
Publication of clinical Phase I/IIa data in the RH5 blood-stage malaria vaccine

Hørsholm, Denmark, April 21, 2021 – ExpreS²ion Biotechnologies ApS (“ExpreS²ion”) and its protein production platform ExpreS2™ have contributed to a scientific article published in the journal *Med*. The article highlights the outcome of the VAC063-study, a Phase I/IIa clinical trial to assess the safety, immunogenicity and efficacy of the blood-stage *Plasmodium falciparum* malaria vaccine candidate RH5.1/AS01_B. In conclusion the RH5.1/AS01_B vaccine is safe, well tolerated, and immunogenic in healthy adults. A significantly reduced blood-stage parasite growth rate was observed in vaccinees following controlled human malaria infection, a defining milestone for the blood-stage malaria vaccine field.

CEO Bent U. Frandsen comments

“It is a pleasure to announce the positive conclusions of the first blood-stage malaria clinical trial, which is run by the University of Oxford, and we are proud that the ExpreS2™ platform has become an enabling technology for this exciting project.”

Minassian *et al.* report that the RH5.1/AS01_B vaccine against blood-stage *Plasmodium falciparum* malaria is safe and immunogenic in the phase I/IIa clinical trial. They demonstrate a significantly reduced blood-stage parasite growth rate in vaccinees following controlled human malaria infection and identify that *in vitro* antibody-mediated growth inhibition activity is associated with challenge outcome. Such a significantly reduced blood-stage parasite growth rate observed in vaccinees following controlled human malaria infection, is a defining milestone for the blood-stage malaria vaccine field.

The scientific article is entitled “Reduced blood-stage malaria growth and immune correlates in humans following RH5 vaccination”. Paper reference: Minassian *et al.*, *Med* (2021), <https://doi.org/10.1016/j.medj.2021.03.01>. The article can also be found via this [link](#).

The RH5.1/AS01_B vaccine

RH5.1 is a novel, recombinant malaria antigen developed at the University of Oxford. It is based on recombinant RH5.1 protein produced in the ExpreS2 platform using *Drosophila Schneider 2* (S2) cells. RH5.1 is a part of a larger protein complex expressed by the malaria parasite during infection, helping it to invade red blood cells and causing the disease. The RH5.1 vaccine is intended to block red blood cell invasion and thus the progression of the disease. The vaccine in the VAC063 study is formulated in the AS01_B adjuvant, a liposome-based vaccine adjuvant system used to improve vaccine immunogenicity and efficacy.

Malaria background

Malaria is a major global problem, with 3.2 billion people living at risk of malaria infection. Despite major advances in malaria control, estimates in 2018 suggest that there were still 228 million clinical cases leading to 405,000 deaths (WHO, World Malaria Report 2019), most of which (70%) occurred in children under five years old. Currently, there is no generally approved vaccine available for malaria, which means that there is a great need for a safe, effective and durable malaria vaccine.

The VAC063 study

The present study is funded by Leidos Inc. as part of the company’s prime contract with the United States Agency for International Development (USAID) for the creation and testing of malaria vaccines. The clinical trial included 67 vaccinated healthy UK volunteers. The primary efficacy endpoint is to establish whether the RH5.1/AS01_B vaccine could demonstrate a reduced parasite multiplication rate (PMR) in vaccinated subjects compared to infectivity controls in a blood-stage controlled human malaria infection (CHMI) model. The trial is registered at ClinicalTrials.gov, NCT02927145.

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About ExpreS²ion

ExpreS²ion Biotechnologies ApS is a fully owned Danish subsidiary of ExpreS²ion Biotech Holding AB with company register number 559033-3729. ExpreS²ion has developed a unique technology platform, ExpreS², for fast and efficient non-clinical development and production of complex proteins for new vaccines and diagnostics. ExpreS² is regulatorily validated for clinical supply. The platform includes functionally modified glycosylation variants for enhanced immunogenicity and pharmacokinetics. Since 2010, the Company has produced more than 300 proteins and 40 virus-like particles (VLPs) in collaboration with leading research institutions and companies. Since 2017, ExpreS²ion develops novel VLP based vaccines through its joint venture AdaptVac ApS. For additional information, please visit www.expres2ionbio.com and www.adaptvac.com.