A Single Course of Provention's PRV-031 (Teplizumab) Delays Type 1 Diabetes Onset in High-Risk Individuals by at Least Two Years

Results from the NIH-Sponsored "At-Risk" Study Published in The New England Journal of Medicine and Presented at the American Diabetes Association Annual Meeting

Company to Host Conference Call on Monday, June 10 th at 8:30 AM Eastern Time

OLDWICK, N.J., June 9, 2019 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq:PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated disease, today announced that results from the National Institutes of Health (NIH)-sponsored "At-Risk" Study were published on-line in The New England Journal of Medicine and presented at the Scientific Sessions of the 79th Annual American Diabetes Association (ADA) meeting. The "At-Risk" Study was sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with additional support from JDRF. The study was conducted by the Type 1 Diabetes TrialNet, an international collaboration aimed at discovering ways to delay or prevent type 1 diabetes (T1D), and evaluated Provention's PRV-031 (teplizumab) for the prevention or delay of clinical T1D in relatives of type 1 diabetics at high-risk of developing the disease. PRV-031 (teplizumab) is an anti-CD3 monoclonal antibody in development for the interception and prevention of clinical T1D.

The "At Risk" Study enrolled 76 participants ages 8 to 49 who were "At-Risk" because they had two or more T1D autoantibodies and abnormal glucose metabolism (dysglycemia); 72% of participants were under the age of 18. Subjects were randomized to receive either PRV-031 (teplizumab) or placebo.

Results from the study showed that a single 14-day course of PRV-031 (teplizumab) significantly delayed the onset and diagnosis of clinical T1D, as compared to placebo, by a median of 2 years in children and adults considered to be at high risk. The median time to clinical diagnosis of T1D for placebo participants was just over 24 months. In comparison, the median time for PRV-031 (teplizumab)-treated participants to clinical diagnosis of T1D was just over 48 months (p=0.006). During the trial, 72% in the placebo group developed clinical diabetes compared to only 43% of the PRV-031 (teplizumab) group. PRV-031 (teplizumab) was well tolerated and the safety data were consistent with prior studies in newly diagnosed patients.

"This groundbreaking study demonstrates that we can use immunotherapy, specifically PRV-031 (teplizumab), to prevent or significantly delay the onset of clinical type 1 diabetes by at least two years in individuals who will almost certainly progress to clinical disease," said Dr. Eleanor Ramos, Provention's Chief Medical Officer and Chief Operating Officer. "More importantly, approximately 60% of subjects in the study did not develop T1D following only one course of PRV-031 therapy, double the placebo group. Teplizumab is the first immune modulator to show a delay in the clinical onset of type 1 diabetes."

Dr. Kevan Herold, M.D., Professor of Immunobiology and Medicine at Yale University, lead author of the study, stated, "These results have real clinical meaning for individuals at-risk of developing clinical type 1 diabetes such as family members of patients. Delaying the onset of clinical T1D may mean the disease burden could be postponed to a point at which patients are better able to manage their disease such as after infancy, elementary school, high school or even college. With PRV-031 (teplizumab), we may now be able to intervene and fundamentally change the progression of T1D for these at-risk subjects. In addition, we look forward to learning more as we observe patients during the study's follow-up period, which will also evaluate the long-term outcomes for those in whom the diagnosis of disease has been delayed to see if they will be diagnosed with T1D or are protected."

"It's remarkable to see that a single course of two-week therapy cut the incidence of diabetes by almost 50 percent during this trial. These data clearly tell us short-term immunotherapy can significantly slow down clinical onset of diabetes. Developing immuno-modulatory drugs that don't require continuous treatment to impact autoimmune disease is a major paradigm shift," said Jeffrey Bluestone, PhD, A.W. and Mary Margaret Clausen Distinguished Professor of Metabolism and Endocrinology at the UC San Francisco (UCSF) Diabetes Center, President, CEO of the Parker Institute for Cancer Immunotherapy, and a Director of Provention Bio.

"We especially want to congratulate TrialNet for conducting this landmark study, and to thank the patients and families involved, as well as the JDRF for their commitment to this study and the patient community," stated Ashleigh Palmer, CEO of Provention Bio. "We are delighted with the results, which reinforce our confidence not

only in PRV-031 (teplizumab), but in Provention's strategic intent to intercept and prevent immune-mediated disease. The ability to delay the onset of clinical T1D is an enormous breakthrough, given that a recent study indicated the life expectancy for patients diagnosed with T1D before the age of ten is reduced by as much as 16 years on average."

Mr. Palmer continued, "Based on these results, we are evaluating a regulatory path forward for PRV-031 in at-risk individuals. We are also assessing PRV-031 in newly-diagnosed T1D patients in our Phase 3 PROTECT study, which commenced in April. Our broader goal for PRV-031 is to address the continuum of T1D and provide therapeutic options for this life-impacting and life-threatening autoimmune disease that, until now, has seen no disease-modifying innovation since the development of insulin a century ago."

Conference Call and Webcast Information

Provention Bio will discuss these results via conference call on Monday, June 10, 2019 at 8:30 AM ET. A webcast presentation will also be available on the Investors page of the Company's website, www.proventionbio.com. To access the call, please dial 1-877-870-4263 (domestic) or 1-412-317-0790 (international) five minutes prior to the start time and ask to be connected to the "Provention Bio Call". A webcast replay of the call will be available beginning at 11:00 AM ET on the day of the call.

About PRV-031 (teplizumab)

PRV-031, also known as teplizumab, is an anti-CD3 monoclonal antibody (mAb), which is being developed for the interception and prevention of type 1 diabetes (T1D). The candidate has been the subject of multiple clinical studies involving more than 1,000 subjects with more than 800 patients receiving PRV-031 in those studies. In previous studies of newly diagnosed patients, PRV-031 has consistently demonstrated the capability of preserving beta cell function and reducing the need for exogenous insulin usage. Provention is currently evaluating PRV-031 in patients with recent onset T1D (the Phase 3 PROTECT Study); additional information on the clinical trial is available at clinicaltrials.gov. Provention is also evaluating opportunities to advance development of teplizumab in relatives of T1D patients at risk for developing the disease.

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), Crohn's disease, celiac disease, lupus, and certain life-threatening viral diseases. Provention's diversified portfolio includes advanced-stage product development candidates that have undergone clinical testing by other companies. 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 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.

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