Provention Bio Announces PRV-031 (Teplizumab) Granted PRIME Designation by the European Medicines Agency

OLDWICK, N.J., Oct. 24, 2019 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today announced the European Medicines Agency (EMA) has granted PRV-031 (teplizumab) PRIority MEdicines (PRIME) designation for the prevention or delay of clinical type 1 diabetes (T1D) in individuals at-risk of developing the disease.

PRIME designation is awarded by the EMA to promising medicines that demonstrate the potential to address substantial unmet medical need based on clinical data. The EMA considers PRIME designations a priority and provides them with special support, including enhanced interactions and dialogue, as well as a pathway for accelerated evaluation and review.

"We are very pleased the EMA recognizes the transformative potential of PRV-031 and has granted this groundbreaking therapy PRIME designation", said Ashleigh Palmer CEO, Provention Bio. "Following on the heels of Breakthrough Therapy Designation from the FDA in August, EMA PRIME further validates the rationale for PRV-031 to prevent or delay the onset of clinical T1D in at-risk subjects. We are committed to working closely with both regulatory agencies to bring PRV-031, as quickly as possible, to the many thousands of T1D at-risk individuals who currently have no options to prevent or delay this catastrophic disease."

PRV-031's PRIME designation was based on clinical data from the "At-Risk" Study conducted by TrialNet, which demonstrated that a single 14-day course of PRV-031 significantly delayed the onset of T1D, as compared to placebo, by a clinically-relevant median of at least 2 years in children and adults at high risk of developing clinical T1D.

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.

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.

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

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

SOURCE Provention Bio, Inc.
