

\$29.3M Gates grant boosts Sanaria

Rockville firm will open new plant to manufacture malaria vaccine

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by Steve Berberich
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Armed with a new \$29.3 million grant, Sanaria Inc. will expand its battle against malaria to a new vaccine plant in Rockville.

With the grant by the Bill and Melinda Gates Foundation announced Thursday, plus a new partnership with the Malaria Vaccine Initiative, Sanaria has reached \$45 million in funding for developing a malaria vaccine.

The money will let Sanaria move out of cramped laboratories that CEO Stephen Hoffman opened with a handful of employees in a warehouse district in east Rockville in 2003. The company, now with 30 employees and contractors, will move into a new, vaccine-making plant along Shady Grove Road in west Rockville in the next few months.

More importantly, Hoffman said, "It feels wonderful to have the money now to take the vaccine through concept to humans."

Sanaria's vaccine is a career-long dream of Hoffman's and is unique, said John G. McNeil, scientific director of the Malaria Vaccine Initiative, a global program to advance and distribute malaria vaccines.

"We are very excited about the approach to this vaccine. We are enthusiastic and eager to transition it to the clinic," McNeil said.

There is no estimate for the global market value of a malaria vaccine because there is not yet a licensed vaccine on the market. But McNeil said the demand would be extraordinary. For example, his group reports that there are probably 350 million to 500 million new malaria infections a year globally.

Sanaria's vaccine is one of 70 experimental malaria vaccines, says the World Health Organization. Sanaria's is the only one composed of whole malaria parasites. Company researchers zap the one-celled parasites with radiation to render them non-infectious.

McNeil said the Gates money will allow Sanaria's partnership with his group to "move quickly to conduct an initial safety and test-of-concept trials using volunteers in the United States."

"What distinguishes our group," Hoffman said, "is that we anticipate that our vaccine will be 90 percent effective in totally preventing malaria. And it would be for African children who really need the vaccine."

He bases his optimism on prior research.

Studies in the 1990s by Hoffman and others showed that volunteers bitten by mosquitoes harboring weakened parasites were protected when they were subsequently bitten by other mosquitoes that carried the unaltered, disease-causing parasite *Plasmodium falciparum*.

Such successful human vaccine immunization testing is considered "the gold standard," Hoffman said. But the approach had not become feasible until Sanaria developed its technology capable of large-scale production of the disarmed, or "attenuated," malaria vaccine made from the irradiated parasites.

Malaria kills more than 2 million people a year, according to WHO. The Malaria Solution Foundation estimates that malaria kills 3,000 children a day.

“The new [Gates] money is going to be very important for Steve,” said Anthony Fauci, director of the National Institute of Allergic and Infectious Diseases in Bethesda.

The institute, part of the National Institutes of Health, has provided Hoffman with a number of grants to help him develop the vaccine, Fauci said.

“As director of this institute, I have always felt that this is quite promising,” he said, calling Hoffman’s preliminary data “very good.” “So I was very pleased to see that the Gates Foundation made that decision to help him get his plant up and growing,” Fauci said.

Hoffman anticipates hiring 10 more employees at the new plant.

Sanaria’s funding has included \$4.1 million from the Department of Defense, \$4.5 million from the infectious disease institute and \$1.1 million from the San Francisco nonprofit Institute for OneWorld Health, affiliated with the Gates Foundation.

After the U.S. Food and Drug Administration approves the vaccine, Sanaria, perhaps with partners, will distribute it where it is most needed, in sub-Saharan Africa, Hoffman said.

“Yes, there are difficulties,” he said, “but that is exactly why we are so gratified to get such a large investment from Gates.”

To finance the global effort, Sanaria will also market the vaccine to travelers and military personnel in the United States and perhaps other developed nations.

“Our mission is to develop a vaccine for infants, to reduce deaths in infants, young children and women,” Hoffman said. But Sanaria will first have to “leverage” the vaccine in developed nation markets, he told The Gazette earlier this year.

The vaccine must “be good enough for the developed world market,” he said, meaning a 90 percent protection rate. Profits in those markets will allow the company to discount the vaccine for needy people in the Third World, he said.

The Gates grant is part of a broader \$83.5 million commitment by the foundation this week that also included funds to other organizations for preventive treatments for infants, diagnostics and advocacy programs.

The foundation coordinated release of the funds with Thursday’s White House Summit on Malaria, bringing together representatives of leading corporations, religious organizations, charities and the federal government. The goal is to cut Africa’s death rate from malaria in half within five years.