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

TUCSON, Ariz., and **OLDWICK**, N.J. May 13, 2020 — The Critical Path Institute (C-Path) and Provention Bio, Inc. (Nasdaq: PRVB) are proud to announce their collaboration to significantly improve the scientific community's insight into type 1 diabetes (T1D) through Provention's contribution of data from the Phase III Protégé study of teplizumab to the T1D Trial Outcome Measures Initiative (TOMI) integrated database. The Protégé study evaluated teplizumab on the preservation of beta cell function in newly onset T1D patients and generated the largest disease modifying interventional clinical trial dataset in T1D with more than 500 patients.

TOMI is an international partnership between academia, the pharmaceutical industry and nonprofit organizations funded by a grant from the world's leading charities dedicated to diabetes research, JDRF and Diabetes UK. The primary goal of the TOMI is to seek the regulatory endorsement of drug development tools with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to accelerate the development of new therapies in T1D.

The Data Contribution Agreement (DCA) between Provention and C-Path will allow for this unique set of clinical trial data to be integrated and managed by C-Path's Data Collaboration Center (DCC) adding to the effort of developing advanced drug development tools including a clinical trial simulation tool (CTST) for regulatory approval. This CTST will help identify optimal clinical endpoints in future studies to improve clinical interpretability of trials, shorten the time to primary outcome and/or minimize the number of participants required in trials.

The Protégé data includes relevant information about disease progression, drug effects and clinical trial design. Contribution of these data is critical to TOMI's work in developing innovative and quantitative tools based on robust data that can be endorsed by regulators and be used in confidence by the pharmaceutical industry to optimize future clinical trial designs.

"C-Path is excited to facilitate the analysis of data with this esteemed group of T1D scientists," said C-Path's Executive Director of the T1D Consortium Inish O'Doherty, Ph.D. "Seeing the T1D community work together to solve challenging questions is encouraging and we are looking forward to the future of drug development in T1D."

“We are proud to contribute such a large set of patient-level data from the Phase III Protégé study of teplizumab to the TOMI,” said Francisco Leon, M.D., Ph.D., Co-founder and Chief Scientific Officer of Provention Bio. “This collaboration embodies our continued support to increase pre-competitive collaborations and to advance effective public-private partnerships in the field of T1D to accelerate drug development.”

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.

Provention Bio, Inc. (Nasdaq: PRVB) is a clinical-stage biopharmaceutical company leveraging a transformational drug development strategy focused on the prevention or interception of immune-mediated disease. Provention’s mission is to source, transform and develop therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune diseases. Provention’s diversified portfolio includes PRV-031 (teplizumab), a pre-commercial-stage candidate that has been shown to delay the onset of end-stage type one diabetes (T1D) in at-risk individuals with pre-symptomatic disease. The Company’s portfolio includes additional clinical-stage product development candidates that have demonstrated proof-of-mechanism and/or proof-of-concept in other autoimmune diseases, including celiac disease and lupus. For more information, please visit proventionbio.com.

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 more than $2.2 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.

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

1. **Diabetes 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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