

Provention Bio and Vactech Announce Publication of Proof-of-Concept Data for a Preclinical Prototype of Coxsackievirus B Vaccine

-- The preclinical prototype vaccine is well-tolerated and provides strong protection against coxsackievirus B infections and diabetes in relevant animal models

-- Results provide a solid scientific basis for human trials with Provention's PRV-101 vaccine

OLDWICK, N.J. and TAMPERE, Finland, May 18, 2020 [/PRNewswire/](#) -- Provention Bio, Inc. (Nasdaq: PRVB), a clinical-stage biopharmaceutical company dedicated to intercepting and preventing immune-mediated disease and its licensor, Vactech Oy (Vactech), a Finnish biotechnology company focused on development of vaccines for Type 1 Diabetes (T1D) and other immune mediated diseases, today announced the publication of results demonstrating that a preclinical prototype of Provention's polyvalent coxsackievirus B (CVB) vaccine, PRV-101, is well-tolerated, immunogenic and highly protective in relevant animal models. Provention is developing PRV-101 as a potential vaccine for acute coxsackievirus infection and for the potential prevention of T1D.

The paper, published in the peer-reviewed journal of *Science Advances* and titled "[A Hexavalent Coxsackievirus B vaccine is Highly Immunogenic and has a Strong Protective Capacity in Mice and Nonhuman Primates,](#)" evaluated the immunogenicity and safety of the prototype vaccine. The study was carried out in collaboration with Tampere University in Finland and Karolinska Institute in Sweden and supported by Vactech material, know-how and intellectual property rights.

"Our results provide a solid scientific basis for human trials with Provention's PRV-101 vaccine. Our observation showing that this prototype works in macaques is highly important since their immune system closely resembles the immune system of humans," said Heikki Hyöty, Professor of Virology at Tampere University, co-founder of Vactech, and an author on the study.

In addition to immunogenicity and safety in non-human primates, the prototype vaccine was efficacious in three relevant murine species. In non-obese diabetic (NOD) mice, which are genetically at risk to develop diabetes, the prototype vaccine did not trigger or accelerate diabetes. In SOCS-1-tg mice, a murine model for virus-induced type 1 diabetes (T1D) in which the insulin-producing beta cells are highly susceptible to CVB-induced destruction, the prototype prevented both infection by CVB and the development of CVB-induced diabetes. In BALB/c mice, a common wild-type murine strain, the prototype vaccine prevented infections known to cause CVB-induced myocarditis (heart infection), a serious complication of acute CVB infection in humans.

"We congratulate the investigators at Karolinska Institute and their collaborators at Tampere University for their compelling research, highly supportive of our PRV-101 vaccine program to prevent acute infection by CVB and the development of CVB-triggered complications such as T1D, celiac disease and myocarditis," said Francisco Leon, M.D., Ph.D., Co-founder and Chief Scientific Officer of Provention Bio. "The published data shows that the vaccine is well tolerated, with no side effects noted in the pancreas or other organs, and effective in preventing acute infections. Importantly, the published results demonstrate the vaccine was effective in preventing the development of diabetes in a relevant mouse model, further validating Provention's mission to intercept or prevent T1D."

Professor Hyöty added, "In addition to preventing the onset of T1D, Provention's PRV-101 vaccine program has potential for other applications and indications. We are encouraged by our published results demonstrating the prevention of infection by CVB strains known to cause myocarditis in humans, one of the most well-documented CVB-related diseases. Myocarditis can lead to dilated cardiomyopathy, a common cause of sudden cardiac deaths in young adults. CVB infection is the most commonly identified cause of this heart disease in developed countries."

The senior authors of the article, Professor Heikki Hyöty and Professor Malin Flodström-Tullberg (Karolinska Institute, Sweden), are members of Provention's PRV-101 scientific advisory board. Professor Hyöty is also a co-founder of Vactech. Provention has licensed the exclusive worldwide rights to Vactech's enterovirus vaccine platform targeting the prevention of CVB infections leading to the onset of T1D and celiac disease.

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. 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.

About Vactech

Vactech develops and licenses vaccines and novel technologies for vaccines and diagnostics with a pipeline of early stage product candidates focused on Type 1 Diabetes, Celiac Disease, Asthma & Allergy and diagnostics.

Vactech's flagship project is a patented enterovirus based preventive Type 1 Diabetes (T1D) vaccine, similar to the widely used enterovirus vaccine against polio. The vaccine is a traditional inactivated vaccine and it has been proved to be safe and effective in mice. In addition, Vactech's IMAVAC™ product line uses Virus Like Particle (VLP) technology which is essential for other vaccines, immunomodulators and diagnostic applications.

Vactech is a privately owned company. We have a track record of collaboration with both industrial and academic partners. Vactech has engaged in strategic partnership with Provention Bio Inc. especially in the field of preventive Type 1 Diabetes vaccine and related applications.

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, the risks listed under "Risk factors" in our annual report on Form 10-K for the year ended December 31, 2019 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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