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Foundation for the NIH Launches Trial to Develop Diabetes Diagnostic Tools

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The Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium announced today the launch of a multi-year clinical study to improve tools for measuring the function of insulin-producing beta cells in people with type 2 diabetes mellitus. Researchers hope the initiative will lead to improved techniques for tracking progression of the disease and pave the way for more effective treatments.

Beta cells within the pancreas produce and release insulin. Loss of the function of these cells compromises the body's ability to control blood sugar and underlies the development of diabetes.

"Today, diabetes researchers are working without the benefit of agreed-upon standards for gauging beta cell function," said Myrlene Staten, Senior Advisor at the National Institute of Diabetes and Digestive and Kidney Diseases and co-chair of the steering committee with oversight of the project. "We anticipate this initiative will give researchers practical tools that can be used to measure beta cell function over time and stimulate research to maintain and improve that function."

Diabetes affects 25.8 million Americans—8.3 percent of the U.S. population, according to the Centers for Disease Control and Prevention. The prevalence is expected to rise sharply in future years due to an aging population more likely to develop type 2 diabetes, increases in minority groups that are at high risk for type 2 diabetes, and people with diabetes living longer. Diabetes is the leading cause of kidney failure, nontraumatic lower-limb amputations, and new cases of blindness among adults in the U.S. It also is a major cause of heart disease and stroke.

The project, "Diabetes Drug Development: Identification and Validation of Markers that Predict Long-Term Beta Cell Function and Mass," managed by the Metabolic Disorders Steering Committee (MDSC) of the FNIH Biomarkers Consortium, is a three-year, $5.1 million clinical study to standardize tests for measuring beta cell function in the clinical setting. It also aims to improve methods for the early prediction of the long-term response to an intervention and for identification of patients at risk for rapid beta cell function deterioration, thereby enabling future clinical studies that examine diabetes progression.

"One of the next frontiers of diabetes therapeutics is to change the progression rate of beta cell failure," said Dr. David Fryburg, project team leader, Principal Consultant, ROI BioPharma, and Chief Medical Officer, Selventa. "This project was developed through a rigorous consensus-building process by a team of experts from across the entire scientific community. Pharmaceutical industry, academic, and government representatives all contributed their clinical trials expertise and scientific support to the design and execution of the studies."

Utilizing a collaborative approach, the FNIH Biomarkers Consortium has brought together diabetes experts from the National Institutes of Health (NIH), Food and Drug Administration (FDA), leading academic institutions, the pharmaceutical industry, and non-profit sector to develop the project. Participating and funding organizations

include: Amylin Pharmaceuticals, Inc., Eli Lilly and Company, Johnson & Johnson Pharmaceutical Research and Development, LLC, Juvenile Diabetes Research Foundation, Merck, Sharp & Dohme Corp, Novartis Institutes for BioMedical Research, Inc., Pfizer, Inc., Sanofi-Aventis, and Takeda Global Research & Development Center, Inc.

“This public private partnership involves key stakeholders in the diabetes field in addressing a critical unmet medical need,” Dr. Steven Paul, FNIH Board of Directors, Acting Chairman of the Biomarkers Consortium Executive Committee. **"The validation of biomarkers to measure the progression of diabetes will greatly facilitate the development of better medicines to treat and potentially prevent this disease and its often disabling complications."**

For more information about this project please visit www.fnih.org.

The Request for Proposals (RFP) for the conduct of the first clinical study protocol with healthy volunteers can be found on biomarkersconsortium.org. Responses are due by May 31, 2011.

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About the Foundation for the NIH

Established by the United States Congress to support the mission of the NIH—improving health through scientific discovery in the search for cures—the Foundation for the NIH is a leader in identifying and addressing complex scientific and health issues. The Foundation is a non-profit, 501(c)(3) charitable organization that raises private-sector funds for a broad portfolio of unique programs that complement and enhance NIH priorities and activities. For additional information about the Foundation for the NIH, please visit www.fnih.org

About the Biomarkers Consortium

The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH) that endeavors to develop, validate, and/or qualify biological markers (biomarkers) to speed the development of medicines and therapies for detection, prevention, diagnosis and treatment of disease and improve patient care. For additional information about the Biomarkers Consortium, please visit www.biomarkersconsortium.org