Intravacc's candidate RSV vaccine demonstrates safety in phase I trial

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High unmet need for effective pediatric RSV vaccine
Continued frequent hospitalization of infected infants and risk to elderly
Partner orientation for further development of this RSV candidate vaccine

***Bilthoven, The Netherlands, 18 August 2020* - Intravacc, a global leader in translational research and development of viral and bacterial vaccines, today announced the publication in the medical journal *Vaccine*, of a clinical phase I study with its candidate Respiratory Syncytial Virus (RSV) vaccine. The vaccine showed excellent induction of immunogenicity after nasal administration to healthy adult volunteers (18-50 years). In addition, the Live Attenuated Vaccine (LAV), constructed with reverse genetics, appears to be safe and well-tolerated. Intravacc is currently orienting on a suitable partner for further joint clinical development of this vaccine in a large pediatric setting.**

A pediatric vaccine against RSV would not only prevent morbidity and mortality in infants and young children but could also reduce transmission to the elderly. The RS virus is the most common cold virus in children under the age of five and poses a serious threat to the elderly as well. Many biotech and pharmaceutical companies have been developing an RSV vaccine since the 1960s, but to this day no vaccine emerged out of this. An estimated 120,000 children worldwide still die of the virus every year, especially in developing countries.

The trial

The conducted trial was a randomized, placebo-controlled phase I study with a first administration in humans of a live attenuated RSV virus without the G (adhesion) protein to evaluate safety, tolerability, excretion and immunogenicity. In preclinical studies, RSVDG showed decreased host cell binding and infectivity. Intranasal immunization of laboratory animals with the RSVDG vaccine protected against replication of wild-type RSV, without aggravating the disease.

An RSV lacking the G-protein is expected to be attenuated, but still able to elicit an effective immune response due to the presence of the surface protein F as the major antigen site and residual infectivity. Using reverse genetics, Intravacc constructed a Live Attenuated Vaccine against RSV from which the coding sequence for the attachment protein (G) was removed from the RSV genome (RSVΔG). Live attenuated vaccines can be administered intranasally, mimicking the natural route of infection and thereby stimulating both local mucosal and systemic immunity.

Volunteers received one dose of vaccine intranasally, the control group a placebo. The side effects were mild and comparable to the placebo group. No measurable amounts of vaccine were excreted after administration, indicating sufficient attenuation of the vaccine.

Since almost everyone is infected with the RSV almost every year, adults have a fairly high background immunity. That makes it difficult to evaluate efficacy in this group. Measured antibody levels were comparable before and after immunization and between vaccine and placebo groups. In a subsequent study it must be demonstrated whether the vaccine is immunogenic to children.

Dr. Jan Groen, Intravacc's CEO says:

Worldwide, RSV is estimated to be the second cause of death after malaria in infants aged 1 to 12 months due to a single pathogen. By the age of two, almost all infants have been exposed to RSV. However, immunity to RSV is incomplete and re-infections are common throughout life. A solution in the form of a vaccine therefore meets a great unmet medical need.

Although the development of an RSV vaccine is very complex, our live attenuated vaccine provides an important first step in the clinical development of an ultimately effective vaccine. We look forward to working with targeted industry partners for the further joint development of this promising vaccine."

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About RSV

Human respiratory syncytial virus (RSV) is a major cause of lower respiratory tract infections, especially in early childhood and in the elderly. In general, it causes mild complaints. Infants and the elderly, however, can become seriously ill. RSV-related acute lower respiratory tract infection accounts for approximately 3.2 million hospital admissions per year worldwide and is a leading cause of death in an estimated 120,000 children under the age of five, especially in developing countries. In the Netherlands, approximately 1 in 100 sick babies require hospitalization.

Despite the clearly unmet medical need for a safe vaccine and the continued development of vaccines since the 1960s, there is currently still no effective approved treatment for persistent RSV infections. Passive immunization with humanized F-specific monoclonal antibodies (palivizumab) is limited to high-risk infants and its use is mainly reserved for high-income countries due to its high cost.

About Intravacc

Based on the Utrecht Science Park, location Bilthoven, The Netherlands, Intravacc is a global leader in translational research and development of viral and bacterial vaccines. As an established independent R&D organization with decades of experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology around the world, including oral polio vaccines, measles vaccines and DPT, Hib and influenza vaccines. Intravacc offers a wide range of expertise for the independent development of vaccines from lead concept to clinical phase I/II studies for partners around the world, such as academia, public health organizations (WHO, BMGF) and biotech and pharmaceutical companies. Intravacc has three proprietary vaccine delivery platforms as well as state-of-the-art research and production facilities (GMP). The company aims to significantly reduce the development risks and costs of new vaccines to contribute to global health and equal access to vaccines. For more information, visit www.intravacc.nl.

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