

Intravacc's inactivated polio vaccine, out licensed to Sinovac, receives market authorization in China

- Sabin-IPV polio vaccine developed by Intravacc contributes to the eradication of polio
- Sinovac's vaccine (sIPV) receives market authorization from the NMPA in China
- Intravacc's cell technology also used for the development of Sinovac's Covid-19 vaccine that was introduced on the market recently and is currently under rolling review by EMA

Bilthoven, the Netherlands, 20 July 2021 – [Intravacc](#), a world leader in translational research and development of vaccines for infectious diseases and therapeutics, today announced that the Chinese National Medical Products Administration (NMPA) formally known as the Chinese FDA, granted Sinovac Biotech LTD market authorization for its Sabin-IPV (sIPV) inactivated polio vaccine, developed by Intravacc and out-licensed to Sinovac. This multivalent polio vaccine was developed by Intravacc for the purpose of providing low and middle-income countries with the opportunity to produce their own safe polio vaccine in the context of the global polio eradication initiative.

The approval of Sinovac's polio vaccine (sIPV) by the NMPA in China is a major milestone in the ongoing efforts towards global polio eradication and to reduce the vaccine-associated paralytic polio (VAPP) caused by oral polio vaccines (OPV), which are based on live attenuated polio viruses. It will also help to close the gap between demand and supply of safe and effective Inactivated Polio Vaccines (IPV) for millions of infants in need of immunization against poliovirus. As a result of the current SarsCov-2 pandemic, the vaccination campaigns to eradicate polio were either put on hold or delayed worldwide. The pandemic may also further delay polio eradication due to indirect effects on vaccine supplies and financial resources.

Three virulent polio strains

Sinovac's polio vaccine contains all three Sabin virulent polio strains. One of the main advantages of using attenuated Sabin poliovirus strains in the production of IPV is that it results in a lower biosafety risk compared to wild-type polioviruses used to manufacture conventional IPV. These IPV vaccines pose a potential biosafety hazard in case they escape from the manufacturing facility.

First vaccines expected in 2021

Sinovac expects to deliver the first polio vaccines for the immunization of infants in 2021. Sinovac is the second manufacturer, following [Korean LG Chem](#), to bring Intravacc's sIPV vaccine to the market. Intravacc will receive milestones and low single digit royalties for its considerable role in the development of this vaccine.

Sinovac's Covid-19 vaccine also based on Intravacc's technology

The vaccine technology developed by Intravacc and transferred to Sinovac was also used for the development of "CoronaVac" Sinovac's inactivated Covid-19 vaccine validated by the WHO for emergency use and over 430 million doses have already been administered globally. In May 2021 the EMA started with the rolling review of Sinovac's Covid-19 vaccine. A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicine during a public health emergency. In that case EMA's human medicines committee (CHMP) reviews data as they become available from ongoing studies.



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

"This is a great example project in which Intravacc's innovation and knowledge have been the foundation of the development of an affordable vaccine that contributes to the reduction of infectious disease burden on a global level. We have recently launched a similar program for our Avacc 10 Covid-19 nasal spray vaccine, intending to make this vaccine available to the world."

Poliomyelitis

Poliomyelitis is an infectious disease caused by the poliovirus. It is transmitted through the oral fecal route. There are 3 serotypes of the virus that cause poliomyelitis in humans. While most infections are asymptomatic, in a few cases the virus moves from the gut to the central nervous system and causes flaccid paralysis. Currently there is no treatment for polio; however, vaccination has proved to be successful. Since the start of poliovirus vaccination in the 1950s, cases world-wide have dropped tremendously and currently there are only a few hundred cases per year. Most of these cases are vaccine-derived after vaccination with oral poliovirus vaccines, where the attenuated poliovirus becomes virulent again due to mutations in the virus. This happens in under-vaccinated areas and takes a long time to develop. Due to the Covid-19 pandemic, vaccination against polio lagged behind in many areas. As a result, there is an increased risk of polio outbreaks in these areas. The use of the inactivated vaccine developed by Intravacc alleviates this problem.

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About Intravacc's Vero cell platform

Intravacc's viral vaccine production process is based on a cGMP-grade, regulatory approved, Vero cell line. This proprietary platform is being used for routine large-scale commercial vaccine manufacturing by Intravacc's customers world-wide. In addition, virus seed lots and clinical batches have regularly been produced and validated on the Vero cells, for example Poliovirus, Enterovirus (EV71), and Respiratory Syncytial Virus (RSV).

About Intravacc

Intravacc, located at Utrecht Science Park Bilthoven in the Netherlands, is a leading global contract development and manufacturing organization of innovative vaccines against infectious diseases. As an established independent CDMO with over 100 years of experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology related to polio vaccines, measles vaccines, DPT vaccines, Hib vaccines and influenza vaccines around the world. Around 40% of childhood disease vaccines are based on Intravacc's proprietary technology. Intravacc offers a wide range of expertise for independent vaccine development, from concept to Phase I/II clinical studies for partners around the world, including universities, public health organizations (WHO, Bill & Melinda Gates Foundation), biotech and pharmaceutical companies. For more information, please visit www.intravacc.nl.

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