

SANARIA[®] PfSPZ VACCINE AGAINST MALARIA RECEIVES FDA FAST TRACK DESIGNATION

(September 22, 2016, Rockville, MD) Sanaria Inc. today announced it has received U.S. Food and Drug Administration (FDA) Fast Track designation for its preventative vaccine for malaria, Sanaria[®] PfSPZ Vaccine. Sanaria believes its PfSPZ Vaccine is the only malaria vaccine to have ever received this distinction.

According to the FDA, “Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.” A drug (*or vaccine*) that receives *Fast Track* designation is eligible for *Accelerated Approval and Priority Review*, which can considerably speed the time to market.

Sanaria[®] PfSPZ Vaccine is in clinical trials in subjects ranging in age from 6-month old infants to adults in the U.S., Europe and Africa. These trials are intended to finalize an immunization regimen to be taken forward into pivotal phase 3 clinical trials that will, if successful, provide the necessary data for licensing the vaccine.

Stephen Hoffman, CEO of Sanaria, said, "U.S. FDA Fast Track designation for our malaria vaccine is a strong indicator that we've gotten beyond the proof of science and are moving toward licensure. We expect PfSPZ Vaccine will be the world's first FDA licensed malaria vaccine, and we will be able to use it to halt transmission and eliminate *Plasmodium falciparum* malaria from geographically defined regions and provide protection against malaria to travelers and military personnel visiting malaria endemic regions."

Sanaria's primary mission is to develop a highly effective vaccine to eliminate malaria from geographically defined areas through mass immunization campaigns, and protect non-immune visitors, including military personnel, going to regions where malaria is transmitted. In phase 1 studies led by the Vaccine Research Center, National Institute of Allergy and Infectious Disease - NIH published in *Science* (2013)¹ and *Nature Medicine* (2016)², Sanaria[®] PfSPZ Vaccine, protected 100% of subjects at 3 weeks after the last dose of vaccine and 55% at 14 months. Completed and ongoing follow-on studies at military and civilian sites in the U.S. and in Germany and Africa are designed to optimize the immunization regimen, so as to achieve high-level protection against all strains of *Plasmodium falciparum* malaria.

To date, 1,165 volunteers have received Sanaria's PfSPZ-based products in more than two dozen clinical trials in the USA, Europe and Africa. Clinical trials are in progress in Tanzania, Kenya, Mali, Burkina Faso, Germany and two sites in the USA, and are

¹ Seder RA *et al.* 2013. Protection against malaria by intravenous immunization with a non-replicating sporozoite vaccine. *Science* 334:475-480

² Ishizuka AS *et al.*, 2016. Protection against malaria at 1 year and immune correlates following PfSPZ vaccination. *Nature Medicine* 22:614-23

intended to begin soon in Equatorial Guinea.

Dr. Kenneth A. Bertram, Principal Assistant for Acquisition for the US Army Medical Research and Materiel Command (USAMRMC), Ft. Detrick, Maryland stated, "The U.S. military continues to be at risk from malaria as we deploy world-wide. We eagerly await a vaccine against this deadly and incapacitating disease. We are excited to continue working with Sanaria, the FDA, and academic partners to develop a safe and effective malaria vaccine for U.S. service members and the world community."

The next trials are also intended to begin the process of establishing the logistics for delivering and administering the vaccine to hundreds of thousands of individuals in mass campaigns. A phase 3 trial in Equatorial Guinea is being planned with funding provided by the Government of Equatorial Guinea and a consortium of three U.S. energy companies including Marathon Oil, Noble Energy, and Atlantic Methanol Production Company.

Dr. Hassan Mshinda, Director General of the Tanzanian Commission on Science and Technology, the African organization that provided funds for the first PfSPZ trial in Africa, said, "We are excited to have the Ifakara Health Institute, a Tanzanian Institute, be working with Sanaria and partners in Equatorial Guinea to move toward phase 3 clinical trials and mass vaccine administration elimination campaigns."

The clinical development plan for PfSPZ Vaccine is regularly updated at meetings of the International PfSPZ Consortium (I-PfSPZ-C), which are attended by representatives of more than 30 organizations from more than 15 countries.

This news release contains certain forward-looking statements that involve known and unknown risks and uncertainties, which may cause actual results to differ materially from anticipated results or achievements expressed or implied by the statements made. Such statements include the availability of an effective vaccine, the expectations for eliminating malaria, and beliefs concerning the suitability of a successful vaccine. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, the Company's ability to raise sufficient funds, the regulatory approval process, clinical trials results, the Company's patent portfolio, dependence on key personnel and other risks associated with vaccine development.

For further information contact Alexander Hoffman, press@sanaria.com, 301-339-0092 or Jaime Baum, newsPROs, PR Counsel, 847-502-3825, jsb@newspros.com.