Intravacc. Innovating vaccines

Press Release

Intravacc and Leiden University developed an animal replacement method for vaccines

- Need for alternatives to animal testing in quality control of vaccines
- Inactivation of vaccines can be traced without using laboratory animals
- Findings published in medical journal *Scientific Reports*

Bilthoven, The Netherlands, 23 July, 2020 – Dutch, Bilthoven based, Intravacc, a global leader in translational research and development of viral and bacterial vaccines, today announced the publication of a study in *Scientific Reports* on alternatives to the use of laboratory animals in vaccine quality control. The study was conducted together with Leiden Academic Center for Drug Research (LACDR) at Leiden University.

A great number of laboratory animals are still being used all over the world for the quality control of vaccines. This also applies for tetanus and diphtheria vaccines, both consisting of bacterial toxins inactivated by formaldehyde. This inactivation largely determines the quality of these vaccines. Researchers from Intravacc and LACDR have been searching for a test that reduces the use of laboratory animals.

To this end, a small but important step in the way vaccines work was reproduced in a test tube. Inactivated model vaccines were treated with an enzyme that plays an important role in the first steps of the immune response. The enzyme, cathepsin S (CS), breaks down vaccines and pathogens into fragments that are recognised by immune cells. The inactivation step with formaldehyde affects the rate of breakdown by CS. It was assumed that the breakdown of inactivated vaccines would be slowed down by CS, but the opposite was the case.

It became apparent that it is possible to accurately and sensitively measure vaccine inactivation by quantifying the formation of vaccine fragments during breakdown by CS. This is remarkable as formaldehyde chemically alters vaccines in dozens of places, resulting in a heterogeneous protein mixture that is difficult to analyse.

This means that it may be possible to replace animal testing in the future for vaccines using this inactivation, such as diphtheria and tetanus toxoids. As these vaccines are effective and inexpensive, they will not be easily replaced by ‘modern’ products.

Dr. Jan Groen, CEO of Intravacc, says:

> *"As a result of the Covid-19 pandemic, some 400 therapies and vaccines against this virus are currently being developed worldwide. This affects the number of laboratory animals used in studies. Intravacc considers limiting the need for animal testing to be particularly important and plays an important role in the development of alternatives for this vaccine-related research. This study shows the progress we are making on this front."*

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About animal testing alternatives

In routine vaccine production, animal testing is still regularly used to ensure the safety and efficacy of vaccines. Animal testing is inaccurate, expensive and raises ethical concerns. In 1959, Russell and Burch published their Principles of Humane Experimental Technique, which laid the foundation for the Reduction, Refinement and Replacement of animal experiments (the 3R Principle). This has led to more thoughtful and responsible use of laboratory animals worldwide for the release of medicines and vaccines. Non-animal methods have been accepted by regulators and intensive development, validation and harmonisation of 3R methods is still ongoing. The Dutch Ministry of Agriculture, Nature and Food Quality fosters 3R research in the Netherlands.

About Intravacc

Intravacc, based in Bilthoven, the Netherlands, a global leader in translational research and the development of viral and bacterial vaccines. As an established independent R&D organization with many years of 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 (GMP) production 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
To learn more, visit **www.intravacc.nl**

About the Leiden Academic Center for Drug Research

Developing new drugs is a complex process in which many parties work together. The researchers at the Leiden Academic Centre for Drug Research (LACDR) are committed to develop new and optimized drugs that are more effective and easier to manufacture. Their work covers the entire development and production of a drug, from molecule to pharmacy. The institute combines knowledge from various disciplines: chemistry, biology, computer science, physics and mathematics. To get the right result the eventual drug, the researchers from Leiden share their fundamental knowledge with partners such as the Leiden University Medical Centre, companies at the Leiden Bio- Science Park, and numerous other Dutch and international institutes and companies.

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