



Clinical phase about to begin

SARS-CoV-2: IDT Biologika fills vaccine candidate

Dessau-Roßlau, 28 July 2020

In the early morning of 24 July IDT Biologika filled the second clinical batch of the newly-developed vaccine candidate against the coronavirus SARS-CoV-2 in Dessau. Now around 1,000 individual vaccine doses with the highest intended dosage level are to be inspected, tested in quality control, labelled and packed before being sent to Hamburg. There the study of clinical phase 1 begins at Universitätsklinikum Eppendorf (UKE), with the presentation of all official approvals and the agreement of the ethics commission. In a total of three phases the safety, dosing, effectiveness and tolerability will be examined over the course of the coming months.

“We are delighted that we have succeeded in developing a vaccine in such a short time, which is now ready for the clinical test phases,” says CEO Dr. Jürgen Betzing. “Our employees have put in an enormous amount of effort over the past few months to get the development of the vaccine and filling up and running. The path that we are now taking will also aid us in future battles against pandemics. Experience shows that in drastic situations we are capable of responding swiftly in joint interaction with partners and a global network,” emphasizes Dr. Betzing.

In the past months scientists at the German Center for Infection Research (DZIF) and partners IDT Biologika, LMU Munich, Marburg University and the UKE Hamburg have been working flat out to research a new vaccine against SARS-CoV-2. Intensive collaboration and an international network of experts together with the expertise of all partners and experience gained in previous joint projects enabled development to occur in record time and in strict observance of the German health protection requirements of the potential recipients. The aim of the alliance is to make safety and probability of effectiveness the utmost priority. Virologist and Chief Science

Officer Dr. Andreas Neubert expects different vaccines to be required for different target groups. The vaccine candidate currently entering the clinical phase is a so-called vector vaccine. For this, genetically-altered and harmless viruses are equipped with genetic information from the coronavirus as carriers. The viruses are not capable of reproducing, but the gene information smuggled in tricks the immune system into identifying an infection and triggering the production of antibodies and a cellular immunity.

The vector vaccine filled at IDT was developed under the leadership of Prof. Gerd Sutter, virologist at LMU Munich, at the DZIF and is based on the "Modified Vaccinia Ankara Virus" (MVA), which was developed as a vaccine against smallpox over 30 years ago. It has also been used successfully and with very good tolerability in the development of a vaccine against the MERS coronavirus, which occurs on the Arabian peninsula, is transmitted from dromedaries to humans with often fatal consequences and is closely related to SARS-CoV-2.

As with the manufacturing process for the MERS vaccine, which was developed by IDT Biologika, the expertise of the family-run company in Dessau was called for to advance the vaccine candidate from work under laboratory conditions to the prospective production of millions of vaccine doses. Based on nearly 100 years of experience in the development and approval of viral and bacterial vaccines, IDT Biologika developed a cell line and a procedure that enabled the large-scale production of an ultrapure MVA vector vaccine, clearing one of the greatest obstacles in vaccine development. Parallel to this, LMU Munich solved the challenge of producing stable MVA vectors. As all previous experience pointed to extremely good tolerability between the IDT cell technology and the MVA vector of the LMU, the most important prerequisites for a safe and effective vaccine have been met.

Prior to the approval process, the clinical study now aims to demonstrate how effective it actually is, how many vaccinations are required, whether and for how long immunity is triggered and what side-effects may occur. "We have filled the vaccine candidates in low and high concentrations of the active ingredients, so that we can determine the right dosage for the future vaccine," Dr. Neubert explains. In phase I the vaccine will be tested at UKE Hamburg in a first stage on healthy volunteers aged between 18 and 45, who were selected from thousands of applicants. Whilst the safety of the vaccine is the primary focus of the study, the

second phase investigates the dosage, tolerability and effectiveness of the preparation with hundreds of volunteers.

In the coming months IDT Biologika aims to continue working with its partners to swiftly bring the vaccine candidate against SARS-CoV-2 into the next clinical phases.



During production, the vaccine filling process can only be viewed from behind the glass pane. Employees Bjoern Dalichau and Andreas Mueller prepare the line for the filling of the SARS-CoV-2 vaccine candidate.



An individual dose of the filled SARS-CoV-2 vaccine candidate. Now the injection bottle is given a visual inspection, labelled and packed before leaving the site.

About IDT Biologika

IDT Biologika – an innovative biotech company with a successful history dating back nearly 100 years. On the basis of modern technologies and high levels of expertise we support customers in the development and manufacture of innovative virus vaccines, gene and immune therapy products as well as biologics employed worldwide as protection against diseases.

German sites are the BioPharmaPark in Dessau-Roßlau and Magdeburg. In the US the IDT Corporation has a manufacturing site for clinical test samples in Rockville, Maryland.

IDT Biologika is a company of the Klocke Group. This specializes in the contract manufacture and packaging of pharmaceuticals, vaccines and cosmetic products. As a traditional, family-run company, the Klocke Group employs over 2,000 people at six production sites worldwide.

Further information can be found on the website of IDT Biologika at www.idt-biologika.com.

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