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Mass. General Hospital, Iacocca Foundation announce completion of Phase I diabetes trial

Safety data submitted to Food and Drug Administration, Phase II plans begin

BOSTON – Massachusetts General Hospital (MGH) and the Iacocca Foundation announce today the completion of the Phase I BCG clinical trial in type 1 diabetes, as well as the submission of all safety reports to the U.S. Food and Drug Administration (FDA) and the MGH data safety monitoring boards. Plans for the Phase II clinical study, which will continue the investigation of bacillus Calmette-Guerin (BCG) vaccination as a treatment for people with existing type 1 diabetes, are actively underway.

"We are making great progress and are really excited to be able to move this potential treatment to the next stage of clinical testing," says Denise Faustman, MD, PhD, director of the Immunobiology Laboratory at the MGH and an associate professor of Medicine at Harvard Medical School.

The results of the MGH trial showed that low-dose, multi-dosing regimens of BCG vaccination were safe in individuals with type 1 diabetes. There were no severe reactions to the vaccine other than the expected inflammation at the injection sites. BCG is a generic drug that is currently approved in the United States for tuberculosis vaccination and for the treatment of bladder cancer.

"This clinical trial is an important event for both the MGH and the Iacocca Foundation, who have been our partners in this process," says Peter Slavin, MD, president and CEO of Massachusetts General Hospital. "We are putting our energies behind moving the trial into Phase II."

The MGH Immunobiology lab, led by Faustman, will now begin planning for a Phase II clinical trial to continue investigating the safety and efficacy of BCG vaccination as a therapeutic agent for the prevention or reversal of type 1 diabetes. The trial will seek to define the exact dose and timing of administration of BCG vaccination to treat advanced type 1 diabetes. The majority of the funds for Faustman's basic research, on which these human studies are based, have come from the Iacocca Foundation. Additional information about the clinical trials can be found at

<http://www.faustmanlab.org>, and individuals interested in participating in future trials should e-mail DiabetesTrial@partners.org.

"We are very pleased to see this work come as far as it has," says Lee A. Iacocca, chairman of the Iacocca Foundation. "I made a promise to see a cure for type 1 diabetes in my lifetime, and I intend to keep it. The public support of this trial and a trial for people with this disease is my dream."

The MGH clinical trial was a double-blind, placebo-controlled Phase I human clinical trial to evaluate the safety of BCG vaccination in volunteers with type 1 diabetes. The basis of the trial is preclinical work done in the Faustman Immunobiology Laboratory, as well as other laboratories worldwide, showing that temporarily elevating levels of an immune modulator called tumor necrosis factor (TNF) can eliminate the abnormal white blood cells found in mice and humans with type 1 diabetes. Administration of the BCG vaccine is known to raise TNF levels in humans.

About Massachusetts General Hospital

Massachusetts General Hospital, established in 1811, is the original and largest teaching hospital of Harvard Medical School. The MGH conducts the largest hospital-based research program in the United States, with an annual research budget of more than \$600 million and major research centers in AIDS, cardiovascular research, cancer, computational and integrative biology, cutaneous biology, human genetics, medical imaging, neurodegenerative disorders, regenerative medicine, systems biology, transplantation biology and photomedicine.

About the Iacocca Foundation

Lee A. Iacocca established the Iacocca Foundation in 1984 in honor of his late wife, Mary K. Iacocca, who died from complications of type 1 diabetes. Since 1984, the Iacocca Foundation has given more than \$30 million to diabetes research. More information is available at www.iacoccafoundation.org. The Iacocca Foundation has offices in Boston and Los Angeles.

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