Intravacc. Innovating vaccines

# Press Release

## Intravacc announces the publication of a GMP process for a semi-synthetic *Shigella* glycoconjugate vaccine candidate from the Institut Pasteur

- Data published in the prestigious journal *ACS Central Science* of the American Chemical Society
- Preclinical and clinical batches complying with ICH guidelines and WHO recommendations
- Phase I clinical study showed vaccine was safe and well tolerated
- Phase II clinical studies ongoing in endemic countries

**Bilthoven, the Netherlands, and Paris, France, 22 March 2022** – **Intravacc,** a world leader in translational research and development of preventive and therapeutic vaccines, today announced the publication of a GMP (Good Manufacturing Practices) manufacturing and formulation process for a monovalent semi-synthetic conjugate vaccine candidate against *Shigella flexneri* 2a (SF2a). This candidate vaccine was developed at the Institut Pasteur (Paris, France) and the GMP process is described in the peer reviewed scientific journal *ACS Central Science* of the American Chemical Society, in a paper entitled "The first-in-human synthetic glycan-based conjugate vaccine candidate against Shigella".

SF2a is a species of enteric bacteria that causes disease in humans. The disease caused by the ingestion of the *Shigella* bacteria is referred to as shigellosis, which is associated with diarrhea.
This publication discloses the yet unreported feasibility of the GMP synthesis of conjugate vaccines featuring a unique homogenous synthetic glycan hapten fine-tuned to protect against an infectious disease. The scale-up feasibility of the bioconjugation step under GMP conditions resulted in a high yielding process, and a reproducible and controllable SF2a vaccine production process. Preclinical and clinical batches for polysaccharide conjugate vaccines and (non-)compendial tests, complying with ICH guidelines and WHO recommendations, were produced. The obtained synthetic glycan-based conjugate vaccine passed all toxicity-related criteria, was immunogenic in rabbits and elicited bactericidal antibodies against SF2a in mice. The induced IgG serum antibodies recognized a large panel of SF2a circulating strains.

The results of the first-in-human trial for the SF2a semi-synthetic glycan-based conjugate vaccine candidate developed at the Institut Pasteur demonstrated safety and immunogenicity. Achievements of the development of this candidate SF2a vaccine are part of Stopenterics, a European consortium which has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013).

An age descending phase IIa trial to investigate the safety and immunogenicity of this SF2a vaccine candidate in the infant target population in endemic countries was initiated in 2020 (clinicaltrials.gov NCT04602975). The estimated completion date is expected in Q3 2023.

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

> *"This is Intravacc's second successful development of a GMP manufacturing process for a conjugate vaccine based on Tetanus. Our first conjugate vaccine for Haemophilus influenza type b (Hib) was transferred to international partners worldwide and has been on the market for several years now."*

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## About *Shigella*

*Shigella* is a species of enteric bacteria that causes disease in humans and other primates. The disease caused by the ingestion of *Shigella* bacteria is referred to as shigellosis, which is associated with diarrhea. About 250 million cases of shigellosis occur annually in low and middle-income countries, causing over 212,000 deaths.
No group of individuals is immune to shigellosis, but certain individuals are at increased risk. Children acquire *Shigella* at the highest rate. *Shigella* is easily spread because of its low infectious dose. Spreading occurs via the oral-fecal route both by person-to-person contact and through eating contaminated food.

## About Intravacc

Intravacc, located at Utrecht Science Park Bilthoven in the Netherlands, is a leading global contract development and manufacturing organization for infectious diseases and therapeutic vaccines. As an established independent CDMO with many years of experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology world-wide for many vaccines including polio-, measles-, DPT-, Hib- and influenza. Around 40% of childhood disease vaccines are based on Intravacc's know-how and 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.

## Contacts:


### Intravacc

Dr. Jan Groen, CEO
P: +31 30 7920 454

Mirjam Hartman, Media relations
P: +31 6 115 969 94
E: press.office@intravacc.nl

### LifeSpring Life Sciences Communication

Leon Melens
P: +31 6 538 16427
E: lmelens@lifespring.nl