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## ExpreS<sup>2</sup>ion co-publishes positive phase I placental malaria vaccine results from the PlacMalVac consortium

ExpreS<sup>2</sup>ion Biotech Holding AB and its affiliate ExpreS<sup>2</sup>ion Biotechnologies ApS ("ExpreS<sup>2</sup>ion") announce that the placental malaria vaccine (PlacMalVac) consortium, of which ExpreS<sup>2</sup>ion is part, has announced successful phase I clinical study results. The PAMVAC vaccine, manufactured using the ExpreS<sup>2</sup> platform, was demonstrated to be safe, well-tolerated and to elicit specific antibody responses in all participants.

The PlacMalVac project started in 2013 as an international consortium project funded by several parties (see below). The aim was to develop a vaccine against placental malaria, including the production and preclinical testing of the vaccine, a first in man phase Ia and Ib clinical trial, as well as preparation for a phase II trial. It is the results of the successful phase Ia trials made in Germany, that have now been published in the scientific journal "Clinical infectious diseases" from Oxford Journals. The article is co-authored by several of ExpreS<sup>2</sup>ion's scientists and its Chief Scientific Officer, Dr. Wian de Jongh. The clinical part of an ongoing phase Ib trial in Africa is also finished, and the results is expected to be published later this year, when immunological follow up and evaluation is finalised.

*"The successful completion of the phase I clinical trial of PAMVAC is encouraging news for the millions of pregnant women and their children that risk being infected with placental malaria during pregnancy each year. It is also a great achievement for the international PlacMalVac consortium behind the vaccine, and we are proud to be a part of this team. The results further validate that our patented ExpreS<sup>2</sup> platform is a world class solution for the development and GMP compliant manufacturing of complex vaccines required for diseases such as malaria," says ExpreS<sup>2</sup>ion's CEO Dr. Steen Klynsner.*

The clinical program for the PAMVAC placental malaria vaccine is potentially continued with a phase II study. In this study, women from geographical areas where malaria is a major threat will receive the vaccine before their first pregnancy.

ExpreS<sup>2</sup>ion contributed to the collaboration through supply of protein antigen variants for selection of the best candidate, as well as development of the production cell line and manufacturing process. Copenhagen University obtained a license to the ExpreS<sup>2</sup> system for the production of the PAMVAC vaccine antigen.

*"As our platform is used both for the development and manufacturing of the PAMVAC vaccine, the project also has a potential value for us in the form of potential future milestone payments and royalties if the vaccine is approved for marketing. While there is no placental malaria vaccine on the market today, the market value will be dictated by the present high economic burden of affected regions and competition to the current treatments, mainly intermittent administration of anti-malaria drugs," says Dr. Steen Klynsner.*

The article on the successful PAMVAC phase Ia clinical results published in "Clinical infectious diseases" from Oxford journals can be found at: <http://dx.doi.org/10.1093/cid/ciy1140>

The ExpreS<sup>2</sup> platform is currently also used in several other malaria vaccines in development. ExpreS<sup>2</sup>ion announced the successful outcome of a phase IIa clinical study on a next generation, blood stage-blocking malaria vaccine led by the Jenner Institute at the University of Oxford on the 31<sup>st</sup> of October 2018. Additionally, the company announced its co-authoring of the groundbreaking results published in Nature on the 12<sup>th</sup> of December 2018 that reveal the structure of a previously missing "key" to malaria infection. The research behind this major discovery was led by ExpreS<sup>2</sup>ion's patent and collaboration partner Walter and Eliza Hall Institute of Medical Research in Australia.

### Placental malaria

Malaria infection during pregnancy is a significant public health problem with substantial risk for the pregnant woman, her foetus, and the new born child. Malaria-associated maternal illness and low birth weight is mostly the result of Plasmodium falciparum infection and occurs predominantly in Africa. Malaria in pregnant women

thus constitutes a major health problem in areas south of the Sahara, manifesting as severe disease, anaemia in the mother, impaired foetal development, low birth weight or spontaneous abortion. Placental malaria has been estimated by the WHO to be responsible for 20,000 maternal and 200,000 infant deaths annually.

### **The PAMVAC program**

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. The European Vaccine Initiative was instrumental in the mobilisation of funds and in the clinical development of the vaccine, where its fast-track strategy is implemented allowing a more efficient development of the vaccine candidate.

### **Funding**

The project was coordinated by Copenhagen University in collaboration with University of Tübingen, Université d'Abomey-Calavi, European Vaccine Initiative, Institut de Recherche pour le Développement, and the companies AGC Biologics (former CMC Biologics) and ExpreS<sup>2</sup>ion Biotechnologies. The preclinical development of the vaccine was supported by Innovation Fund Denmark, the Bill and Melinda Gates foundation and the Danish Ministry of Higher Education and Science. The cGMP manufacture was in part funded by the German Federal Ministry of Education and Research (BMBF) through Kreditanstalt für Wiederaufbau (KfW) and European Vaccine Initiative. The PlacMalVac (University of Copenhagen, Denmark) project entailing the cGMP manufacture, the clinical trial and preparations for phase II trials was funded by the European Union Seventh Framework Programme, FP7-HEALTH-2012-INNOVATION.

More detailed information on the clinical trial can be found at:

<https://clinicaltrials.gov/ct2/show/NCT02647489?cond=placenta+malaria&rank=4>

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*This press release contains information that ExpreS<sup>2</sup>ion is obligated to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact person set out above on January 10, 2019.*

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### **About ExpreS<sup>2</sup>ion**

ExpreS<sup>2</sup>ion Biotechnologies ApS is a fully owned Danish subsidiary of ExpreS<sup>2</sup>ion Biotech Holding AB with company register number 559033-3729. The subsidiary has developed a unique proprietary platform technology, ExpreS<sup>2</sup>, that can be used for fast and efficient preclinical and clinical development as well as robust production of complex proteins for new vaccines and diagnostics. Since the Company was founded in 2010, it has produced more than 250 proteins and 35 virus-like particles (VLPs) in collaboration with leading research institutions and companies, demonstrating superior efficiency and success rates. In addition, ExpreS<sup>2</sup>ion develops novel VLP based vaccines through the joint venture AdaptVac ApS which was founded in 2017.