Critical Path Institute Launches Type 1 Diabetes Consortium

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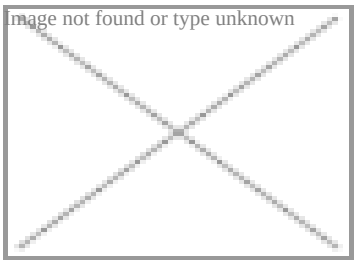

Critical Path Institute Launches Type 1 Diabetes Consortium

Tucson, Ariz., March 20, 2017 –Critical Path Institute (C-Path) is pleased to announce the launch of the Type 1 Diabetes (T1D) Consortium. Funded by The Leona M. and Harry B. Helmsley Charitable Trust; Janssen Research & Development, LLC; JDRF International; and Sanofi, the T1D Consortium will work to qualify islet autoimmunity antibodies as prognostic biomarkers to be used in the development of therapies for the treatment, and ultimately the prevention, of T1D.

The T1D Consortium is also working collaboratively with INNODIA, a consortium under the Innovative Medicines Initiative (IMI). INNODIA is a European-based, public-private partnership with the ambition to significantly improve our understanding of type 1 diabetes and to pave the way to novel therapeutic options to prevent and cure T1D.

“C-Path is eager to apply its expertise in cross-industry collaboration, regulatory science, and project and data management to the field of type 1 diabetes research and prevention,” said C-Path President and CEO Dr. Martha Brumfield. “The late George Eisenbarth, a leader in the field of T1D research, observed that ‘the clock to T1D has started when islet antibodies are first detected.’ Achieving regulatory qualification of these antibodies as biomarkers will lead to better clinical trial design and more accurate identification of individuals who would likely benefit from early intervention.”

The specific biomarkers of interest include (Pro)-insulin autoantibody (IAA), Glutamic acid decarboxylase 65 (GAD65) autoantibody, Islet antigen 2 (IA-2) autoantibody, and Zinc transporter 8 (ZnT8) autoantibody. The presence of these autoantibodies, in conjunction with blood glucose levels, helps scientists separate T1D into three stages. In stage 1, autoantibodies can be detected in patients but the patients have normal blood glucose levels. In stage 2, the same autoantibodies are present, but the patients start to exhibit dysregulation of their blood glucose levels. Stage 3 patients have autoantibodies and high blood glucose levels indicative of diabetes; in addition, many display the typical clinical signs and symptoms of T1D, which may include weight loss, polyuria, fatigue, and diabetic ketoacidosis, among others. The goal of preventing symptomatic T1D rests in the ability to identify those patients in the early stages of the disease, which will allow early interventions focused on either slowing or halting their progression to the symptomatic disease state.

“We will apply these biomarkers together with the staging approach to design new clinical trials, conduct the trials more effectively, and ultimately, develop interventions to arrest progression to symptomatic type 1 diabetes,” said Dr. Jessica Dunne, Director of Discovery Research at JDRF.

The initial goal of the T1D Consortium is to achieve the regulatory qualification (from both the US Food and Drug Administration and the European Medicines Agency) of the islet autoantibodies as prognostic biomarkers for T1D disease progression in pre-symptomatic T1D patients. These autoantibodies may also be used as an enrichment factor in clinical trials to identify subjects in the pre-symptomatic stages of the disease with a high risk of disease progression to symptomatic. Ultimately, the prevention of the appearance of these autoantibodies could possibly be used as a surrogate marker for prevention of T1D in clinical trials.

By 2050, the number of youth diagnosed with T1D in the US alone is projected to more than triple. The ability to screen for risk and stage of T1D prior to symptoms appearing presents a valuable opportunity to delay, and ultimately prevent, symptomatic T1D. By employing the resources of all its members, and engaging with regulatory agencies at each step of the process, C-Path’s T1D Consortium can achieve these regulatory science deliverables.

“The innovative, cross-collaborative approach of the T1D Consortium, its emphasis on sharing data, resources, cost, and risk, and its long-term vision are aligned with the goals of our prevention initiative at Helmsley,” said Gina Agiostratidou, director of Helmsley’s Type 1 Diabetes Program. “We are proud to be a supporting partner of this C-Path initiative.”

About the Organizations:

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Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US Food and Drug Administration (FDA). C-Path’s mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established 12 global, public-private partnerships that currently include over 1,450 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.

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The Leona M. and Harry B. Helmsley Charitable Trust aspires to improve lives by supporting effective organizations in health, place-based initiatives, education and human services. Since beginning active grantmaking in 2008, Helmsley has committed more than $1.8 billion for a wide range of charitable purposes. Learn more about Helmsley at helmsleytrust.org.

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INNODIA is an international consortium under the Innovative Medicines Initiative (IMI). Twenty-six academic institutions and clinics, four industrial partners (EFPIA), two patient organizations, and one SME have joined forces to significantly improve the understanding of type 1 diabetes and to pave the way to novel therapeutic options to prevent and cure this disease (www.innodia.eu).

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JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested nearly $2 billion in research funding since our inception. We are an organization built on a grassroots model of people connecting in their local communities, collaborating regionally for efficiency and broader fundraising impact, and uniting on a national stage to pool resources, passion, and energy. We collaborate with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers throughout the United States and our six international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D. For more information, please visit jdrf.org or follow us on Twitter: @JDRF.

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Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

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