

Intravacc and Therapyx jointly develop the world's first prophylactic gonorrhea vaccine

- Gonorrhea is the second most common bacterial infectious disease worldwide
- Vaccine based on IL12 in combination with intravacc's gonorrhea OMV targeting mucosal immunization
- Induce an adaptive immune response for long term protection against the gonorrhea bacteria
- Mucosal vaccine platforms offer a broader perspective also for respiratory virus vaccines, such as Covid-19 and influenza

Bilthoven, The Netherlands, 25 August, 2020 – Intravacc, a global leader in translational research and development of viral and bacterial vaccines, has partnered with American, Buffalo, NY, based Therapyx, to further develop and optimize the world's first prophylactic vaccine against gonorrhea, NGoXIM. For this Therapyx received a \$ 2.8 million Phase IIB grant in the US and has chosen to partner with Intravacc for its unique capabilities and infrastructure for the optimization of vaccines, vaccine processes and vaccine technologies.

NGoXIM is a microsphere vaccine with encapsulated interleukin-12 (IL-12) and outer bacterial membrane vesicles from *Neisseria gonorrhoeae*, developed with Intravacc's OMV platform. This vaccine therefore consists of a combination of adjuvant and antigen, specifically designed for mucosal immunization. Vaccination with NGoXIM has been shown to induce potent and persistent antibacterial activity in primates. In this collaboration, the parties will focus on enhancing and optimizing the specific adaptive immune response in non-human primates as a prelude to testing in humans. This should ultimately lead to a vaccine that provides lasting protection against infection with the *Neisseria gonorrhoeae* bacteria.

Gonorrhea

Gonorrhea is the second most common bacterial infectious disease in the US, with a reported incidence of more than 300,000 cases per year. The *Neisseria gonorrhoeae* bacteria, a gram-negative aerobic 0.6–1.0 µm bacteria, is the cause of this sexually transmitted disease. Due to under-reporting and asymptomatic disease course, the true incidence is believed to be more than double. There is currently no effective gonorrhea vaccine available and the disease is known to be contracted repeatedly without apparently developing protective immunity as a result of previous infection. In addition, antibiotic resistance is increasingly common for this bacterium. The US-based Center for Disease Control and Prevention has listed antibiotic resistant *N. gonorrhoeae* as one of the top three pathogens that "pose an immediate threat to public health that must be urgently and aggressively addressed".

Dr. Jan Groen, Intravacc's CEO, comments:

"We are proud to partner with Therapyx in the further optimization and development of the world's first gonorrhea vaccine. Vaccination with the candidate vaccine inducing a potent and lasting antibacterial activity in primates, not only shows the proof-of-principle for NGoXIM, but also the potency of the mucosal vaccine platform in general. This rapidly adaptable platform



for the engineering and development of mucosal vaccines has enormous potential for challenging respiratory viral infections, including influenza and COVID-19, among others. With our unique infrastructure and pilot plant for the optimization of vaccines, vaccine processes and vaccine technologies, we can contribute to accelerated further development of this promising vaccine, for which there is a great worldwide medical need."

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About Intravacc's OMV platform technology

For the development of vaccines, Intravacc has designed and developed a platform based on outer membrane vesicles (OMVs) - spherical particles with intrinsic adjuvant properties. The OMVs can be rigged with immunogenic peptides and/or proteins that stimulate effective adaptive immunity. The OMV carrier has been optimized to induce a more effective immune response against these newly introduced antigens. Intravacc has also developed genetic tools to increase the yield of OMVs, reduce the toxicity and achieve the desired antigenic composition. Intravacc's OMV platform is fully scalable and allows rapid and efficient modification of the antigen composition, either through genetic modification of the bacterial host or by associating antigens with stored OMVs.

About Intravacc

Intravacc, located at the Utrecht Science Park, Location Bilthoven in The Netherlands, is a global leading organization with many years of experience in translational vaccinology. As an established independent clinical development and manufacturing organization (CDMO) in the vaccine industry, Intravacc has transferred its technology and know-how worldwide, including oral polio vaccines, measles vaccines and DPT, Hib and influenza vaccines. Intravacc offers a wide range of expertise bridging the gap between discovery, pilot scale GMP bioproduction, through to phase I/II clinical trials for partners such as academia, public health organizations (WHO, Bill & Melinda Gates Foundation) and biotech and pharmaceutical companies.

Please visit for more info www.intravacc.nl.

About Therapyx

Therapyx, based in Buffalo, NY, is a privately held development-stage biotechnology company committed to innovating our industry and changing the future of pharmaceuticals by engaging in the discovery and development of microparticulate immune therapeutics to treat infectious disease, immune-mediated inflammatory disorders and cancer. For more info, please visit www.therapyxinc.com.

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