Multi-center clinical trial launched to investigate new treatment for pediatric type 1 diabetes

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Researchers at Massachusetts General Hospital (MGH), in partnership with NYU Langone Health, have launched a multi-center clinical trial to

investigate a new treatment for pediatric type 1 diabetes even in subjects with established disease. Also known as juvenile onset diabetes, type 1 diabetes is a life-altering autoimmune disease predominantly diagnosed in children in which the body is no longer able to regulate blood sugars. There are currently no approved therapies to reverse or slow the progression of type 1 diabetes. Insulin, the last major therapeutic innovation in the treatment of type 1 diabetes, was introduced more than 100 years ago.

"The physical, financial and psychological impact a type 1 diabetes diagnosis has on children and their families cannot be underestimated. The concept that a practical, safe and very affordable vaccine with known clinical benefits can potentially reverse type 1 diabetes by possibly lowering HbA1c, a measure of glucose, and possibly decrease insulin, has to be explored. NYU Langone Health is excited to participate," says Siham Accacha, MD, pediatric endocrinologist at NYU Langone Health and co-investigator of the Repeat BCG Vaccinations for the Treatment of Pediatric Type 1 Diabetes study.

The BCG vaccine is an avirulent tuberculosis strain Mycobacterium bovis historically given to protect against tuberculosis and, since its introduction in 1921, has been the most widely administered vaccine in the history of medicine. Considered to be extremely safe, BCG is on the World Health Organization's List of Essential Medicines and is given to roughly 100 million children per year globally. BCG is also one of the most affordable medicines, costing less than a dollar a dose in many parts of the world.

"BCG is a very old vaccine, but recently has been at the center of an explosion of clinical trial research showing benefit in multiple autoimmunity diseases and diverse infectious disease. We know the timing and strain of BCG vaccination is pivotal to outcomes. This is the first time multiple doses of a highly efficacious strain of BCG has been

given to adolescents with at least 2 years of type 1 diabetes," says Denise Faustman, MD, Ph.D., director of the Immunobiology Laboratory at Massachusetts General Hospital and co-investigator on the study.

A Phase I clinical trial of BCG in adults with established type 1 diabetes showed significant efficacy in changing the primary biomarkers in established type 1 diabetes including a potential disease-modulating ability to alter the underlying immune disfunction. In long-term follow-up, a clear clinical effect, most importantly, statistically significant improvement in HbA1c, the primary biomarker of blood sugar control in type 1 diabetes. This new study, "Repeat BCG Vaccinations for The Treatment of Pediatric Type 1 Diabetes," will enroll 150 patients aged 12 to 17 in a placebo-controlled study of two injections of BCG spaced four weeks apart. To learn more or enroll in the trial click here or email: diabetestrial@partners.org.

Provided by Massachusetts General Hospital

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