Provention Announces Positive Data from Phase 1b PREVAIL Study of PRV-3279

-PRV-3279 Inhibited the Function of B Cells, Durably and Without Depletion-

-PRV-3279 was Well Tolerated in Healthy Volunteers-

-Results Support Parallel Development of PRV-3279 as Treatment for B Cell-Mediated Autoimmune Disorders such as Lupus, and for the Prevention of Immunogenicity of Biotherapeutics, Including Gene Therapy-

OLDWICK, N.J., March 12, 2020 /PRNewswire/ -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical-stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated diseases, today announced positive top-line results from the Phase 1b portion of the PREVAIL (PRV-3279 EVAluation In Lupus) study evaluating PRV-3279 in healthy volunteers. PRV-3279 is a humanized diabody 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 and prevent or reduce the immunogenicity of biotherapeutics, including gene therapy products.

The Phase 1b portion of the PREVAIL study was a double-blind, placebo-controlled, multiple ascending dose study in 16 healthy volunteers. PRV-3279 was well-tolerated, with no serious adverse events. Pharmacokinetic parameters were generally dose-proportional, and high levels of B cell engagement resulted in durable pharmacodynamic responses. As expected, PRV-3279 did not deplete B cells and demonstrated dose-proportional, extensive and sustained binding to circulating B lymphocytes, as well as an extended pharmacodynamic effect as demonstrated by the reduction in circulating immunoglobulin M levels. While anti-drug antibody production was observed at both dose levels tested, immunogenicity was found not to affect exposure, safety or pharmacodynamic parameters.

"These results build on prior clinical data with PRV-3279 and existing evidence of the role of CD32B in lupus. These data further increase our enthusiasm for this potentially groundbreaking treatment of B-cell driven immunologic conditions with high unmet need, such as lupus," 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 and durable inhibition of activated B cells without depletion, similar to the effects of our other drug, teplizumab, on T cells. PRV-3279 may therefore, ultimately strike an optimal balance between safety and efficacy in lupus and other B cell-mediated autoimmune disorders. In addition, PRV-3279 has a unique potential to serve as the backbone in the prevention of immunogenicity associated with gene therapy and other biotherapeutics. The data reported today provides a strong rationale to pursue this dual development path."

Based on the results, Provention plans to commence the Phase 2a portion of the PREVAIL study in lupus patients in the first half of 2021. These Phase 1b results will also enable a second development pathway for the prevention of immunogenicity of biotherapeutics such as gene therapy products.

"These results advance our mission focused on intercepting or preventing a broad range of immune-mediated diseases," said Ashleigh Palmer, CEO and Co-founder, Provention Bio. "Similar to teplizumab, our lead candidate for the prevention or delay of type 1 diabetes, PRV-3279 has the potential to intercept the disease process and transform the treatment landscape for its targeted indications. In addition to advancing to the proof-of-concept, Phase 2 portion of the PREVAIL study in lupus patients, we are exploring collaboration opportunities to support the development of PRV-3279 to prevent or reduce the immunogenicity associated with biotherapeutics such as gene therapy."

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 has the potential to address a wide variety of other autoimmune conditions where B cells play a role, from large indications such as rheumatoid arthritis and multiple sclerosis, to orphan diseases such as idiopathic thrombocytopenic purpura, neuromyelitis optica, pemphigus or myasthenia gravis. Provention has prioritized lupus as our lead autoimmune indication for its unmet need and

since proof-of-mechanism for CD32B agonism has been established in this disease. 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 Systemic Lupus Erythematosus (SLE)

Systemic lupus erythematosus (SLE)**,** also known as lupus, is a chronic autoimmune disorder that can affect nearly every major organ system, causing inflammation, tissue injury, organ damage, and in some patients, organ failure. At least 1.5 million Americans are afflicted by lupus. The pathogenesis of lupus is characterized by an abnormal overactivation of B cells and subsequent pathologic production of autoantibodies. Mutations in the CD32B gene in humans are associated with an increased likelihood of lupus, and reduced expression of CD32B is apparent in B cells from lupus patients.

About Provention Bio, Inc.

Provention Bio, Inc. (Nasdaq: PRVB) is a clinical-stage biopharmaceutical company leveraging a transformational drug development strategy focused on the prevention or interception of immune-mediated disease. Provention's mission is to source, transform and develop therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune diseases. Provention's diversified portfolio includes PRV-031 (teplizumab), a pre-commercial-stage candidate that has been shown to delay the onset of end-stage type one diabetes (T1D) in at-risk individuals with pre-symptomatic disease. Teplizumab has been granted Breakthrough Therapy designation from the U.S. Food and Drug Administration. The company's portfolio includes additional clinical-stage product development candidates that have demonstrated proof-of-mechanism and/or proof-of-concept in other autoimmune diseases, including celiac disease and lupus.

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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