

Sanaria to test malaria vaccine

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by Steve Berberich
Staff Writer

While Sanaria Inc. works to keep its focus on developing revenue streams, the estimated 3,000 children who die each day in a global resurgence of malaria add a humanitarian perspective for the Rockville company.

Next week Sanaria, headed by CEO Stephen Hoffman, will begin manufacturing its first run of a unique and promising malaria vaccine. By spring, the company will have several thousand doses of the vaccine ready for testing its toxicity and dosage levels, paving the way for clinical trials to begin next January.

With research grant money now topping \$10 million, Sanaria's concept is clearly on the radar screens of government, military and academic vaccine laboratories, as well as world development foundations.

The company's production and pre-clinical trial phase funding comprises \$4.1 million from the Department of Defense, \$4.5 million from the National Institute of Allergic and Infectious Diseases, and \$1.1 million from the San Francisco nonprofit pharmaceutical company Institute for OneWorld Health, which is affiliated with the Bill and Melinda Gates Foundation.

"Making a malaria vaccine is one of the most important uses of science and technology that we can do today," said Melinda Moree, director of the Malaria Vaccine Initiative at the Program for Appropriate Technology in Health. "I commend Sanaria as a business for trying to get it done and out to the world's most needy." Moree's initiative has received more than \$250 million from the Gates Foundation to support many malaria vaccine projects.

Sanaria's vaccine plan is the "best show in town," wrote the late Maurice Hillman, former director of the Merck Institute for Vaccinology in the journal Nature, adding that "it might even be the only show in town."

Hoffman knows the vaccine must sell well enough in developed markets to finance the company's more humanitarian concerns.

"Our mission is to develop a vaccine for infants, to reduce deaths in infants, young children and women," he said. But Sanaria will first have to "leverage" the vaccine in developed nation markets, he said.

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.

Worldwide, there are as many as 70 scientific efforts aimed at developing a malaria vaccine, according to the World Health Organization. Moree said many use modern molecular biology techniques to develop vaccines from subunits or small pieces of protein from the single-celled parasite, Plasmodium falciparum, that causes human malaria. Other researchers, at the University of Seattle, use recombinant DNA techniques to make mutations in the whole parasite to develop vaccines.

Several years ago, Hoffman decided to try using a disarmed version of the whole parasite in a malaria vaccine. He founded Sanaria in July 2003 with that single goal in mind. The Sanaria vaccine is a suspension of P. falciparum rendered harmless by a quick zap of radiation.

The idea had been tested more than 20 years ago by researchers at the University of Maryland, Baltimore, and the Navy, but later abandoned as impractical and unnecessary in an age of subunit protein vaccine work.

Robert Thompson, who knew Hoffman when both were executives with Celera Genomics Inc. in Rockville, said they discussed future plans shortly after Hoffman left Celera.

“When Steve told me about this, I thought it was so delightfully elegant,” Thompson said. “We could simply expose mosquitoes to radiation and the parasites sporozoite [asexual seed] that are extracted from them can become a vaccine.” Thompson said he joined Hoffman immediately.

Before he was with Celera, Hoffman was director of the malaria vaccine program at the Naval Medical Research Center in Silver Spring. Thompson had been COO at Celera and responsible for putting together an infrastructure of 300 gene-sequencing computers — at the time, the world’s largest data center for genomic information, Hoffman said.

Sometime this summer, Thompson said, Sanaria will move to a larger manufacturing facility in Montgomery County and hire as many as 14 more employees. The eventual markets for the vaccine will be U.S. military personnel assigned to high-risk malaria regions of the world, travelers and general populations in underdeveloped nations in Africa and other malaria zones.

Hoffman said one obstacle to developing a successful vaccine is that the parasite has many life stages and changes forms in its cycle through mosquitoes and humans. In their “Malaria Vaccine Development: Status Report,” researchers Stephanie James and Louis Miller of the National Institute of Allergy and Infectious Diseases’ Laboratory of Parasitic Diseases reported that “clinical studies carried out since the 1970s demonstrated that experimental vaccination with attenuated sporozoites can effectively immunize patients against a subsequent malaria infection.”

Thompson said humanitarian concerns drive the company.

“This kills more children in Africa than AIDS or any other disease,” he said.

Malaria kills more than 2 million people a year, and 450 million are now infected, according to WHO.

The Malaria Solution Foundation estimates that malaria kills 3,000 children a day and that eradicating the disease would drive up the gross domestic product of sub-Saharan Africa by 30 percent.

Malaria has had a resurgence in the past 30 years because the parasite has become drug-resistant, but Thompson said it probably will not mutate enough to render the Sanaria vaccine ineffective.

“It works. We already know that. We only want to make the vaccine to the highest standard,” Thompson said. If the parasite does mutate, Sanaria will have an opportunity to re-culture the more virulent strain for a new version of the vaccine, he said.

Experts say a vaccine, made from recombinant DNA, in phase 2 clinical trials from GlaxoSmithKline is the most advanced toward commercial use, with mixed but generally positive results.

The Glaxo vaccine probably will not be used as a traveler’s vaccine, Moree said. “Eventually, ideally, you’ll have a really efficacious vaccine that will work for travelers and in needy populations,” she said.