

Bombs Away: Genocea's Herpes Vaccine Goes Down In Flames



By Josh Bloom — September 25, 2017



RIP Genocea's Herpes Simplex Vaccine

For those of you who may have been counting on Genocea's GEN-003 to treat or even cure your genital herpes, this is a very bad day. The company just announced that it was discontinuing the development of 003 as a potential vaccine for herpes simplex virus (HSV) and was "exploring strategic alternatives." **(1)**

In a press release, company spokesperson Jennifer LaVin wrote, *"To our teammates who've given so much to advance GEN-003, we offer our profound thanks for their dedication. Due to their efforts, GEN-003 has the potential to serve as a cornerstone treatment for genital herpes infections. We see this strategic process, which is already underway, as the best way to drive to commercial launch of and maximize shareholder value from GEN-003."*

A valid question is how? The company is ceasing all spending on GEN-003 and cutting its workforce by 40 percent, so it is very difficult to see how Genocea will find any scientific or commercial value for it.

Instead, the company will now change its focus to developing cancer immunotherapies and has another vaccine called GEN-009, which targets the T cell antigens on cancer cells. Genocea will file an IND **(2)** in 2018.

Chip Clark, president and chief executive officer **(3)** of Genocea, speaking about the company's new technology platform said, *"With our research and development efforts now focused entirely on neoantigen cancer vaccines, we believe the power of ATLAS to identify the right vaccine antigens, combined with our vaccinology expertise, gives us the opportunity to create value for our shareholders by developing best-in-class vaccines for cancer patients and achieving leadership in this exciting field."*

It's a sad day for patients but reaffirms one of the worst pitfalls of drug discovery and development, and the main reason why successful drugs end up being so expensive. Science is hard. Genocea reported modest but positive results in Phase II trials, which I wrote about this past March. (See: [Herpes Vaccine GEN-003: Back In The News, But The News Isn't Great](#) ^[1]), but it wasn't enough. It is not uncommon for a drug to look hopeful in Phase II trials but then to fail in more rigorous Phase III trials. And the later the candidate fails, the greater the cost. A failed Phase III trial is far worse. Much more money will have been spent. So the company decided it would be unwise to pursue a vaccine that would be unlikely to gain FDA approval. These kinds of decisions must be made every day in the world of drug discovery.

Drug and vaccine discovery is difficult and herpes has been especially challenging. This failure is disheartening for HSV sufferers, but don't give up. There are other candidates under development and, given the huge number of people who are infected with the virus, more will follow. Sometimes failures are important also. They may show what doesn't work and guide scientists down more productive paths. This is how drug research works: slow, one uncertainty after another, many failures, and occasionally a success. In the end, no one did anything wrong. It's just a really tough business. Always has been.

Notes:

(1) In the world of drug development, the term "exploring strategic alternatives" is almost always a euphemism for "we are hoping that someone will buy it, but don't count on it."

(2) An Investigational New Drug application (IND) contains safety and efficacy data in animals and must be approved by the FDA before any human testing can begin. Even if the IND is approved by the FDA, [only 10%](#) ^[2]of drugs at this early stage will be approved.

(3) For my interview with Chip Clark, see "[Genocea's Herpes Vaccine Update: An Interview With Chip Clark, CEO](#)" ^[3]"

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[1] <https://www.acsh.org/news/2017/03/30/herpes-vaccine-gen-003-back-news-news-isnt-great-11071>

[2] <http://www.sciencedirect.com/science/article/pii/S2452302X1600036X>

[3] <https://www.acsh.org/news/2017/05/26/genocean-herpes-vaccine-update-interview-chip-clark-ceo-11325>