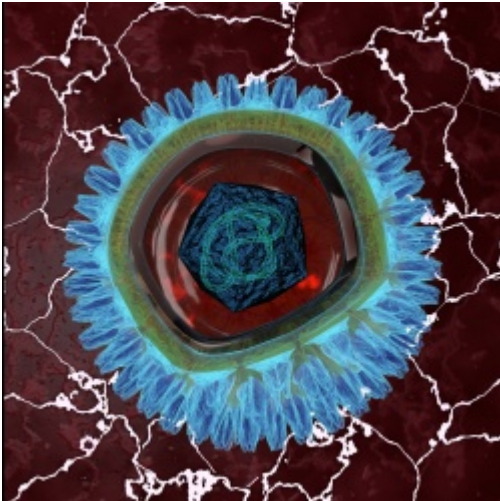


Herpes Vaccine GEN-003: Back in the News, But the News Isn't Great



By Josh Bloom — March 30, 2017



A herpesvirus. Image: Shutterstock

A paper in the *Journal of Infectious Disease* provides clinical data for Genocea's genital herpes vaccine GEN-003. The good news is that infected patients did respond to the vaccine. The not-so-good news is that the response was not as impressive as patients would hope. Here is a summary:

In Phase Ia/II trials **(1)**, a total of 134 participants who were infected with HSV-2 were given a total of three injections of 003 three weeks apart. Three different doses of the vaccine were given, and the enrollees received genital swabs for four weeks before administration of the vaccine, and four more weeks after they got the last injection.

Summary of the results:

- The vaccine was safe
- The rate of viral shedding **(2)** for participants who received the 30 µg dose was reduced from 13.4% to 6.4%
- The rate of viral shedding for participants who received the 100 µg dose was reduced from 15.0% to 10.3%
- Biochemical markers of response, T-cells and viral antibodies, increased after dosing, indicating that 003 did stimulate the immune system
- The rate of lesions in participants who got either the 30 µg or 100 µg dose was cut in half.

Comments:

- A >50 percent reduction in shedding is significant but is unlikely to prevent transmission of the virus during times of asymptomatic shedding. People will still be infectious half as often

as they would be without the vaccine.

- The 33 percent reduction in shedding at the higher dose (100 µg) is less than the 50 percent reduction at the lower dose. This is puzzling.
- There is no apparent advantage of GEN-003 over valacyclovir (Valtrex)—the standard of care for treating and preventing outbreaks.

Impressions: From these data, GEN-003 would seem to have an uphill battle. Based on my experience, It is unlikely that the company (and future investors) will be satisfied with a vaccine that works about as well as Valtrex. Given the moderate degree of efficacy seen in infected patients, 003 seems unlikely to work well prophylactically.

There are other herpes vaccines in the works but this is the most advanced, having done clinical trials. [You can read about other herpes vaccines here](#) [1].

Notes:

(1) Phase I trials are usually conducted in a small group of volunteers to determine safety. Sometimes Phase I trials are subdivided - Phase 1a for safety, and Phase 1b for efficacy. In Phase II trials, the drug is given to a larger group of people to see if it is effective and to further evaluate its safety.

(2) Herpes is insidious. People can be infectious even when they are asymptomatic. This means that the virus emerged from the nerve root, but does not lead to an outbreak. Many people are infected with HSV-1 and HSV-2 without even knowing it until they take a blood test.

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[1] http://acsh.org/search?search_api_views_fulltext=herpes+vaccine