Provention Bio Initiates Phase 1b/2a PREVAIL Clinical Trial Evaluating PRV-3279 in Lupus

-Bispecific Diabody Designed to Intercept B-Cell Mediated Autoimmune Diseases-

OLDWICK, N.J., Aug. 8, 2019 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated disease, today announced that it has dosed the first patients in its PREVAIL (PRV-3279 EVAluation In Lupus) study, a Phase 1b/2a clinical trial evaluating PRV-3279. PRV-3279 is a humanized diabody (a bispecific scaffold biologic molecule) targeting the B-cell surface proteins, CD32B and CD79B, which has the potential to intercept the pathophysiology of systemic lupus erythematosus (SLE) and other B cell-mediated autoimmune diseases.

The PREVAIL study consists of two parts: a Phase 1b trial in healthy volunteers, followed by a Phase 2a trial in SLE patients. The randomized, double-blind, placebo-controlled, multiple ascending dose Phase 1a study will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity of PRV-3279 in 16 healthy volunteers. Upon successful completion of the Phase 1a study, Provention plans to initiate the Phase 2a portion of the study in lupus patients.

"PRV-3279 offers an elegant mechanism of action designed to intercept and ameliorate the overactive B cell-driven pathology of lupus and other autoimmune diseases," stated Francisco Leon, M.D., Ph.D., Co-founder and Chief Scientific Officer of Provention Bio. "We believe that PRV-3279 is uniquely differentiated to allow for rapid inhibition of activated B cells, while sparing non-activated B cells from depletion or inactivation, thereby offering the potential for a more effective yet safer alternative to current B-cell targeted therapies. We look forward to reporting data from Part 1 of the study in the first half of 2020."

Results from a prior single ascending dose Phase 1 study established proof of mechanism and showed that PRV-3279 was well-tolerated. In addition, a single dose of PRV-3279 demonstrated an inhibitory effect on the immunogenicity of hepatitis A vaccine provided to volunteers during the trial.

About PRV-3279

PRV-3279 is a humanized diabody (a bispecific scaffold biologic molecule) targeting the B-cell surface proteins, CD32B and CD79B. Simultaneous engagement of the CD32B and CD79B receptors triggers inhibition of B cell function and suppression of autoantibody production, thereby regulating B cells without causing depletion. Provention is initially developing PRV-3279 for the interception of systemic lupus erythematosus (SLE), a chronic autoimmune disorder characterized by an abnormal overactivation of B cells and subsequent pathologic production of auto-antibodies. PRV-3279 also has the potential to prevent or reduce the immunogenicity of biotherapeutics, including but not limited to gene therapy vectors and transgenes. Provention is currently evaluating PRV-3279 in the PREVAIL (PRV-3279 EVAluation In Lupus) study; additional information on the clinical trial is available at www.clinicaltrials.gov (Number NCT03955666).

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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