Intravacc. Innovating vaccines

Press Release

Intravacc publishes positive phase I Shigella conjugate vaccine data

- **High medical need for Shigella vaccine**
- **Over 250 million infections worldwide annually**
- **Vaccine was well tolerated and induced a significant increase in functional antibodies**
- **Data published in prestigious journal *The Lancet Infectious Diseases***

Bilthoven, The Netherlands, 16 November 2020 – Intravacc, one of the leading translational research and development vaccine institutes with an extensive track record in developing viral and bacterial vaccines, today announced the results of a clinical study with an experimental vaccine against Shigella, intestinal bacteria that cause severe diarrhea and dysentery. Data were published in the prestigious journal **The Lancet Infectious diseases.** The paper was authored by a team of researchers and clinicians at Tel Aviv University, Tel Aviv Sourasky Medical Center, Institut Pasteur, Ariel University and Intravacc. The clinical study in healthy adults shows that the vaccine is well tolerated and immunogenic. Intravacc developed a production process for this conjugate vaccine, manufactured the GMP batch and did stability testing and batch release.

Currently there is no vaccine available against Shigella. This experimental Shigella vaccine (SF2a-TT15), developed by Institut Pasteur, is a conjugate vaccine consisting of a synthetic oligosaccharide chemically linked to tetanus toxoid. The oligosaccharide mimics a part of bacterial lipopolysaccharide (LPS), which is abundantly present in the outer membrane of Shigella bacteria.

Prof.Dr. Virgil Schijns, Intravacc's CSO, commented:

> *"We are very pleased with the results of this phase one study. We are able to do this because of our unique expertise in conjugate vaccine development This now allows us to continue with a human challenge model and a phase 2 study in children."*

The vaccine was given three times to 64 seronegative volunteers in two doses and with and without aluminium hydroxide adjuvant. Both doses induced significantly increased serum IgG titres as well as an increase in memory B cells. The non-adjuvanted high dose induced a 25-fold increase in IgG GMT after one injection while the non-adjuvanted low dose induced a 5-fold increase, compared with baseline. Alum significantly enhanced the specific IgG response at both doses after the 3rd injection. At high dose, the vaccine also induced a 4-fold or greater rise in serum bactericidal titres in 80% of the volunteers receiving the adjuvanted dose and in 100% of those receiving the non-adjuvanted vaccine. Only mild adverse effects were reported, (**The Lancet Infectious Diseases**).

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

> *"Intravacc and its partners are very pleased to contribute to this significant public health problem. This clearly demonstrates Intravacc's broad experience and knowledge in developing, manufacturing and clinical validation of candidate vaccines"*

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About Shigella

Shigella is a species of enteric bacteria that causes disease in humans and other primates. The disease caused by the ingestion of Shigella bacteria is referred to as shigellosis, which is associated with

diarrhea and other gastrointestinal symptoms. About 250 million cases of shigellosis occur annually in low and middle-income countries, causing over 212,000 (Shigella morbidity & mortality).
No group of individuals is immune to shigellosis, but certain individuals are at increased risk. Small children acquire Shigella at the highest rate. Shigella is easily spread because of its low infectious dose. Spreading occurs via the oral-faecal route both by person-to-person contact and through eating contaminated food.

About Intravacc

Bilthoven, Netherlands, based Intravacc is one of the world's leading institutes for translational vaccinology. As an established independent R&D organization with over 100 years' experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology all over the globe, including oral polio vaccines, measles vaccines, and DPT, Hib and influenza vaccines. Intravacc offers a wide range of expertise to independently develop vaccines from lead concept to clinical phase I/II studies for partners worldwide such as academia, public health organizations (WHO, BMGF), and biotech and pharmaceutical companies.
Intravacc also has its own proprietary vaccine platform and established state-of-the-art research and production (GMP) facilities. Its aim is to substantially reduce development risks and costs of new vaccines in order to contribute to global health and equity in access to vaccines worldwide.

For more information, please visit www.intravacc.nl

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