Provention Bio Announces Key Addition to its Leadership Team

- Appoints Dr. Sherron Kell as SVP of Clinical Development and Program Lead for PRV-031 (Teplizumab) -

OLDWICK, N.J., Aug. 20, 2019 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today announced the appointment of Sherron Kell, MD, MPH as Senior Vice President of Clinical Development. Dr. Kell will lead the PRV-031 (teplizumab) program, including the oversight of the Phase 3 PROTECT study and clinical support of anticipated regulatory submissions, and will report to Dr. Eleanor (Leni) Ramos, Chief Medical and Operating Officer. PRV-031 (teplizumab) is an anti-CD3 monoclonal antibody in development for the interception and prevention of clinical type 1 diabetes (T1D). PRV-031 (teplizumab) has been granted Breakthrough Therapy Designation for the prevention or delay of clinical T1D in individuals at-risk of developing the disease and orphan designation for newly diagnosed T1D.

"The addition of Sherron further enhances our leadership team during a transformational time for Provention," stated Ashleigh Palmer, CEO of Provention Bio. "Sherron's expertise and extensive clinical development experience will be invaluable as we execute our clinical and regulatory strategy for PRV-031 (teplizumab) for the interception and prevention of T1D."

Dr. Ramos added, "We are excited to bring Sherron on board to lead the PRV-031 program, particularly as we build momentum following the recent publication of the 'At Risk' data and subsequent Breakthrough Therapy Designation from the FDA. She has over 20 years of clinical development, pharmacovigilance/drug safety and medical affairs experience across multiple therapeutic areas, including metabolic and endocrine disorders. Her proven track record in leading late stage clinical trials and supporting regulatory submissions will provide additional depth and capabilities as we advance teplizumab closer to patients in need."

Dr. Kell most recently served as Vice President at Impax Pharmaceuticals, now Amneal Pharmaceuticals, overseeing Clinical R&D, Medical Affairs and the Pharmacovigilance and Drug Safety departments across all stages of clinical studies. Previously, she was Senior Director, Clinical R&D at Johnson & Johnson, and Scientific Director at Novartis Pharmaceuticals.

Dr. Kell received her medical degree from the University of Alabama School of Medicine and her Masters of Public Health degree in Epidemiology at the University of Alabama at Birmingham School of Public Health. She completed her residency in Internal Medicine at the Baptist Medical Center in Birmingham, Alabama, and her fellowship in Geriatric Medicine at the University of Alabama.

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. Data published in the *New England Journal of Medicine* showed that a single 14-day course of PRV-031 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. 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. PRV-031 has been granted Breakthrough Therapy Designation for the prevention or delay of clinical type 1 diabetes (T1D) in individuals at-risk of developing the disease. PRV-031 has been granted orphan designation for newly diagnosed T1D patients.

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.

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