

Intravacc Announces Favorable Preclinical Data for its Candidate Intranasal Gonorrhea Vaccine Avacc 11[®]

- Pre-clinical data of Avacc 11[®] demonstrated protection against gonorrhea infection
- Global incidence rate of this sexual transmitted disease is at 87 million infections per year
- OMV technology is a powerful tool to induce protective systemic and mucosal immunity
- Data published in the peer reviewed journal MSphere of the [American Society of Microbiology](#)

Bilthoven, The Netherlands, 16 January 2023 – [Intravacc](#), a world leader in translational research and development of preventive and therapeutic vaccines, today announced favorable pre-clinical data for Avacc 11[®], the prophylactic intranasal gonorrhea candidate vaccine Intravacc develops in partnership with [Therapyx inc.](#) The results of the candidate, a proprietary outer membrane vesicle (OMV) platform-based gonorrhea vaccine combined with encapsulated IL-12, showed protection against subsequent infection with *Neisseria gonorrhoeae* (NG). Results were published in the peer reviewed journal MSphere of the [American Society of Microbiology](#). In October 2022, Intravacc was awarded a \$14.6 Million [NIH/NIAID contract](#) to further develop this intranasal candidate gonorrhea vaccine.

In a previous pre-clinical study, the candidate gonococcal vaccine consisting of OMVs and microsphere (ms)-encapsulated interleukin-12 (IL-12 ms) (Therapyx Inc.) was administered intravaginal, inducing systemic, mucosal and T-cell (TH1) driven immune responses. After a vaginal challenge with NG, the animals were resistant to infection. However, the intravaginal vaccination route may be impractical for human vaccine development as it is inapplicable for males and may not be acceptable to women.

In this study mice were vaccinated via the intranasal route and the results of this intranasal study were similar to the intravaginal vaccination route. Intranasal immunization resulted in high serum IgG, salivary IgA, and vaginal IgG and IgA anti-gonococcal antibodies when OMVs were administered with IL-12 ms. The serum IgG and salivary IgA anti-bodies induced in male mice was similar to the response induced in female mice. Gamma interferon (IFN- γ) production by CD4 T cells from iliac lymph nodes was elevated after vaccination intranasally or intravaginally. Female mice immunized with OMVs plus IL-12 ms by either route resisted challenge with NG to an equal extent, and resistance generated by intranasal immunization extended to heterologous strains of NG.

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

“Together with our partner Therapyx, we are very pleased with the preclinical data of the intranasal candidate vaccine Avacc 11[®]. This intranasal gonococcal vaccine is more suitable to fight gonorrhea infections, which are becoming increasingly resistant to antibiotic treatments.”

Gonorrhea

Gonorrhea is a sexually transmitted disease (STD) caused by the *Neisseria gonorrhoeae* bacteria with a global annual estimated incidence rate of 87 million infections per year. Due to underreporting and asymptomatic disease, the true incidence is believed to be more than double as the reported incidence. NG, a Gram-negative aerobic 0.6–1.0 μm bacteria, is the cause of this STD. The symptoms of gonorrhea include a pus-like discharge from the vagina or penis, pain when peeing and, in women, bleeding between periods. Around 1 in 10 infected men and almost half of infected women do not experience any symptoms. Currently there is no effective gonorrhea vaccine available, and the disease is known to be contracted repeatedly without apparently developing protective immunity. In addition, antibiotic



resistance is increasingly common for this bacterium. *N. gonorrhoeae* is on the WHO high-priority list of antimicrobial resistant bacteria.

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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 immune-stimulating properties. The OMVs can be designed 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 the OMVs, reduce the toxicity and achieve the desired antigenic composition. Intravacc's OMV platform is 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 Utrecht Science Park Bilthoven in the Netherlands, is a leading global contract development and manufacturing organization for infectious diseases and therapeutic vaccines. As an established independent CDMO with many years of experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology world-wide for many vaccines including polio, measles, DPT, Hib and influenza. Around 40% of childhood disease vaccines are based on Intravacc's know-how and 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.

About Therapyx

Therapyx is a privately held pharmaceutical company headquartered in Buffalo New York. The Company is developing a proprietary drug delivery system based on the encapsulation of highly potent protein therapeutics into micro-particles that engineer slow, controlled, local release of drug substances while preserving bioactivity, reduced toxicity and long-term shelf-stability.

For more information see the company's website www.Therapyxinc.com.

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