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Novocell reports successful use of stem cells to generate insulin in mice

Novocell, Inc., a stem cell engineering company, today announced data demonstrating for the first time that human embryonic stem (hES) cells can be turned into pancreatic cells capable of producing insulin in mice. The findings are reported in an article appearing on-line today, in advance of print publication, in the journal *Nature Biotechnology*. This research provides evidence supporting the potential future use of hES cells to replace insulin-producing pancreatic cells that are destroyed in people with Type 1 diabetes, requiring them to receive regular insulin treatment.

The findings build on two previously reported studies by Novocell (*Nature Biotechnology* 2005 and 2006), whereby Novocell scientists demonstrated a process that successfully engineers hES cells into specific cells necessary for pancreas formation, and endocrine cells capable of producing insulin and other pancreatic hormones.

In this new work, Novocell has demonstrated that implantation of hES-derived pancreatic cells into mice results in the generation of glucose-responsive insulin producing cells. These cells exhibit properties characteristic of functional adult pancreatic insulin producing cells in the pancreas. Most importantly, these hES-derived cells provide protection in an animal model of diabetes characterized by loss of pancreatic insulin producing cells.

“Our data provide the first compelling evidence that hES cells can serve as a renewable source of functional insulin producing cells for diabetes cell replacement therapies,” said Emmanuel Baetge, Ph.D., Chief Scientific Officer of Novocell and senior author of the publication. “It also provides strong evidence that hES cell-derived endoderm cells are able to generate glucose-responsive insulin secreting cells that are functionally similar to adult human beta cells.”

Current cellular therapy for diabetes is performed by transplanting donor-derived human islets combined with chronic immunosuppression. While this has been demonstrated to be an effective therapy, the limited availability of donated pancreatic islets and the adverse side effects of long-term immunosuppression make this replacement therapy unsuitable for the general diabetes population.

Together with its stem cell engineering technology for insulin-producing cells, Novocell has also developed a delivery process by which such cells might be delivered to patients without the need for chronic immunosuppression. Novocell’s encapsulation technology provides a protective, coating for cells, thus allowing them to be more readily accepted in the body without the chronic use of immunosuppressive drugs. This encapsulation technology has been successfully tested in human clinical trials using human islets isolated from donor organs.

“By developing proprietary processes to successfully generate insulin-producing cells from hES cells in

vivo and protecting these cells from immune system rejection, we have created a potential treatment option that could lead to the first widespread application of cell replacement therapy for the treatment of diabetes,” said Alan J. Lewis, Ph.D., President and Chief Executive Officer of Novocell. “We look forward to the continued advancement of these technologies that hold such promise for transforming the treatment of diabetes.”

About Diabetes

Type 1, or insulin-dependent diabetes occurs when the pancreas ceases to produce insulin due to an autoimmune response that causes the selective destruction of insulin producing cells. People with Type 1 diabetes must take daily insulin and are candidates for pancreatic islet cell transplantation, which provides the potential to treat the disease. The disease is most common in children and young adults, accounting for approximately 10 percent of diabetes cases. The Juvenile Diabetes Research Foundation estimates that more than 1.1 million people suffer from Type 1 diabetes in the United States alone. Additionally, approximately 30 percent of people with Type 2 diabetes require insulin therapy and could potentially benefit from islet cell transplantation

About Novocell

Novocell, Inc. is a stem cell engineering company with research operations in San Diego, California and Athens, Georgia, dedicated to creating, delivering and commercializing cell and drug therapies for diabetes and other chronic diseases. Novocell has three primary technologies: stem cell engineering, cell encapsulation and drug discovery. The Company was founded in 1999 and merged with CyThera, Inc. and BresaGen, Inc. in 2004. For more information, please visit www.novocell.com