Provention Bio Announces Agreements with MacroGenics for Two Clinical-Stage Assets for the Treatment of Autoimmune Disorders

-- Provention acquires PRV-031 (teplizumab) and plans to initiate pivotal Phase 3 clinical trial to intercept early-onset type 1 diabetes, a pediatric orphan indication
-- Provention licenses and plans to advance PRV-3279 (formerly MGD010) as a potential treatment for systemic lupus erythematosus

OLDWICK, N.J., May 9, 2018 /PRNewswire/ -- Provention Bio, Inc., a clinical-stage biopharmaceutical company dedicated to sourcing, developing and commercializing novel therapeutics aimed at intercepting and preventing immune-mediated diseases, announced today that it has entered into agreements with MacroGenics, Inc. involving two clinical-stage assets. Provention has acquired all rights to teplizumab to be further developed as PRV-031 and licensing rights to MGD010 for development as PRV-3279.

"Our agreements with MacroGenics expand Provention's pipeline with two additional clinical-stage assets that align perfectly with our mission to intercept or prevent immune-mediated diseases," explained Ashleigh Palmer, co-founder and CEO of Provention Bio, Inc. "In less than a year since announcing our founding financing, Provention has secured five clinical stage assets in the burgeoning field of disease prevention and interception."

"Given MacroGenics' current focus on its immuno-oncology pipeline, we believe Provention Bio will be an excellent partner to progress these programs and potentially bring these innovative medicines to patients suffering from serious autoimmune disorders," explained Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics.

Under the terms of the agreements, MacroGenics will receive a warrant to purchase a minority equity interest in Provention, and will be eligible to receive future milestone payments and royalties on future net sales.

PRV-031
PRV-031, a humanized, anti-CD3 monoclonal antibody, is expected to commence pivotal Phase 3 clinical trials in late 2019. The study will explore using PRV-031's, two-cycle treatment on approximately 350 pediatric and adolescent patients with an early-onset type 1 diabetes (T1D) diagnosis to demonstrate preservation of beta cell function, improvement in glycemic control and decreased insulin use.

"Data from previous clinical studies of PRV-031 have indicated the drug's potential to intercept the progression of recently-diagnosed T1D by resetting the immune system and stopping the immunologic attack on the beta cells of the pancreas, as measured by C-peptide levels," explained Eleanor L. Ramos, MD, Provention's Chief Medical and Chief Operating Officer. "The goal of such treatment is to reduce the reliance on exogenous insulin and decrease the complications associated with chronic insulin therapy and poor glycemic control."

"Preserving the insulin-producing cells in type 1 diabetes patients with a prospect of insulin treatment independence, remains the ultimate goal of new therapeutics," explained Jeffrey A. Bluestone, Ph.D., Director, Hormone Research Institute, University of California, San Francisco. "I am delighted to learn that Provention is committed to continuing the development of PRV-031, which has been shown in multiple small clinical studies to preserve a person's insulin production and reduce the consequences of high blood sugar levels."

"We are excited that Provention is expanding its T1D platform, with the goal of ultimately reducing the impact of this disease on a global scale, building on opportunities that were in part historically funded by JDRF," said Jonathan Behr, Ph.D., Managing Director of the JDRF T1D Fund, which participated in Provention's founding financing last year. "We look forward to continuing to work closely with Ashleigh and his team to further advance the mission of early interception, prevention, and treatment for people impacted by chronic diseases like T1D."

PRV-3279
PRV-3279, a humanized bi-specific molecule that was designed to simultaneously target the B-cell surface proteins CD32B and CD79B. Provention plans to continue PRV-3279 development in a multiple ascending dose Phase 1b/2a study as a potential treatment for systemic lupus erythematosus (SLE) at Provention.

"We are excited about the novel mechanism of action of the bispecific biologic PRV-3279," said Francisco Leon,

MD, Ph.D., Co-founder and Chief Scientific Officer of Provention. "Among the many B cell-driven immune diseases PRV-3279 can potentially address, we have chosen systemic lupus erythematosus as our initial indication, as it has substantial unmet needs and very few effective therapies."

PRV-3279 has been studied in humans and shown to be well tolerated. Proof of mechanism (PoM) and its inhibitory effect on induced immune response were demonstrated in a Phase 1a single ascending dose study. Provention plans to continue clinical development to determine if PRV-3279 can intercept the pathophysiology of SLE by preventing the production of autoantibodies by abnormally active B cells.

About Provention Bio, Inc.
Provention Bio, Inc. is a clinical-stage biopharmaceutical company leveraging a transformational drug development strategy that is focused on the prevention or interception of immune-mediated disease. Our diverse portfolio was assembled with product candidates that have undergone clinical testing but may have been underdeveloped or deprioritized assets at other companies. Provention's mission is to in-license, transform and develop clinical-stage, or nearly clinical-stage, therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune and inflammatory diseases including: type 1 diabetes (T1D), Crohn's disease, ulcerative colitis, lupus, and certain life-threating viral diseases. For more information on Provention Bio, please visit www.proventionbio.com.

About T1D
Type 1 diabetes (T1D) is an autoimmune disease in which a person's pancreas stops producing insulin, a hormone that enables people to get energy from food. It occurs when the body's immune system attacks and destroys the insulin-producing cells in the pancreas, called beta cells. While its causes are not yet entirely understood, scientists believe that both genetic factors and environmental triggers are involved. Its onset has nothing to do with diet or lifestyle. There is nothing you can do to prevent T1D, and—at present—nothing you can do to get rid of it.

About Systemic Lupus Erythematosus
SLE 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. Organ systems commonly affected by SLE include the central nervous system, kidneys, gastrointestinal system, mucous membranes, heart, skin, hematologic system, musculoskeletal system, and lungs, with specific organ involvement defining subsets of the disease such as lupus nephritis. SLE often waxes and wanes in affected individuals throughout life. Comorbidities, such as infections, malignancies, hypertension, lipid disorders, and diabetes, increase the risk of disability and death in patients with SLE. According to the Lupus Foundation of America, at least 1.5 million Americans are afflicted by SLE and more than 16,000 new cases of lupus are reported annually across the country. It is estimated that 5 million people throughout the world suffer from some form of lupus. Lupus affects primarily women of childbearing age (15–44 years). However, men, children, and teenagers can also develop 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; and our need for additional financing. 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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