C-Path and Diamyd Medical Announce Data Sharing Collaboration to Develop Advanced Drug Development Tools in Type 1 Diabetes

TUCSON, Ariz., and **STOCKHOLM**, Sweden. December 16, 2020 — The Critical Path Institute (C-Path) and Diamyd Medical (DMYD B; Nasdaq First North Growth Market) are proud to announce their collaboration to significantly improve the scientific community's insight into type 1 diabetes (T1D) through Diamyd Medical's contribution of fully anonymized data from a European Phase III trial to the Trial Outcome Markers Initiative (TOMI-T1D) integrated database. The Phase III trial evaluated the use of the diabetes vaccine Diamyd®, an antigen-specific immunotherapy based on the auto-antigen GAD (glutamic acid decarboxylase), to induce immunological tolerance and stop the autoimmune destruction of insulin producing cells. The Data Contribution Agreement (DCA) between Diamyd Medical and C-Path will allow for this unique set of fully anonymized clinical trial data to be integrated into an ever-growing list of committed trial data sets within the TOMI-T1D project.

TOMI-T1D is an international partnership between academia, the pharmaceutical industry and nonprofit organizations. It is funded by the world's leading charities dedicated to diabetes research, JDRF, and Diabetes UK, guided by both organizations' strong commitment to facilitate deep interrogation of consolidated community-wide trial data as a means to accelerate clinical research and therapeutic development for T1D. TOMI-T1D aims to create a clinical trial simulation tool (CTST) with large and diverse clinical datasets from the T1D community. The project also seeks to engage the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to identify opportunities for regulatory endorsement of such drug development tools.

The Diamyd Medical data includes relevant information about disease progression, drug effects and clinical trial design. Contribution of these robust data sets from industry led trials is critical to TOMI-T1D's work in developing innovative and quantitative tools that can facilitate clinical development efforts and be endorsed by regulators for future use by the pharmaceutical industry to optimize the design of future clinical trials.

"Progress towards the establishment of approved therapies for people with T1D is critically reliant on participation from our partners in industry with their data," said Simi Ahmed and Elizabeth Robertson, on behalf of the charity partnership. "This is indeed a right step in that direction," said Colin Dayan, lead PI at Cardiff University.

“We are thrilled that Diamyd Medical is taking a leading role and championing precompetitive collaborations advancing type 1 diabetes regulatory science solutions,” said C-Path Executive Director Inish O’Doherty, Ph.D. “Their data will help in the construction and evaluation of a clinical trial simulation tool to assist in the development of novel therapies for type 1 diabetes patients.”

“We are very honored to be part of this important collaboration -involving key stakeholders within the T1D landscape,” said Ulf Hannelius, President & CEO of Diamyd Medical. “As we are moving into an era of precision medicine in type 1 diabetes, we can expect to see significant therapeutic advances, and access to high quality data will be integral to maximizing these efforts.”

To learn more about the TOMI-T1D project visit: https://c-path.org/programs/tomi-t1d/

TOMI-T1D is solely funded by JDRF and Diabetes UK. Critical Path Institute is supported by the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) and is 69% funded by FDA/HHS, totaling $19,471,171, and 31% funded by non-government source(s), totaling $8,612,313. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.

About the Organizations:

Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. 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 numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path US is headquartered in Tucson, Arizona and C-Path, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit c-path.org and c-path.eu.

Diamyd Medical develops therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have been shown in a genetically predefined patient group in a large-scale metastudy as well as in the Company’s European Phase IIb trial DIAGNODE-2, where the diabetes vaccine is administered directly into a lymph node in children and young adults with newly diagnosed type 1 diabetes. A new facility for vaccine manufacturing is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. An investigator-initiated Remygen® trial in patients living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital. Diamyd Medical is one of the major

shareholders in the stem cell company NextCell Pharma AB. Diamyd Medical's B-share is traded on Nasdaq First North Growth Market under the ticker DMYD B. FNCA Sweden AB is the Company's Certified Adviser; phone: +46 8-528 00 399, e-mail: info@fnca.se.

JDRF's mission is to accelerate life-changing breakthroughs to cure, prevent, and treat T1D and its complications. To accomplish this, JDRF has invested more than $2.5 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 five 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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1. **Diabetes UK**'s UK's aim is creating a world where diabetes can do no harm. Diabetes is the most devastating and fastest growing health crisis of our time, affecting more people than any other serious health condition in the UK – more than dementia and cancer combined. There is currently no known cure for any type of diabetes. With the right treatment, knowledge and support people living with diabetes can lead a long, full and healthy life. For more information about diabetes and the charity's work, visit www.diabetes.org.uk.
2. Diabetes is a condition where there is too much glucose in the blood because the body cannot use it properly. If not managed well, both type 1 and type 2 diabetes can lead to devastating complications. Diabetes is one of the leading causes of preventable sight loss in people of working age in the UK and is a major cause of lower limb amputation, kidney failure and stroke.
3. People with **type 1** diabetes cannot produce insulin. About 10 per cent of people with diabetes have type 1. No one knows exactly what causes it, but it's not to do with being overweight and it isn't currently preventable. It's the most common type of diabetes in children and young adults, starting suddenly and getting worse quickly. Type 1 diabetes is treated by daily insulin doses – taken either by injections or via an insulin pump. It is also recommended to follow a healthy diet and take regular physical activity.
4. People with **type 2** diabetes don't produce enough insulin or the insulin they produce doesn't work properly (known as insulin resistance). Around 90 per cent of people with diabetes have type 2. They might get type 2 diabetes because of their family history, age and ethnic background puts them at increased risk. They are also more likely to get type 2 diabetes if they are overweight. It starts gradually, usually later in life, and it can be years before they realise they have it. Type 2 diabetes is treated with a healthy diet and increased physical activity. In addition, tablets and/or insulin can be required.

For more information on reporting on diabetes, download our journalists' guide: Diabetes in the News: A Guide for Journalists on Reporting on Diabetes (PDF, 3MB).

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