Intravacc. Innovating vaccines

Press Release

Intravacc Awarded US$14.6 Million NIH/NIAID Contract to Develop Intranasal Gonorrhea Vaccine

- Gonorrhea is on the WHO high-priority list of antimicrobial resistant bacteria
- World's first intranasal prophylactic gonorrhea vaccine candidate
- Mucosal vaccine platforms provides a broad opportunity for viral and bacterial vaccines

Bilthoven, The Netherlands, 5 October 2022 – **Intravacc,** a world leader in translational research and development of preventive and therapeutic vaccines, today announced that it has been awarded a contract with base and options that may total US$14.6 million from the US National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), for the development of a prophylactic intranasal vaccine against *Neisseria gonorrhoeae* (NG). Gonorrhea is a sexually transmitted disease caused by the NG bacteria. Intravacc will develop a prophylactic vaccine based on its proprietary outer membrane vesicles (OMV) platform technology.

The NG vaccine, called NGoXIM, is based on gonococcal OMVs combined with sustained-release microspheres containing recombinant human IL-12, and will be administered intranasally. Proof-of-concept studies with NGoXIM have already shown the vaccine to be effective in animal models, inducing a potent, lasting, and cross-protective immune response. Intravacc will develop a complete production process for NGoXIM to generate vaccine batches under Good Manufacturing Practices. The company will work towards a non-clinical toxicity (TOX) and Clinical Trial Material batch to execute a Phase I study in healthy adults, investigating the safety of the vaccine and generating efficacy data. The IL-12 containing microspheres called GneX12 will be developed and produced by Therapyx Inc.

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. Due to under-reporting and asymptomatic disease course, the true incidence is believed to be more than double the reported incidence. NG, a gram-negative aerobic 0.6–1.0 µm bacteria, is the cause of this sexually transmitted disease. 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. Gonorrhea is on the WHO high-priority list of antimicrobial resistant bacteria.

The project is funded by Federal funds from the National Institute of Allergy & Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N93022C00058.

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

> *"Together with our sub-contractor Therapyx, we are honored that NIH and NIAID have awarded us this contract, allowing both of us to demonstrate the safety and tolerability of our intranasal gonorrhea vaccine candidate, NGoXIM (Avacc 11)."*

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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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