Update on a new clinical Phase Ib trial for the RH5.1 blood-stage malaria vaccine

Hørsholm, Denmark, July 21, 2021 – ExpreS²ion Biotech Holding AB's affiliate ExpreS²ion Biotechnologies ApS ("ExpreS²ion") announces that University of Oxford has initiated the VAC080-study, a Phase Ib clinical trial to assess the safety and immunogenicity of the blood-stage *Plasmodium falciparum* malaria vaccine candidate RH5.1/Matrix-M in adults and infants living in Tanzania.

The RH5.1 blood-stage malaria protein vaccine has previously been administered to 67 healthy UK adults, with various doses, and was found to be safe and well tolerated. The study is estimated to be completed in H2 2023. The primary aim of the new Phase Ib trial is to assess the safety and immunogenicity of the RH5.1/Matrix-M formulation in a malaria-endemic population for the first time.

CEO Bent U. Frandsen comments
"*It is a pleasure to announce that University of Oxford has initiated this exciting malaria study in Tanzania, and thus being able to progress with their clinical development plans despite the challenges presented due to the COVID-19 pandemic. Our ExpreS²™ platform continues to be selected for the production of hard-to-express proteins in leading clinical programs, in this case the recombinant RH5.1 protein.*"

The RH5.1/Matrix-M vaccine against blood-stage *Plasmodium falciparum* malaria is an updated formulation of RH5.1, where the adjuvant Matrix-M has been implemented instead of the previously used $AS01_B$ adjuvant. Published data with other vaccines in clinical development suggest that the Matrix-M adjuvant induces strong immune responses. The new Phase Ib trial of RH5.1/Matrix-M will assess vaccine safety, and the immune responses against the RH5 antigen, in particular the ability of vaccine-induced antibodies to inhibit malaria parasite growth *in vitro*.

The RH5.1/Matrix-M 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 induce antibodies that block red blood cell invasion and thus the progression of the disease. The vaccine in the VAC080 study is formulated in the Matrix-M adjuvant, a saponin-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 VAC080 study
The present study is funded by the EDCTP Multi-Stage Malaria Vaccine Consortium (MMVC), and is taking place at the Ifakara Health Institute in Bagamoyo, Tanzania. A total of 60 participants will be enrolled consisting of healthy adults (18-45 years) and infants (5-17 months) residing in Bagamoyo district, Tanzania. Participants will be recruited from areas of low malaria transmission in Bagamoyo town and areas of high malaria transmission within Bagamoyo district. All participants will be followed for 2-2.5 years after the first vaccination with RH5.1/Matrix-M vaccination. The duration of the entire study will be 2-2.5 years per participant from the time of first vaccination. The trial is registered at ClinicalTrials.gov, NCT04318002.

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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.