

Intravacc announces positive preclinical data for its OMV-based Lyme vaccine

- Neisserial OMV based Lyme vaccine elicit high antibody titers in mice
- Further evidence for Intravacc's versatile multi-disease OMV platform
- Data are published in peer reviewed journal *Vaccine*

Bilthoven, The Netherlands, 13 April 2021 –[Intravacc](#), a world leader in translational research and development of preventive and therapeutic vaccines, today announced positive preclinical data for its OMV based Lyme disease vaccine. Publication of this study in the peer reviewed scientific journal *Vaccine* titled "Vaccination with meningococcal outer membrane vesicles carrying *Borrelia* OspA protects against experimental Lyme borreliosis" describes the pre-clinical data of the candidate Lyme vaccine based on Intravacc's OMV platform. This study shows that OMV's expressing *Borrelia* (lipo)proteins is a promising vaccine concept that might lead to protect humans against Lyme disease.

Currently, no vaccine against Lyme disease, the fastest growing and most common tick-borne illness in North America and Europe, is available for humans. If untreated, symptoms may include loss of the ability to move one or both sides of the face, joint pains, severe headaches with neck stiffness, or heart palpitations. Antibiotics are the primary treatment and are usually successful, but only when given in time. A vaccine would limit the use of antibiotics and the potential rise of antibiotic resistance.

Safety evidence of OMV's

Vaccination of animals has shown that Intravacc's OMV-based vaccines can protect against various pathogens. Toxicology studies with various OMV-based vaccines showed no tissue and organ damage in the animals. OMV based meningococcal vaccine phase I and II studies have shown that they are safe in both children and adults. Today one OMV-based vaccine has been approved by the EMA and is on the market.

The Study

The study conducted in collaboration with the Amsterdam Medical Center in the Netherlands evaluated Intravacc's genetically modified meningococci, resulting in bacteria producing immunogenic vesicles (OMV) expressing Lyme lipoprotein OspA on the surface of these vesicles. Groups of eight mice were vaccinated at day zero, 14 and 28 with either 40 µg OMVs, expressing OspA and the control group received the same amount of empty OMV's.

To measure the protection after vaccination, animals were infected with live *Borrelia burgdorferi* by needle injection on day 42 and on day 62 all mice were sacrificed, and blood and organs were collected and tested for the presence of borrelia by culture and DNA testing. At the same time points, blood samples were collected from all the animals. Strong antibody responses were induced in animals that received OMV-OspA. Whereas in the control group no borrelia specific antibodies were detected. In the skin of one of the eight animals, live bacteria were detected. Traces of *Borrelia* specific DNA were detected in one to two animals.

This study shows that OMV-based vaccines expressing *Borrelia* (lipo)proteins are an easy and feasible vaccination method protecting against Lyme disease, and could result in a promising prophylactic vaccine for humans.



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

"This is yet another proof that our OMV platform is versatile and effective in addressing a variety of diseases. We show that it is possible to couple OMV to external antigens and that the bacterium can also be modified to express the antigens. In addition to the great results shown for Lyme disease, the platform can be utilized for vaccine development for virtually any disease."

About Lyme disease

Lyme disease is present in over 80 countries world-wide. According to a survey by the Dutch National Institute for Public Health and the Environment (RIVM) the number of patients that have been infected every year has more than quadrupled in the past 20 years. Lyme disease, also called Lyme borreliosis, is the fastest growing and most common tick-borne illness in North America and Europe. The bacterium *Borrelia burgdorferi* is spread by ticks during a blood feed. Clinical manifestations occur usually weeks to months after the tick bite. Most frequent symptoms are red circular rash (Erythema migraine), fatigue, fever, headache, mild stiff neck, arthralgia and myalgia. When the tick is removed rapidly, the chance of contracting Lyme disease is slim. Once infected antibiotics can be successful in treating the disease. However, timing of treatment is critical and 5-10% of the patients do not respond to treatment. When the bite has not been noted or treatment is too late or not effective, the disease can cause more serious complications affecting the joints, heart or nervous system. Severe cases amount annually to approximately 85.000 in the EU.

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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 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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