

HIV/AIDS vaccine developed at Western proceeding to human clinical trials

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The first and only preventative HIV vaccine based on a genetically modified killed whole virus has received approval by the United States Food and Drug Administration (FDA) to start human clinical trials.

Developed by Dr. Chil-Yong Kang and his team at The University of Western Ontario, with the support of Sumagen Canada, the vaccine (SAV001) holds tremendous promise, having already proven to stimulate strong immune responses in preliminary toxicology tests with no [adverse effects](#) or safety risks. It is the only [HIV vaccine](#) currently under development in Canada, and one of only a few in the world.

"[FDA approval](#) for human clinical trials is an extremely significant [milestone](#) for our vaccine, which has the potential to save the lives of millions of people around the world by preventing [HIV infection](#)," says Kang, a researcher and professor at Western's Schulich School of Medicine & Dentistry.

Western President Amit Chakma says, "This joint venture between Sumagen and Western is a prime example of what collaboration between private industry and university researchers can achieve. Dr. Kang and his team are to be commended for their exceptional talent and remarkable persistence in developing a vaccine that addresses a tragic health crisis affecting millions of people around the globe."

Dr. Dong Joon Kim, a representative of Sumagen Co. Ltd. says, "Our company has committed substantial resources to this project since 2005

and we are very pleased to reach this milestone. It is our desire to continue growing our business in Canada and being a part of the business community in London."

HIV/AIDS has killed more than 28 million people worldwide, and more than 35 million people currently live with the virus infection. Since the virus was characterized in 1983, there have been numerous trials through pharmaceutical companies and academic institutions around the world to develop vaccines; however, no commercialized vaccine has been developed to date. Other HIV vaccines evaluated through human clinical trials have focused on either one specific component of HIV as an antigen, genetic vaccine using recombinant DNA, or recombinant viruses carrying the HIV genes. Kang's vaccine is unique in that it uses a killed whole HIV-1, much like the killed whole virus vaccines for polio, influenza, rabies and hepatitis A. The HIV-1 is genetically engineered so it is non-pathogenic and can be produced in large quantities.

Before it can be commercialized, the SAV001 vaccine must go through three phases of human clinical trials:

- Phase I, set to begin in January 2012, will double check the safety of the vaccine in humans, involving only 40 HIV-positive volunteers.
- Phase II will measure immune responses in humans, involving approximately 600 HIV-negative volunteers who are in the high-risk category for HIV infection.
- Phase III will measure the efficacy of the vaccine, involving approximately 6,000 HIV-negative volunteers who are also in the high-risk category for [HIV](#) infection.

Through WORLDdiscoveries, Western's technology transfer office, Sumagen Canada has secured patents for the SAV001 vaccine in more than 70 countries, including the U.S., the European Union, China, India

and South Korea. The vaccine has been manufactured at a bio-safety level 3 (BSL3) good manufacturing practice (GMP) facility in the U.S.

Provided by University of Western Ontario

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