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From the Boston Business Journal:

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MGH study shows vaccine could permanently reverse type 1 diabetes

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Two years after beginning a groundbreaking phase II clinical trial in reversing type 1 diabetes, researchers from **Massachusetts General Hospital** have discovered that a vaccine could permanently reverse the disease.

The five-year long, mid-stage clinical trial is looking at the bacillus Calmette-Guerin vaccine, an inexpensive and already generic vaccine that is used around the world to prevent tuberculosis.

Dr. Denise Faustman, director of the Massachusetts General Hospital immunobiology laboratory and principal investigator of the trial, said interim results show that unlike other vaccines that irritate white blood cells to prompt an immune response, the BCG vaccine affects white blood cells at the genetic level, regulating which



COURTESY/MGH

Dr. Denise Faustman

genes are expressed and which are not. The body consequently stops producing the abnormal white blood cells responsible for the autoimmune disease, suggesting that the vaccine could permanently reverse type 1 diabetes.

“The vaccine actually resets your genes to restore normality,” Faustman said in an interview. “What it is showing is it’s not merely the vaccine you’re being given and it causes inflammation or an immune response. It’s actually working at the most basic DNA level to normalize expression of genes related to this abnormal immune response.”

The findings were presented Saturday during the 77th Scientific Sessions of the **American Diabetes Association**, one of the largest diabetes gatherings in the country.

The findings not only bring a broader understanding to ongoing studies of the vaccine for type 1 diabetes, but also explain why the vaccine is so effective in treating other autoimmune disorders — from multiple sclerosis (studies with the vaccine are ongoing in Italy) to food allergies (studies with the vaccine are ongoing in Australia).

“It’s because the immune system hasn’t been reset correctly in childhood,” Faustman said. “There are trials using this vaccine to reverse allergies in Australia. It’s putting the environment back into people.”

Used in China, Africa and South America to vaccinate against TB, the BCG vaccine has been utilized 4 billion times over the last 100 years. Last year alone, 100 million doses of the vaccine were given to newborns. Because TB isn’t common in the U.S., children here do not receive the vaccine.

The microorganism originates from the dirt. Faustman said the rise of autoimmune disorders, and the increase of food allergies and gluten intolerance, is tied to the fact that humans no longer interact with the dirt in the way they once did.

Clinical trials with the vaccine are ongoing. The lab has nearly recruited all of the 150 people for Phase II clinical trials, which have been funded largely by support from the Iacocca Family Foundation. Faustman’s lab is looking for the final \$5 million of the \$25 million necessary to finish the trial.

The goal of the latest clinical trial is to replicate results from the first phase of clinical trials, as well as analyze the dosing necessary to make the vaccine work

quickly. Faustman's lab has also conducted six-years of follow-up on Phase I patients within the latest study to see how patients are doing long-term. The results from those findings will be published by the end of the year.

Results from Phase 1 clinical trials, published in 2012, showed that the treatment eliminated defective immune cells that attack the pancreas, temporarily restoring the ability of the pancreas to produce small amounts of insulin. The data from that initial study only tracked patients over 20 weeks.

Success would be groundbreaking. Using an inexpensive vaccine that's already generic to reverse juvenile-onset diabetes would save the health care system billions of dollars and save patients from lifelong complication associated with the disease. According to the U.S. Centers for Disease Control and Prevention, annual medical costs for children with either type 1 or type 2 diabetes is \$9,061 — about six times the amount for youths without the disease.

While most vaccines are used preventatively, Faustman envisions making this vaccine available to anyone suffering from an autoimmune disorder.

"We're trying to figure out the dose that's effective and how significant of an impact it can have," Faustman said.

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