



EU funding for clinical trials of a placental malaria vaccine

Copenhagen, 1st March 2013. **PlacMalVac** - a project coordinated by University of Copenhagen has received an FP7 EU grant, which will enable the first clinical trial of a VAR2CSA based vaccine to target malaria parasites infecting pregnant women.

The international consortium includes the Centre for Medical Parasitology (CMP) from University of Copenhagen (Denmark), Expres²ion Biotechnologies (Denmark), Institut de Recherche pour le Développement (France), European Vaccine Initiative (EVI, Germany), Université d'Abomey-Calavi (Benin), & University of Tübingen (Germany). The clinical development program was initiated in 2012 with support from the Danish National Advanced Technology Foundation.

Professor Ali Salanti from the University of Copenhagen: "The funding from DNATF allowed us to commence a very ambitious and high risk vaccine development project, and in this project we managed to define and show proof of concept for the malaria vaccine and we are currently addressing manufacturability of the vaccine" The funding from EU FP7 will enable us to continue the development including upstream and downstream process development, GMP production, Phase Ia and Ib human clinical trials, as well as preparations for Phase II clinical trials.

Professor Thor G. Theander from the University of Copenhagen: "This will be the first clinical trial using the parasite antigens that cause severe disease syndromes. The vaccine attempts not to eliminate the infection but to eliminate the disease. At Centre for Medical Parasitology we are all thrilled to have this opportunity and it marks an intermediate highpoint of many years of committed research. If the vaccine is safe it will, however, require many years of continued international support before it can help pregnant women and their unborn children."

Dr. Charlotte Dyring, CEO of Expres²ion Biotechnologies: "We are proud to be part of this significant effort in the fight against malaria. Our partnership with CMP has allowed us to leverage our *Drosophila* S2 cells-based protein expression platform capabilities to contribute to developing a potential vaccine for the millions of people impacted by placental malaria. Our platform is very well suited for production of complex and challenging antigens and has good scalability, which is one of the reasons why it is the choice of expression platform for this and other malaria projects."

Placental malaria

Women, who have acquired immunity against malaria during childhood, nevertheless become susceptible to malaria again during their first pregnancies. Parasites accumulate in the placenta, where a combination of altered blood flow and expression of chondroitin sulphate A (CSA) provides a new niche for parasites to sequester. Malaria in pregnant women thus constitutes a major health problem in areas south of the Sahara, manifesting as severe disease, anemia in the mother, impaired fetal development, low birth weight or spontaneous abortion. Placental malaria (PM) has been estimated by the WHO to be responsible for 20.000

maternal and 200.000 infant deaths annually. Fortunately, women can acquire immunity against PM, and in malaria endemic areas the average birth weight is significantly higher among second- and third- compared to first-born babies. This relatively fast development of protection has raised the hope that a vaccine for PM can be developed.

Worldwide collaborations on the vaccine

In 2003 Professor Ali Salanti and others at University of Copenhagen discovered the antigen VAR2CSA, which enable parasite accumulation in the placenta. Since then collaborations with many groups around the world, especially Professor Philippe Deloron at Institut de Recherche pour le Développement, France, has enabled the preclinical development of the vaccine. ExpreS²ion Biotechnologies has provided the protein antigen variants for selection of the best candidate and will develop the manufacturing process. The Phase I clinical trials will be lead by Dr. Odile Leroy (EVI) and Professor Peter Kremsner (University of Tübingen), and preparations for a Phase II clinical trial will be led by Professor Achille Massougboji (Université d'Abomey-Calavi) and Dr Jean-Philippe Chippaux (Université d'Abomey-Calavi).

About Centre for Medical Parasitology

Centre for Medical Parasitology (CMP) is a collaboration between University of Copenhagen and Rigshospitalet and the centre's research is focused on malaria. CMP is part of a well-established international scientific network, composed of scientists in Europe, Africa, America and Australia. More than 60 scientists and technicians are affiliated at CMP. www.cmp.ku.dk/english

About ExpreS²ion Biotechnologies ApS

ExpreS²ion Biotechnologies has developed a complete proprietary protein expression platform, ExpreS², based on engineered Drosophila Schneider-2 (S2) cells, to serve recombinant protein production needs of research teams and recombinant subunit vaccine developers. ExpreS² allows quick access to proteins, excellent protein expression capability, scalability, applicability to high cell density production processes and regulatory friendliness. ExpreS²ion Biotechnologies offers technology platform licensing opportunities for use in R&D and commercial protein manufacturing. For more information visit www.expres2ionbio.com

About Institut de Recherche pour le Développement

UMR 216 represents a unique combination of cellular and molecular biologists, epidemiologists, and biostatisticians, for whom malaria in pregnancy or in infancy is the major topic of interest. Over the last 17 years, we have conducted field- and laboratory-based malaria research projects in sub-Saharan Africa, leading to the formation of an extensive international network of partnerships in developing (Africa) and developed (Europe, USA) countries. Currently 9 senior scientists, 1 post doc, 10 PhD students and 3 technicians work in projects related to malaria in pregnancy or the infant.

About European Vaccine Initiative

The EVI Secretariat consists of senior experts with proven experience and expertise in vaccine Research and Development (R&D), and support staff. Since its inception EVI (EMVI) has supported numerous scientists from Europe and low income countries, 1) contributing to the development of 24 malaria antigens in 29 vaccine formulations 2) advancing 10 vaccine

candidates into phase I clinical trials, two of which have been transitioned to partners for further development in Africa, and 3) taking a leadership role in efforts to standardise and harmonise vaccine development efforts in Europe.

About Université d'Abomey Calavi

The Centre d'Etude et de Recherche sur le paludisme associé à la grossesse et à l'enfance (CERPAGE) at UAC is directed by Professor Massougbojji. CERPAGE includes two new and fully functional research laboratories, respectively in immunology and molecular biology of parasites. The department is involved in malaria research since many years, mainly in field studies related to the epidemiology of malaria and efficacy of anti-malarial drugs, including randomised double-blind clinical trial.

About University of Tübingen

The Institute of Tropical Medicine of the University of Tübingen was founded in 1956 with the mandate to perform biomedical research, clinical duties and training of students and post graduates in the areas of Tropical medicine, Human parasitology and travel medicine. At present, our institute is an excellence research and educational institution in Europe with strong worldwide networks of partners.

Related news

<http://isim.ku.dk/news/2012/eurostar-grant-for-malaria-research/>

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