Provention Bio Joins the C-Path Type 1 Diabetes (T1D) Consortium

OLDWICK, N.J., Nov. 28, 2018 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq:PRVB), a clinical-stage biopharmaceutical company dedicated to sourcing, developing and commercializing novel therapeutics aimed at intercepting and preventing immune-mediated diseases, announced today that the company has joined the Critical Path Institute's Type 1 Diabetes (T1D) Consortium. Founded in March 2017 by the Critical Path Institute (C-Path), C-Path's T1D Consortium is focused on understanding the scientific and regulatory expectations associated with the application of biomarkers used to optimize clinical trial designs in this disease. Currently, the T1D Consortium is actively engaged in the regulatory qualification of islet autoantibodies as susceptibility/risk biomarkers to be used as enrichment criteria in the development of therapies for the treatment, and ultimately the prevention, of T1D. Current membership includes Janssen Research & Development, LLC (Janssen), JDRF International (JDRF), Novo Nordisk, Sanofi and The Leona M. and Harry B. Helmsley Charitable Trust.

"We are extremely honored to be granted membership into the T1D Consortium and welcome the opportunity to work alongside such an esteemed group of researchers and companies, including our current collaborators, Janssen and JDRF, in pursuit of the ultimate goal of preventing or intercepting T1D," said Ashleigh Palmer, Provention Bio's Co-Founder and Chief Executive Officer. "A core tenet of the T1D Consortium and its parent organization, C-Path, is to foster advances in science and research through collaboration. This mindset aligns perfectly with Provention's business and development philosophy and our strategy of partnering with leading pharmaceutical companies to identify and re-deploy drugs for the purpose of intercepting and preventing immune-mediated diseases, such as T1D."

"We look forward to Provention Bio joining the T1D Consortium and providing their perspective as we work together with all of our members to qualify susceptibility/risk biomarkers to support clinical trials of new medicines for T1D patients in need," said Inish O'Doherty, Executive Director of the T1D Consortium.

Jessica Dunne, Director of Research at JDRF and the Co-Director of the T1D Consortium added, "We at JDRF believe that regulatory qualification of islet autoantibodies as a susceptibility/risk biomarker is a critical step for delaying and ultimately preventing T1D, and we are excited to welcome Provention Bio into the T1D Consortium. Their commitment to delivering therapies to individuals living with, and at-risk for developing, T1D is well-aligned with both JDRF and the Consortium."

Additional C-Path T1D Consortium members include academic collaborators in the US and Europe, along with the institutional observers, the United States Food and Drug Administration (US FDA), National Institutes of Health (NIH), European Medicines Agency (EMA) and Innovative Medicines Initiative (IMI).

The initial goal of the C-Path T1D Consortium is to achieve FDA and EMA regulatory qualification of the islet autoantibodies as susceptibility/risk biomarkers for T1D disease progression, facilitating the conduct of T1D interception studies. The addition of Provention Bio to the consortium will provide the impetus to build on this initial regulatory foundation and enable the examination of the presentation of the islet autoantibodies as a clinically meaningful outcome in T1D prevention clinical trials.

Dr. Francisco Leon, Chief Scientific Officer of Provention Bio, concluded, "We look forward to lending our vision, insight and experience as we continue to advance our two T1D clinical programs, PRV-031 and PRV-

101, recognizing that intercepting T1D rests in the ability to identify those patients in the early stages of the disease and the islet autoantibody qualification provides us the means to do this. We hope to build on this effort for the initial presentation of the islet autoantibodies to be considered a clinically meaningful outcome in T1D prevention trials."

About T1D
Type 1 diabetes (T1D) is an autoimmune disease that occurs when a person's pancreas stops producing insulin, the hormone that controls blood-sugar levels. T1D develops when the insulin-producing pancreatic beta cells are mistakenly destroyed by the body's immune system. The cause of this attack is still being researched, however scientists believe the cause may have genetic and environmental components, including viral infection. Presently, there is no known preventative approach or cure for T1D.

About Critical Path Institute
C-Path (Critical Path Institute) 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 over 1,500 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of major pharmaceutical and biotech companies. C-Path is headquartered in Tucson, Arizona, with additional staff in multiple remote locations. For more information, visit, www.c-path.org.

About JDRF
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 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

About Provention Bio, Inc.
Provention Bio, Inc. (Nasdaq: PRVB) is a clinical-stage biopharmaceutical company leveraging a transformational drug development strategy that is focused on the prevention or interception of immune-mediated disease. Provention's diverse portfolio was assembled with product candidates that have undergone clinical testing but may have been underdeveloped or deprioritized assets at other companies. Provention's mission is to in-license, transform and develop clinical-stage, or nearly clinical-stage, therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune and inflammatory diseases including: type 1 diabetes (T1D), Crohn's disease, ulcerative colitis, celiac disease, lupus, and certain life-threatening viral diseases. For more information on Provention Bio, please visit www.proventionbio.com.

Forward Looking Statements
Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Provention's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to failure to obtain FDA approvals or clearances and noncompliance with FDA regulations; uncertainties of patent protection and litigation; limited research and development efforts and dependence upon third parties; substantial

competition; our need for additional financing and the risks listed under "Risk factors" in our quarterly report on Form 10-Q for the quarter ended September 30, 2018 and any subsequent filings with the Securities and Exchange Commission (SEC). As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Provention does not undertake an obligation to update or revise any forward-looking statement. The information set forth herein speaks only as of the date hereof.

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