therapeutic solutions that would help bring the biochemical constitution of the patient to homeostasis.

Technology Overview

CureDM's product Pancreate™, Human proIslet Peptide (HIP), effectively addresses the above mentioned challenges by its mechanism of re populating the pancreas with new islet structures. Pancreate™ is derived from a sequence of the human Reg3a protein. It is a 14-amino acid peptide inducing regeneration of new islets that contain alpha, beta, gamma, and delta cells, all of which are essential to control glucose homeostasis. It is projected that treatment with Pancreate™ involves once or twice daily dosing for a period of months followed by maintenance dosing. During this period, the patient's dosages of insulin injections may be drastically reduced and ultimately eliminated as Pancreate™ stimulates islet neogenesis and enhances the natural secretion of the patients own insulin in response to glucose levels in the blood.

While patients suffering from type-1 diabetes require a combination of Pancreate™ with an immune tolerance agent, to protect the new islets from autoimmune attack, patients with type-2 diabetes could receive Pancreate™ along with existing therapies thereby amplifying their effect. In other words, Pancreate™ serves the function of an adjuvant in the treatment rendered to type-2 diabetes patients. Furthermore, in patients with pre-diabetes, Pancreate™ could be used to prevent the progression of pre-diabetes by alleviating stress on existing islets.

Innovative Features

Treatment with Pancreate™ results in a 4-fold increase in insulin secretion in human pancreatic ductal tissue cultures and a 3-fold increase in islet numbers in a diabetic mouse model. Pancreate™ addresses the underlying disease pathology of not only reduced islet mass, but reduced islet numbers among diabetes patients. Ultimately, Pancreate™ will be combined with an immune tolerance agent for type-1 diabetes to protect new islets generated by Pancreate™ from autoimmune attack and deployed in various ways in type 2 patients. Based on extensive animal data, normalization of diabetes related biomarkers have occurred in as little as 10 weeks and diabetic animals were rendered insulin free after 21 days of treatment. To date, no other

therapy has reached the market with such potential outcomes based on the mechanism of islet neogenesis.

Best Practices

CureDM has created, stabilized, and characterized this unique peptide in a numerous pre-clinical studies. In these studies, researchers have shown that HIP enhances insulin secretion in human pancreatic ductal tissue devoid of islets. This discovery was published in the journal *Endocrine Practice* in December 2008. CureDM is now in the process of completing the key toxicological studies required to file an IND. Moreover, the company expects to initiate clinical trials in both, type-1 and 2 diabetes in early 2010. The USPTO issued a Composition of Matter Patent to CureDM in 2008 for the structure and use of HIP in diabetes and related disorders based upon the pre-clinical studies both in human pancreatic ductal tissue and in pre-clinical studies for diabetes. The *in vitro* proof of concept studies was carried out with Dr. Shaoping Deng, Director of the Human Islet Laboratory at the University of Pennsylvania, who now heads a similar function at Harvard/Massachusetts General, where CureDM continues the collaboration.

Conclusion

In recognition of its development of the Human proIslet Peptide (HIP) and the innovation shown in combining its application to existing diabetes therapies, Frost & Sullivan is pleased to present CureDM, Inc. with the 2009 North American Excellence in Healthcare Product Innovation of the Year Award in the field of diabetes mellitus therapeutics.

Award Description

Frost & Sullivan's Technology Innovation Award is bestowed upon a company (or individual) that has carried out new research, which has resulted in innovation(s) that have or are expected to bring significant contributions to the industry in terms of adoption, change, and competitive posture. This award recognizes the quality and depth of a company's research and development program as well as the vision and risk-taking that enabled it to undertake such an endeavor.

Research Methodology

To choose the award recipient, Frost & Sullivan's analyst team tracks innovation in key hi-tech markets. The selection process includes primary participant interviews and extensive primary and secondary research via the bottom-up approach. The analyst team shortlists candidates based on a set of qualitative and quantitative measurements. The analysts also consider the pace of research and technology innovation, and the significance or potential relevance of the innovation to the overall industry. The ultimate award recipient is chosen after a thorough evaluation of this research.

Measurement Criteria

In addition to the methodology described above, there are specific criteria used to determine the final rankings. The recipient of this award has excelled based on one or more of the following criteria:

- Significance of the innovation(s) in the industry, and across industries (if applicable).
- Potential of the products of innovation(s) to become industry standard(s).
- Competitive advantage of innovation vis-à-vis other related innovations.
- Impact (or potential impact) of innovation(s) on company or industry mind share and/or company bottom line.
- Breadth of intellectual property related to the innovation(s), that is, patents, scientific publications, and papers in peer-reviewed journals.

About Best Practices

Frost & Sullivan Best Practices Awards recognize companies in a variety of regional and global markets for demonstrating outstanding achievement and superior performance in areas such as leadership, technological innovation, customer service, and strategic product development. Industry analysts compare market participants and measure performance through in-depth interviews, analysis, and extensive secondary research in order to identify best practices in the industry.

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