

BMI Vaccine Breakthrough Promises Polio-Free World

4th February 2020: Biological Mimetics, Inc., a vaccine design company based in Frederick, MD, has announced their development of a next-generation polio vaccine that is safer, more potent, and less expensive to manufacture than current polio vaccines in an effort to boost eradication.

The polio vaccine has been one of the major medical success stories as the incidence of poliomyelitis has been eliminated in almost all countries and global eradication appears close at hand. Polio serotypes 2 and 3 have been successfully eradicated and efforts to eliminate Polio 1 are continuing. Once eradicated, the current vaccines will need modernization to maintain a polio-free world. The Oral Poliovirus Vaccine (OPV) is an inexpensive and effective vaccine and has been the workhorse of eradication efforts. However, the attenuated strains of OPV can revert to pathogenic forms and this vaccine has been phased out in most countries in favor of the Inactivated Poliovirus Vaccine (IPV) which is a killed-virus, injectable vaccine. As eradication progresses, the biosafety and biosecurity concerns associated with current manufacturing of IPV from pathogenic strains will become increasingly serious.

In a call to action, the WHO urged the community to develop and deploy safer polio vaccines, ideally based on inactivated non-pathogenic viruses, which are safer to manufacture, stimulate robust immunity, and are more affordable. Thus, there is a distinct need for an updated vaccine which will maintain immunity for the coming decades.

BMI's new poliovirus vaccine, *ultraIPV*, promises to be a key advance that secures and sustains a polio-free world. The vaccine is based on a novel, non-chemical method of inactivating attenuated Sabin strains. This proprietary inactivation process utilizes a powerful antioxidant complex that reduces damage to immunity-enhancing vaccine components which can be destroyed by chemical inactivation methods. The process enables the use of attenuated strains and avoids safety concerns surrounding the current production of inactivated polio vaccine (IPV) from dangerous pathogenic strains.

Preclinical testing suggests that the *ultraIPV* delivers higher immunogenicity per milligram of virus compared to IPV which will allow the production of more doses per unit of purified viruses. A reduction in the amount of input virus will lead to reduced manufacturing costs which will be a key driver in the acceptance of the new vaccine. Critically, *ultraIPV* production is compatible with attenuated strains of virus which will simplify the manufacturing process and reduce biosafety concerns.

The global market for polio vaccines is anticipated to record robust CAGR in the coming years. The worldwide market is expected to grow at a CAGR of roughly 5.0% over the next five years, reaching 1,630 million US\$ in 2024, from 1,210 million US\$ in 2019 (www.marketwatch.com) And, with the continued phase-out of OPV in developing countries, the global use of IPV is expected to increase.

President of BMI, Dr. Gregory Tobin, stated, "We are very encouraged about our advances in vaccine development and production leading to our *ultraIPV* vaccine and aim to reach out to industry leaders in this space to explore partnership opportunities in the coming months. In addition, this proprietary

radiation-inactivated vaccine approach has been applied successfully to against alpha viruses like chikungunya and VEEV and deadly antibiotic-resistant bacteria.”

Dr. Tobin concluded, “This is an unprecedented opportunity for BMI and it’s business partners, as our *ultraIPV*, once successfully implemented, will tick all of WHO’s boxes to enable the maintenance of global polio eradication. We are actively seeking business partners for manufacturing and commercialization of the *ultraIPV*.”

The early work leading to *ultraIPV*, which utilizes an earlier version of the proprietary technology, was developed in collaboration with Dr. Michael Daly at the Uniformed Services University Health Sciences and has been recently published in PLOS ONE and is available to read at the following link: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0228006>. The team included Drs. Chumakov and Kouiyavskaya at the Food and Drug Administration (FDA), and Dr. Meeks at DTRA. R&D relating to this innovation was supported by a Defense Threat Reduction Agency (DTRA) contract and an National Institutes of Health (NIH) grant to BMI.

“Today, pathogenic viruses evolved from OPV cause more polio cases than natural “wild” viruses. The spread of vaccine-derived viruses endangers the progress of global eradication. An inexpensive and reliable inactivated Sabin vaccine could help solve this problem,” Daly said.

About Biologic Mimetics, Inc.

Biologic Mimetics, Inc. is a privately held biotechnology company located in Frederick, MD. In addition to its work with radiation-inactivated vaccines, the Company is the inventor and leading practitioner of the Immune Refocusing Technology, a rational antigen design platform. For more information, visit www.biologalmimetics.com

Those interested in learning more or partnering for commercialization of *ultraIPV* are encouraged to contact Dr. Tobin at polio@bmi-md.com and visit the company’s website www.bmi-vaccine.com.