

Provention Bio, Inc. Announces Clinical Program Focused on Intercepting and Preventing the Onset of Type 1 Diabetes

- Enterovirus vaccine platform in-licensed from Vactech Oy will be developed to "pre-empt" type 1 diabetes by targeting coxsackievirus B infection

- JDRF T1D Fund investment to advance Provention's lead program, which aims to potentially reduce new type 1 diabetes cases by 50%

LEBANON, N.J. and BOSTON, July 18, 2017 /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 the in-licensing of an enterovirus vaccine platform, which the company is initially developing to reduce the onset of type 1 diabetes (T1D) by vaccinating at-risk populations against coxsackievirus B (CVB) infection. Research suggests that CVB infection could be responsible for more than half of T1D cases worldwide.

Provention in-licensed the platform from Finnish biotechnology company, Vactech Oy, and will use an investment by the JDRF T1D Fund to advance the program. The financing from the JDRF T1D Fund is part of Provention's \$28.4 million founding financing. The investment will support the advancement of the T1D program toward an anticipated first-in-human proof-of-mechanism and proof-of-concept program. Terms of the licensing agreement with Vactech have not been disclosed.

"Creating a world without T1D includes prevention," said Jonathan Behr, Managing Director of the T1D Fund "Provention's anti-viral vaccine potentially offers the prospect of drastically reducing the number of people impacted by the challenges of T1D." The JDRF T1D Fund is devoted to identifying and funding the best early-stage, high impact T1D commercial opportunities.

Ashleigh Palmer, co-founder and CEO of Provention Bio, stated, "We are extremely excited to be launching our lead program in type 1 diabetes and are grateful to Vactech for allowing us the opportunity to license and develop its proprietary enterovirus vaccine platform. Equally, the JDRF T1D Fund's confidence in our approach to reduce the impact of type 1 diabetes on a global basis leaves us deeply humbled. Imagine the possibility of reducing at least half of the world's cases of type 1 diabetes. With the help of the JDRF T1D Fund, Vactech, our cofounder MDB Capital Group LLC, and other founding investors, including Johnson & Johnson Innovation - JJDC, Inc., we are attempting to make this vision a reality."

Raimo Harju, CEO of Vactech Oy, commented, "The licensing agreement with Provention and the initiation of its vaccine development program targeting type 1 diabetes is a watershed moment for Vactech as it validates our exhaustive research into the link between coxsackievirus B and type 1 diabetes, while expanding our enterovirus platform into a substantial global development and commercialization opportunity. We look forward to working closely with Provention as it seeks to change the paradigm of type 1 diabetes and initiates other clinical development programs targeting the interception and prevention of immune-mediated disease."

Type 1 Diabetes & Coxsackievirus B Infection

T1D is a life-impacting chronic disease caused by immune destruction of the insulin-producing cells in the pancreas. Today, there is no cure. The only means for managing this devastating disease is life-long blood glucose monitoring and insulin replacement by way of injection/infusion or, potentially, whole organ pancreas or pancreatic islet cell transplantation.

However, global longitudinal studies of more than 200,000 children screened and more than 17,000 followed over two decades in Finland by Vactech's scientific founders and their collaborators have identified CVB infection as a likely trigger for T1D onset. From this research, it was discovered that the diabetes process often starts after CVB infection. Insulin-producing cells in the pancreas express specialized receptors used for cellular infection by CVB. As a result, an exacerbated immune reaction against the virus may be involved in triggering the autoimmunity targeting the pancreas and gut, which appears to precede the onset of T1D.

Importantly, CVB-associated risk of T1D was significantly reduced in children whose mothers have had a CVB infection, thereby suggesting a transfer of protective CVB antibodies to their offspring via placenta and breast milk. This observation suggests the potential benefit of CVB vaccination for children.

Francisco Leon, MD, Ph.D., scientific co-founder of Provention, said, "By identifying and targeting potential disease precursors, such as the well-chronicled link between coxsackievirus B infection and type 1 diabetes, Provention Bio hopes to intercept, slow and reverse the progression of a variety of chronic diseases. Our coxsackievirus B vaccine, if successful, could prevent more than 50% of type 1 diabetes cases."

About Provention Bio, Inc.

Provention Bio, Inc. is a clinical stage biopharmaceutical company dedicated to sourcing, developing and commercializing novel therapeutics and cutting-edge solutions to intercept and prevent immune-mediated disease. Our "predict and prevent" therapeutic model is focused on developing drugs that intervene before the targeted disease begins, re-appears or progresses. This approach is unique in the biopharmaceutical industry and offers unprecedented potential to reduce the high morbidity, mortality and escalating costs of chronic autoimmune and inflammatory diseases, such as type 1 diabetes (T1D), Crohn's disease, and ulcerative colitis, as well as emerging viral infections. For more information on Provention Bio, please visit www.proventionbio.com.

About Vactech Oy

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, which has been licensed to Provention Bio, Inc., is a traditional inactivated vaccine that 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 with a track record of collaboration with big pharma on the level of Good Laboratory Practice (GLP). For more information on Vactech, please visit www.vactech.fi

About The JDRF T1D Fund

The JDRF T1D Fund (www.t1dfund.org) is a venture philanthropy fund accelerating life-changing solutions to treat, prevent, and cure type 1 diabetes (T1D) through catalytic commercial investments. Through its investments in partnership with private capital, including venture capital, pharma and foundations, the T1D Fund seeks to attract the private investment necessary to advance drugs, devices, diagnostics, and vaccines into the hands of those living with T1D. The T1D Fund invests in areas strategically aligned with JDRF, with an exclusive focus on the best commercial opportunities. The T1D Fund will reinvest any realized gains into new investments to further its mission.

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