Provention Bio Highlights Critical New Research Studies on Type One Diabetes

JDRF T1D Fund Study Estimates 2.3 Million People at Risk Globally to Develop Stage 3 T1D, Which Already Affects 18 Million People Globally

Journal of American Medicine Association Research Publication Finds Screening for T1D Significantly Reduces the Risk of Diabetic Ketoacidosis

OLDWICK, N.J., Feb. 6, 2020 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today highlighted several new research studies on the increasing prevalence of type one diabetes (T1D) and the importance of screening for this life-impacting and life-threatening autoimmune disease.

The JDRF T1D Fund, JDRF, and Health Advances recently published a white paper titled "*Modeling the Total Economic Value of Novel Type 1 Diabetes (T1D) Therapeutic Concepts"* which estimates there are 18 million people living with clinically diagnosed Stage 3 T1D globally, and an additional 2.3 million with pre-symptomatic Stage 1 and Stage 2 T1D, including at least 300,000 in the United States. The research examines both the direct and the indirect costs, such as productivity loss, associated with the economic burden of T1D. It suggests $30 billion in annual costs in the United States, less than 40% of which are attributed to direct medical costs and healthcare services. Additionally, they conclude that while sustainable "cures" could alleviate the $30 billion economic burden in the United States; in the interim, disease modifying therapies close to the clinic can bring more than $3 billion in value annually. Pre-symptomatic Stage 1 and Stage 2 T1D, which are evidenced by the presence of multiple islet autoantibodies and autoimmune destruction of the insulin-producing beta cells of the pancreas, indicates that the individual is on the path to be diagnosed with clinical, insulin-dependent Stage 3 T1D.

A separate study published in the *Journal of the American Medical Association*, titled "Yield of a Public Health Screening of Children for Islet Autoantibodies in Bavaria, Germany", highlighted the importance of screening for T1D and the significant reduction in diabetic ketoacidosis (DKA) resulting from screening. The study, conducted by Dr. Anette-Gabriele Ziegler of the Institute of Diabetes Research, suggests that public health screening for T1D in pre-symptomatic stages may reduce disease burden and severity, as well as enable disease interception strategies with novel agents.

"We commend the T1D Fund, JDRF, Dr. Ziegler and all of the individuals involved in conducting important research that advances the field of T1D," stated Ashleigh Palmer, CEO of Provention Bio. "Experts increasingly agree that the key to impacting the current trajectory of T1D is to screen for individuals with early stages of T1D, at-risk of developing clinical T1D, so that the disease could be prevented or delayed. At a minimum, early identification of patients with Stage 1 and Stage 2 T1D will reduce life-threatening DKA."

Mr. Palmer continued, "We are working diligently to develop teplizumab, which showed in a prior study that a single 14-day course of therapy, delays the onset of insulin-dependent Stage 3 T1D in at-risk individuals by a median of at least two years[1]. We are on track to submit a biologics license application (BLA) for teplizumab in the fourth quarter of this year. If approved, we believe teplizumab will be the first disease modifying drug approved for T1D since insulin therapy was first introduced in 1922."

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 mission is to in-license, transform and develop therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune and inflammatory diseases including: type 1 diabetes (T1D), celiac disease and lupus. Provention's diversified portfolio includes advanced-stage product development candidates that have undergone clinical testing by other companies.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, including statements related to timing of submission of the BLA. 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 annual report on Form 10-K for the year ended December 31, 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.

Investors:
Sam Martin, Argot Partners
sam@argotpartners.com
212-600-1902

Media:
David Rosen, Argot Partners
david.rosen@argotpartners.com
212-600-1902

[1] Herold KC et al. *An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes*. N Engl J Med Aug 15 2019; 381:603-613

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