Novel Biotherapy for Type I Diabetes Presented at This Year's American Diabetes Association Meeting

SymbioCellTech's "Neo-Islet" technology, a minimally invasive, economical, and safe Stem Cell-enabled functional Cure for T1DM without immunosuppressive drugs.

Aiming for a functional cure to diabetes

SALT LAKE CITY, UT, USA, September 6, 2023 /EINPresswire.com/ -- SymbioCellTech (SCT), the regenerative medicine company, has released results of a three-year Investigational New Animal Drug (INAD) study that underscore the safety, effectiveness and feasibility of using Neo-Islets(™) in treating diabetic dogs, and offering such dog owners some hope for their pets. While this version of NI therapy is specifically formulated for dogs, the promising results from this dog study have positive and important implications for upcoming human trials which will test a human formulation of Neo-Islets(™).

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>
> *Anna Gooch, PhD*

Under the guidance of the U.S. Food and Drug Administration, SCT researchers began treatment of nine dogs (Bichon mix, Chihuahua mix and Jack Russell terriers), each diabetic and each dependent on insulin. The company administered Neo-Islets(™), a cellular replacement therapy that reestablishes adequate production of insulin. The INAD study focused on three objectives and "we met all our endpoints," according to SCT chief science officer Dr. Anna Gooch.

The impact of Neo-Islet(™) therapy is durable – six of the dogs in the study are now three years past treatment, the other three are still within the study protocols.

The primary concern was the safety of Neo-Islet(™) therapy. There were no serious adverse events related to the use of Neo-Islets in the study, nor was there any serious deterioration in liver function, lipids, electrolytes, renal function (kidney function) or blood cell counts.

In addition to safety, SCT sought to determine whether or not Neo-Islets(™) therapy is a feasible approach. In the study, 12 therapeutic doses were produced and that yield was sufficient to treat

all nine dogs, with four of them receiving a second dose and one a double dose. Dr. Gooch pointed out that “the process of creating Neo-Islets (™) is efficient, and we’ve demonstrated that we can produce what patients require.”

“What’s really promising is that these dog studies offered further evidence, and in a larger mammal, of the effectiveness of Neo-Islets(™),” according to SCT founder and CEO Dr. Christof Westenfelder. Serum glucose levels, the measure of blood sugar that reflects whether or not a patient is diabetic, fell to about 99 milligrams per deciliter, the normal range, and HbA1C levels dropped an average of four percent, also into the range considered normal for these dogs.

In addition to the observed better blood sugar control, dogs’ need for insulin dropped significantly over the treatment period. Dogs tend to need more insulin than humans, so the impact of Neo-Islet™ therapy on dog diabetes suggests that it can be even more impactful on humans. “We did this without any evidence of disease progression, or any damage to major organs,” Westenfelder added.

This third endpoint of the study stands out because it was accomplished without the use of any anti-rejection drugs, which are a burdensome, potentially harmful, and a problematic requirement of most other, otherwise promising diabetes biotherapies.

Dr. Gooch summed up the results of the INAD study with a brief acknowledgement of the work still ahead and a glimpse of its potential.

“We will continue to improve the efficacy of Neo-Islet(™) therapy in dogs by working on modifying the dose, adjusting its rate of achieving maximum potency and taking some other steps to make it even more useful in treating T1DM. With these very positive results treating diabetic dogs, and given the lower insulin requirements in Type 1 Diabetic humans compared to dogs, we are very hopeful about the implications this study has for people, and we are moving closer to the FDA-directed trials in humans, a real breakthrough for millions of diabetics.”

ABOUT SYMBIOCELLTECH:
SymbioCellTech (SCT) is a late preclinical stage Regenerative Medicine Company based in Salt Lake City, UT. The company has created a novel NEO-ISLETS(TM) technology that is readily scalable and that will reduce, and potentially eliminate, the daily insulin injection needs of people with Type I Diabetes mellitus. The NEO-ISLET(TM) technology has demonstrated its safety and efficacy in an Investigational New Animal Drug study in diabetic dogs and offers the potential to significantly increase available doses, eliminate the need for anti-rejection drugs and is a permanent solution for diabetics.

DISCLAIMER: FORWARD-LOOKING STATEMENTS
This press release contains forward-looking statements including (a) statements by Anna Gooch, Ph.D., and Christof Westenfelder, M.D., in this press release, (b) our plans, expectations for, and the potential benefits of NEO-ISLETS(™), and (c) our plans for additional research. While

SymbioCellTech believes the forward-looking statements contained in this press release are accurate, these forward-looking statements represent the company's beliefs as of this press release. Risks and uncertainties could cause actual events or results to differ materially from those expressed or implied by such forward-looking statements. Those risks and uncertainties include, among other things, that these data may not be indicative of final clinical trial results, that data from the company's research and development programs may not support further development of its products due to safety, efficacy, and other risks.

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