Intravacc. Innovating vaccines

# Press Release

## Intravacc announces completion of formulation and manufacturing process development of PRV-101 vaccine candidate for Provention Bio

- Potentially the first preventive vaccine for coxsackievirus B, a risk factor associated with type 1 diabetes and celiac disease
- First dosing of PRV-101 in the PROVENT Phase I clinical trial started in January 2021

**Bilthoven, the Netherlands, 19 January 2021** – **Intravacc,** a world leader in translational research and development of vaccines, today announced that a candidate polyvalent inactivated coxsackievirus B (CVB) vaccine it developed and manufactured for Provention Bio in less than 36 months, has entered into a first in human Phase I clinical study called PROVENT (PROtocol for coxsackievirus Vaccine in healthy volunteers) .

Provention Bio is clinical stage biopharmaceutical company, that selected Intravacc in 2018 to lead product development and manufacturing of clinical study material for Provention's vaccine candidate (PRV-101). This CVB vaccine candidate is developed for the intended prevention of acute CVB infection and the potential delay or prevention of type 1 diabetes (T1D) and celiac disease. Intravacc used its proprietary and regulatory approved Vero cell platform to develop a cGMP-grade viral vaccine production process for the polyvalent CVB vaccine candidate.

CVB is a common enterovirus that frequently causes acute morbidity such as respiratory disease, meningitis, pericarditis and otitis. CVB is also the leading cause of viral myocarditis, a common condition that can cause fatal arrythmia and lead to a serious chronic myocarditis that often needs heart transplantation. In addition, persistent CVB infection is significantly associated with the development of T1D and celiac disease. With currently no preventive or disease modifying treatments available for T1D, its complications present a serious unmet medical need and up to 2.3 million people may be at risk of T1D globally. PRV-101 has the potential to be the first vaccine to prevent up to ~50% of T1D and ~20% of celiac disease.

**Dr. Jan Groen, Intravacc's CEO, said:**

> *"We are very proud to have been able to successfully complete the contract development and manufacturing project for Provention Bio in such a short period of time and to attribute substantially to the first preventive candidate vaccine for T1D and celiac disease. This project provides further validation of Intravacc's Vero cell platform."*

PROVENT is a placebo-controlled, double-blind, randomized Phase I first-in-human clinical study being conducted at the Clinical Research Services Turku - CRST Oy, a clinical trial unit in Turku, Finland. The study's primary endpoint is the safety of two dose levels of PRV-101 in healthy adult volunteers provided three administrations with 4-week intervals. Tolerability and immunogenicity will also be evaluated. Results of PROVENT are expected in the second half of 2021.

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## About PRV-101

PRV-101 is an investigational polyvalent vaccine being developed for the prevention of acute coxsackievirus B (CVB) infection and the potential delay or prevention of type 1 diabetes (T1D) and celiac disease. It is specifically designed to prevent autoimmunity by the primary prevention of a putative infectious trigger. PRV-101 has the potential to be the first vaccine to prevent CVB as well as up to approximately 50% of T1D and approximately 20% of celiac disease. Patents covering the use of PRV-101 in these indications have been licensed by Provention Bio from Vactech Oy. Netherlands-based Intravacc was selected to lead product development and manufacturing of clinical trial material for PRV-101.

## About Provention Bio, Inc.

Provention Bio, Inc. (Nasdaq: PRVB) is a biopharmaceutical company focused on advancing the development of investigational therapies that may intercept and prevent debilitating and life-threatening immune-mediated disease. The Company has submitted a BLA to the FDA for its lead investigational drug candidate, teplizumab, for the delay or prevention of clinical type 1 diabetes (T1D) in at-risk individuals. The Company's pipeline includes additional clinical-stage product candidates that have demonstrated in pre-clinical or clinical studies proof-of-mechanism and/or proof-of-concept in other autoimmune diseases, including celiac disease and lupus. Visit www.ProventionBio.com for more information. Twitter: @ProventionBio.

## About Intravacc's Vero cell platform

Intravacc's viral vaccine production process is based on a cGMP-grade, regulatory approved, Vero cell line. This proprietary platform is being used for routine large-scale commercial vaccine manufacturing by Intravacc's customers world-wide. In addition, virus seed lots and clinical batches have regularly been produced and validated on the Vero cells, for example Poliovirus, Enterovirus (EV71), and Respiratory Syncytial Virus (RSV).

## About Intravacc

Intravacc, located at Utrecht Science Park Bilthoven in the Netherlands, is a leading global contract development and manufacturing organization of innovative vaccines against infectious diseases. As an established independent CDMO with over 100 years of experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology related to polio vaccines, measles vaccines, DPT vaccines, Hib vaccines and influenza vaccines around the world. Around 40% of childhood disease vaccines are based on Intravacc's proprietary technology. Intravacc offers a wide range of expertise for independent vaccine development, from concept to Phase I/II clinical studies for partners around the world, including universities, public health organizations (WHO, Bill & Melinda Gates Foundation), biotech and pharmaceutical companies. For more information, please visit www.intravacc.nl.

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