Intravacc Receives US NIH/NIAID Contract to Develop Enterovirus D68 Vaccine

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Growing concerns about global spread of this respiratory enterovirus
Vaccine to protect children from Acute Flaccid Myelitis
Development of inactivated EV D68 vaccine, through to Phase I clinical testing

Bilthoven, The Netherlands, 8 September, 2020 – Intravacc, a global leader in translational research and development of viral and bacterial vaccines, today announced that it has been awarded a contract with base and options that may total US$9.4 million from the US National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), for the development of a prophylactic vaccine against enterovirus D68 (EV D68). EV D68 is a respiratory virus that can cause childhood paralysis, Acute Flaccid Myelitis (AFM). Intravacc will develop an inactivated EV D68 vaccine, based on Intravacc's proprietary Vero cell technology, from early product selection through to Phase I clinical testing.

During the past decade, EV D68 infections have notably increased in North America, Europe and Asia. In 2014, the United States experienced a large outbreak of severe respiratory disease caused by EV D68, which is increasingly being recognized as a significant respiratory pathogen in children. No effective vaccines or antiviral drugs are currently available, and it is anticipated that the virus may cause larger outbreaks in the future. In this contract, an inactivated EV D68 vaccine will be developed up to first-in-human testing, including virus rescue, assay and process development, preclinical and toxicology studies and production of clinical trial material. The EV D68 vaccine to be developed under the contract will be the first AFM vaccine to go through to clinical development.

The project has been funded in whole or in part with US Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N93020C00037.

Dr. Jan Groen, Intravacc's Chief Executive Officer, comments:

"We are gratified to enter into this co-development contract with the NIH/NIAID for an inactivated EV D68 vaccine to protect children from AFM in foreseen EV D68 outbreaks. Intravacc has a strong track record and expertise in the development of enteroviral vaccines for e.g. polio and Hand, Foot, Mouth disease on our unique Vero cell platform. For Intravacc this contract means a major recognition to be able to extend our portfolio with such a novel groundbreaking vaccine."

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About Vero cell platform technology

For the development of vaccines against viral pathogens, Intravacc has designed and developed the Vero cell production platform. This platform features several distinctive advantages, including i) availability of GMP-grade Vero cell banks at Intravacc, ii) a longstanding safety record for the VERO cell platform used to manufacture human vaccines, and iii) completely animal component free production processes that are used for development of vaccines. Intravacc has a great track record and extensive knowledge available on Vero cells to attain high production yields for multiple vaccines.

Currently, the established and proven Vero cell platform technology has been successfully applied for all three generations of currently available inactivated poliovirus vaccines (IPV) approaches; based either on the conventional wild type strains (cIPV), the attenuated Sabin strains (sIPV), or on the further attenuated genetically engineered poliovirus strains (iIPV).

The sIPV vaccine technology developed at Intravacc was tested for the World Health Organization in Phase 1 clinical trials. Hereafter the technology for sIPV production was transferred to several partners of which three are expected to enter the market this year. For the Bill & Melinda Gates Foundation Intravacc has recently produced the nOPV2 Master and Working Seed lots, and this vaccine is now being tested in Phase II clinical trials.

In addition to polio vaccines, the Vero cell platform is also used for development of a live attenuated RSV vaccine and several multivalent enteroviral vaccines that are currently in development.

About Intravacc

The Netherlands-based Intravacc is one of the world's leading institutes for translational vaccinology. As an established independent CDMO 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 polio vaccines, measles vaccines, DPT vaccines, Hib vaccines, 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. To learn more, visit https://www.intravacc.nl/

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