Herpes Vaccine Update: Gen-003 Phase II Results

By Josh Bloom — November 7, 2016

In March, I reported on stage II results of the first ever herpes vaccine [1] and its effectiveness in people who were infected with herpes. Data from trials of Genocea Biosciences' GEN-003 showed a modest, but real, effect in reducing symptoms and shedding (1) in people who were infected with HSV-2 (genital herpes).

Last month, I reported on Rational Vaccines' Theravax [2], which claimed to have significant advantages over 003; although, it is important to keep in mind that their conclusion was based on a tiny pilot study, not a clinical trial, and they have refused to show any results. It was also done in a foreign country to avoid FDA oversight. An interview with Rational's CSO Dr. William Halford can be read here [3].


We can't fairly compare the two vaccines, since GEN-003 is conducting real trials and Theravax has yet to show any data for animal models or even its St. Kitts pilot study, but the table below summarizes data from GEN-003 (at 6 and 12 months) and claims from Theravax (September 2016).
Impressions:

Genocea is following legitimate clinical protocols to seek approval for 003 in the US, and its vaccine has been evaluated in more than 300 people. The vaccine, which is given once, is effective in reducing both the number of outbreaks and viral shedding but appears to offer no advantage over Valtrex (2), which is the current standard of care.

It does not protect against HSV-1, which - although often presumed to only cause "oral herpes" - can also cause genital herpes. In fact, in young women in the US, HSV-1 is responsible for more cases of genital herpes [8] than HSV-2. The historical lack of success of synthetic vaccines is troubling.

Rational Vaccines may sound more promising, but there is also no data for Theravax, which requires three injections. We know what GEN-003 does because they are playing by U.S. rules. Rational has intentionally bypassed the FDA and did a pilot test in a country with basically non-existent clinical trial standards - but is then making claims about success in the U.S.

At this time, the lack of data require that any conclusions that are drawn must be done so with caution. But, the historical success of live attenuated vaccines is is probably the most important factor here.

**Recommendation for investors:**

Call me. Ask what I would do. Then, do the exact opposite, and watch the dough roll in. This method is more reliable than gravity.

Notes:

(1) Shedding is the time when virus is actively being produced, but no symptoms are present.
People who are shedding are contagious.

(2) Valtrex is a pro-drug of acyclovir—the actual antiviral drug. For an explanation of how acyclovir works, see "How Do Herpes Drugs Work?" To learn how pro-drugs work, and why they are usually superior, see ADHD Sufferers—Pay Attention: Here’s How Vyvanse Works.

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