

## A novel therapy for genital herpes engages immune cells to provide significant patient benefits

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A phase II clinical trial demonstrated that a new type of treatment for genital herpes, an immunotherapy called GEN-003, may reduce the activity of the virus and the number of days with recurrent herpes. This effect of treatment, given by a series of three injections, appears to last for up to at least one year. The research is presented at the ASM Microbe research meeting in Boston.

"GEN-003 is believed to work through a different pathway from most vaccines by recruiting T cells, which are critical to controlling chronic infections such as herpes," said Dr. Fife, MD, PhD, an investigator and Professor of Medicine at Indiana University. In addition, GEN-003 is also designed to stimulate antibodies to help neutralize the virus.

310 participants with a history of chronic, recurrent genital herpes received three shots of one of six different vaccine doses, 21 days apart. Over 1 year, participants were tested for stimulation of the immune system against the <a href="herpes virus">herpes virus</a>, the frequency that the herpes virus was detectable on the skin around the genital area ("viral shedding"), and the number of days that herpes outbreaks ("lesions") were visible. GEN-003 treatment drove significant reductions in the rate of viral shedding and lesion frequency compared to rates before treatment. Immune response data are being analyzed and will be the topic of a future presentation.

"The importance of these clinical findings is that it represents a new



approach to treatment, and may provide a new option for patients suffering from chronic, recurrent genital herpes," said Dr. Fife. Current treatments consist of antiviral medications, which may be taken episodically to treat acute lesion outbreaks, or daily to reduce the number of outbreaks and the risk of transmitting the herpes simplex 2 (HSV-2) virus to sexual contacts.

GEN-003 may provide relief similar to that available with daily antiviral medications, but with improved convenience. "GEN-003 is expected to be tested in combination with antiviral medications to potentially provide a level of relief not currently achievable.

"While several previous preventative vaccines have failed in the past, the new approach taken with GEN-003, arming the T cell immune system, may one day lead to an effective prophylactic <a href="herpes">herpes</a> vaccine," said Dr. Fife.

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