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For immediate release: Partnership for Cures and Friends United Announce Completion of a Sponsored Phase I Diabetes Trial at the Massachusetts General Hospital

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

August 20, 2010, CHICAGO, IL – Not-for-profit funding partners Partnership for Cures and Friends United for Juvenile Diabetes Research (Friends United) announce the completion of the Phase I BCG human clinical trial in type 1 diabetes, a translational study conducted at the Massachusetts General Hospital (MGH) and sponsored in part by both groups. Plans for the Phase II clinical study, which will continue the investigation of bacillus Calmette-Guérin (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," said Denise Faustman, MD, PhD, director of the Immunobiology Laboratory at the MGH and an associate professor of Medicine at Harvard Medical School. "It is even more exciting to be doing this research by repurposing an affordable drug with a good safety profile."

The results of the 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. The MGH Immunobiology lab, led by Dr. Faustman, will 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.

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

Partnership for Cures raises funds for this type of Rediscovery Research™ that reuses, recombines and reapplies existing science and medicine to quickly, safely and affordably create new treatments for patients with catastrophic diseases.

"This is a great example of a researcher and an institution that put the patient first," said Dr. Bruce Bloom, who leads Partnership for Cures. "This BCG treatment is not likely to create great profits or make anyone famous, but it is likely to make significant impact for patients. That's what medical research should be all about--helping patients live longer, higher quality lives. We are very excited to be a part of this effort and many others like it."

A number of other philanthropic organizations, including Friends United for Juvenile Diabetes Research, have created patient impact by providing funds to help translate this basic science research to the clinic.

“We have been raising funds for type I diabetes research for over ten years. Dr. Faustman was the first researcher to offer us the chance to directly touch the lives of people with this horrible disease,” said Susan Mandell of Friends United, a Chicago-based voluntary healthcare organization. “It gives us hope that a better treatment or cure will become a reality for those suffering from this dreadful disease.”

The MGH clinical trial was a double-blinded, 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.

Additional information about the clinical trials can be found at: www.faustmanlab.org. Individuals interested in participating in future trials should e-mail DiabetesTrial@partners.org.

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 Partnership for Cures

Partnership for Cures is a Chicago based supporting organization raising funds for global Rediscovery Research™ that reuses, recombines and reapplies existing science and medicine to quickly, safely and affordably create new treatments for patients with catastrophic diseases. In 1998, Goldman Philanthropic Partners (GPP), a private operating foundation, was founded to accelerate the discovery of new treatments to improve the quality of life for people with disease. In 2005, Partnership for Cures was established as a 501(c)(3) public charity to carry on and expand that GPP mission. To learn more, go to <http://www.4cures.org> or e-mail Bruce@4cures.org.

About Friends United for Juvenile Diabetes

Friends United is a grass roots organization which began as a small group of friends with a mission to help fund research to cure Type I Diabetes. They are a volunteer organization, most from Chicago and the surrounding suburbs, and many personally affected by diabetes. They remain seriously committed to our mission and are proud of the significant contributions we have made toward funding some of the most cutting-edge research in the field. You can find FUJDR on the web at <http://www.friends-united.org>.

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