Provention Bio Selects Intravacc as Product Development and Manufacturing Partner for Coxsackievirus B Vaccine

- Coxsackievirus B appears to be an important trigger for type 1 diabetes
- Acute Coxsackievirus B infection and its complications present a serious unmet need in pediatrics
- L2D Services providing product development, regulatory and project management support

LEBANON, N.J., May 7, 2018 /PRNewswire/ -- Provention Bio, Inc. (Provention), 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 selected Netherlands-based Intravacc to lead product development and manufacturing of clinical trial material for Provention's Coxsackievirus B (CVB) vaccine (PRV-101). France-based L2D Services SARL/Leads-To-Development (L2D) is providing expert development, regulatory and project management support to ensure rapid progress of PRV-101 into clinical development.

CVB, an enterovirus, has been identified as a possible common trigger for type 1 diabetes (T1D) onset. Vaccination of at-risk populations against CVB infection may lead to the prevention or delay in onset of T1D. The CVB vaccine was developed initially by Vactech Ltd. of Finland and licensed to Provention in April, 2017. Provention is planning to initiate first in-human clinical trials in 2020.

Enteroviruses are responsible for an estimated 30 million infections annually in the US. CVB contributes significantly to enteroviral healthcare costs, since it can result in hospitalization and severe morbidity. Usually asymptomatic or presenting as cold-like symptoms, fever, rash, hand-foot-mouth disease, and/or mild gastrointestinal distress, CVB infections can occasionally cause more serious and sometimes life-threatening illnesses including pericarditis, myocarditis, meningitis and pancreatitis.

Provention, in partnership with Intravacc, Vactech and L2D is now developing its CVB vaccine for large scale manufacture of clinical trial material in accordance with current Good Manufacturing Practices (cGMP). Intravacc was chosen as Provention's manufacturing partner based on its expertise and excellent track in enterovirus vaccine development, including IPV, sIPV, EV-71, and CV-A16, as well as Intravacc's state-of-the-art vaccine cGMP production facilities. PRV-101 will be developed using Intravacc's proven and well-established platform technology, including certain proprietary cell lines and production processes.

Ashleigh Palmer, co-founder and CEO of Provention Bio, stated, "Selecting Intravacc for PRV-101's cGMP production is an important next step in our plan to initiate a potentially transformative clinical program to develop a vaccine to prevent acute coxsackievirus B infection and, ultimately, prevent or delay the onset of as much as half of the world's cases of T1D. We welcome this opportunity to work alongside Intravacc, Vactech and L2D to advance our PRV-101 program to the clinic."

Intravacc's CEO Thijs Veerman, MSc, commented, "We are very excited to be involved in this project. Intravacc is uniquely positioned to develop cGMP clinical material for this vaccine and ensure its specifications, quality and patient-readiness. We have the necessary knowledge, expertise and experience to advance Provention's PRV-101 program to the next stage and beyond."

About Type 1 Diabetes and 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, pancreatic cell transplantation.

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 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 and associated celiac disease.

Importantly, the CVB-related risk of T1D autoimmunity was significantly reduced in children whose mothers previously 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.

About Intravacc

Intravacc, based in Bilthoven, the Netherlands, is an established R&D organisation with more than 100 years' experience in the optimisation of vaccines, vaccine processes and vaccine technologies. Intravacc has state-of-the-art production facilities and its aim is to substantially reduce development risks and costs of new vaccines in order to contribute to global health and equity in access to vaccines worldwide. For more information on Intravacc, please visit www.intravacc.nl.

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 Vactech Ltd.

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 is a privately owned company having 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. Please see the company's website at www.vactech.fi for additional information.

About L2D

L2D is a Paris-based company that provides drug development and regulatory affairs support, with a particular emphasis on preclinical development and clinical trial applications. L2D can provide support in the generation and execution of preclinical development plans and has expertise in all aspects of production (CMC), toxicology and safety pharmacology. L2D also has expertise in early stage regulatory affairs including product classification, formal scientific advice with the FDA, EMA or national competent authorities, orphan drug designation requests and writing both EU and US clinical trial applications/INDs. For more information on L2D, please visit www.leadstodevelopment.com.

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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