



AFRICAN MALARIA NETWORK TRUST

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PRESS RELEASE

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AMANET Launches Clinical Trial of Candidate Malaria Vaccine AMA1 in Mali

The African Malaria Network Trust (AMANET) has launched a Phase Ib candidate malaria vaccine trial in Mali, marking an important milestone in its quest to contribute to the development of effective tools against malaria. .

AMANET is sponsoring a Phase I trial of the candidate malaria vaccine AMA1 (apical membrane antigen 1) to confirm its safety in healthy adults in Bandiagara, Mali. The vaccine trial is being run by a well-qualified Malian team of doctors, researchers and scientist from the Malaria Research and Training Centre (MRTC) at the Medical School, University of Bamako, led by Prof Ogobara Doumbo, the director of MRTC.

Speaking during the launch Dr Mahamadou Thera, the principal investigator of the trial, said "We are very excited to be part of this important milestone in the fight against malaria in Africa. This trial is being conducted at the highest ethical and good clinical practice (GCP) standards, everything is in place, and the team is very well prepared".

The AMA1 vaccine was invented by a team led by Dr Alan Thomas and based at the Biomedical Primate Research Centre (BPRC) in Rijswijk, The Netherlands. The vaccine was initially developed by the European Malaria Vaccine Initiative (EMVI) based at Copenhagen Denmark, which has been responsible for the manufacture and earlier clinical trials in Europe. AMANET, which is based in Dar es Salaam, Tanzania, is the sponsor of AMA1 clinical trials in Africa. AMANET receives major funding for this and other malaria vaccine trials from the European Commission - EuropeAid Cooperation Office (AIDCO).

The AMA1 vaccine has already demonstrated safety and ability to induce immune responses in trials conducted in European adults. The vaccine targets a protein used by the *Plasmodium falciparum* malaria parasite to invade red-blood cells. The stage of the parasite that invades red blood cells (the merozoite) is a logical target for a malaria vaccine since blockade of red blood cell invasion would prevent clinical disease as well as prevent progression to severe malaria and death.

Africa bears the heaviest burden of malaria. The most dangerous parasite species, *Plasmodium falciparum*, is responsible for more than one million deaths worldwide each year. More than 90% of these deaths occur among children aged five years or less and pregnant mothers in sub-Saharan African. In areas of stable malaria transmission, 25% of all-cause mortality in children aged five years or less has been directly attributed to malaria.

Given the limits of the current malaria control tools, and the successes achieved by vaccines in the prevention and control of other diseases, development of a safe and effective malaria vaccine would be a major boost in the battle against malaria. In general, vaccines help the body to prepare in advance to fight illnesses and potentially deadly diseases.

Essentially, vaccines give the body a preview of the invading agent, allowing it to learn how to defend itself. If the body is subsequently invaded by that particular infection, the body's immune system is ready and responds promptly to avoid or minimize the illness.

An ideal malaria vaccine would prevent all infection by priming the immune system to destroy all malaria parasites, whether in the liver, or free swimming in the blood, or even, though theoretically, while "hidden" inside red blood cells. Hitherto, there is no licensed vaccine against malaria and the several factors responsible for the failure have been ably articulated elsewhere.

The size and genetic complexity of the malaria parasite (*Plasmodium*) means that each malaria infection presents thousands of challenges to the human immune system. Scientists have been grappling to understand which of these can be a useful target for vaccine development. Moreover, the parasite changes through several life stages even while in the human host, presenting a different subset of molecules for the immune system to combat at each stage. To add to the list of difficulties, the parasite has evolved

a series of strategies that allow it to confuse, hide, and misdirect the human immune system and also to resist some effects of some previously effective drugs. Not surprisingly, to develop immunity against malaria as it occurs naturally, one has to suffer repeated attacks for several years.

Recently, the situation looks more promising as a good number of potential targets have been identified, and several candidate malaria vaccines produced.

Forty (40) adults are participating in the Mali AMA1 malaria vaccine trial, of these, half (20) are being immunised with the AMA1 malaria vaccine and the other half will serve as a control group receiving a vaccine against tetanus. Each trial participant will receive three injections in the schedule on days 0, 28 and 56. Each vaccination dose will be followed by an active 14-day surveillance period to look for side effects, and then the research volunteers will be passively followed up for one year.

This current study is the first time the AMA1 candidate vaccine from the EMVI consortium is being administered to individuals living in malaria endemic areas. A cautious safety approach has been taken to lead to testing of the vaccine in the target group (infants), in a step wise manner. The study has been approved by the Faculty of Medicine, Pharmacy and Dentistry of Bamako Institutional Ethics Review Committee and the Malian Ministry of Health approved the use of the experimental malaria vaccine. If found to be safe in adults, the next step of the trial will involve children to further demonstrate safety and also show that the vaccine induces appropriate immune responses.

Speaking on this launch and on the upcoming trials, the AMANET Clinical Trials Coordinator, Dr Roma Chilengi said, “The search for a malaria vaccine for Africa has been one of AMANET’s cherished goals. The launch of this trial demonstrates AMANET commitment on this regard”.

Ever since its inception, AMANET has demonstrated leadership in malaria research and development in Africa. Besides strengthening capacity and sponsoring vaccine trials, AMANET has trained nearly 1,000 African researchers in workshops in bioethics, good clinical practice (GCP), design and methodology of intervention trials, data management, molecular biology and immunology of malaria vaccine development, management and leadership of malaria research institutions, accounting and procurement, health research

ethics (HRE) and several more. AMANET recently launched a free web-based basic course in HRE, designed to provide training for hundreds of investigators and ERC members.

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