# Provention Bio Announces Breakthrough Therapy Designation for Teplizumab (PRV-031) for the Prevention or Delay of Clinical Type 1 Diabetes in At-Risk Individuals

OLDWICK, N.J., Aug. 5, 2019 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq:PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated disease, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) to teplizumab (PRV-031) for the prevention or delay of clinical type 1 diabetes (T1D) in individuals at-risk of developing the disease.

BTD is an FDA program designed to expedite the development and review of therapeutic candidates intended to treat serious or life-threatening diseases. To qualify for this designation, preliminary clinical evidence has to indicate that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. The benefits to Provention of this BTD include more intensive and interactive guidance from FDA on an efficient drug development program, access to a scientific liaison to help expedite review time, and eligibility for Priority Review if relevant criteria are met.

The FDA decision on BTD was based on clinical data from the "At-Risk" Study conducted by TrialNet, which 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 at least 2 years in children and adults considered to be at high risk of developing clinical T1D.

"We are pleased that the FDA recognizes the transformative potential of PRV-031 in T1D, and we are committed to working with the Agency to bring this candidate to patients as quickly as possible," stated Ashleigh Palmer, CEO of Provention Bio. "The groundbreaking data from the 'At Risk' trial showed, for the first time, the potential to delay the onset of T1D in individuals who are almost certain to develop clinical disease. With this designation in place, we plan to leverage that landmark data, as well as the robust safety database from prior teplizumab studies, to support a registration filing. We look forward to discussing next steps with the FDA and providing an update on the process in the coming months."

**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 newly diagnosed with clinical T1D (the Phase 3 PROTECT Study); additional information on the clinical trial is available at www.clinicaltrials.gov.

**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, and lupus. 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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