ExpreS^{2}ion Biotech Holding AB
Press Release, 2018-10-24

ExpreS^{2}ion announces upcoming presentation of Phase I/IIa malaria vaccine trial results by Jenner Institute

Horsholm, Denmark, October 18, 2016 – Today, ExpreS^{2}ion Biotech Holding AB ("ExpreS^{2}ion") announces that its collaboration partner, Jenner Institute of the University of Oxford, will present the results from the Phase I/IIa clinical studies of its RH5.1 blood stage malaria vaccine at the annual American Society of Tropical Medicine and Hygiene (ASTMH) meeting on the 31st of October in New Orleans.

The study assesses the safety, immunogenicity, and efficacy of the blood-stage *Plasmodium falciparum* malaria antigen RH5.1, which is produced with ExpreS^{2}ion's technology platform ExpreS^2.

"We are excited that the results from the Jenner Institute's clinical Phase I/IIa malaria study can now be presented. Our ExpreS^2 platform has been instrumental in the development of this vaccine, and we will of course announce our view on the results as soon as they become public," says ExpreS^{2}ion's CEO Dr. Steen Klysner.

The RH5.1 vaccine
RH5.1 is a novel, recombinant malaria antigen developed at the Jenner Institute. It is based on a recombinant RH5.1 protein produced with the ExpreS^2 platform using *Drosophila* Schneider-2 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 effectively block the progression of the disease.

The clinical study
The phase I/IIa 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 study has been running for more than a year to assess the safety, immune responses, dosing regimen and efficacy of RH5.1. The results will be presented by Angela M. Minassian from the Jenner institute of Oxford at a session at ASTHM in New Orleans, scheduled October 31, at 12:00 PM - 1:45 PM. The presentation will address safety as well as efficacy and durability of the vaccine response in healthy volunteers challenged with *P. falciparum* malaria parasites.

The abstract can be found at:
https://www.abstractsonline.com/pp8/#!/4692/presentation/18959

Malaria
Malaria is a major global problem, with 3.2 billion people living at risk of malaria infection. In 2015, malaria was thought to have caused 438,000 deaths, 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 malaria vaccine.

American Society of Tropical Medicine and Hygiene (**ASTMH**)
ASTMH is a non-profit organisation of scientists, clinicians, students and program professionals whose longstanding mission is to promote global health through the prevention and control of infectious and other diseases that disproportionately afflict the global poor. ASTMH members work in areas of research, health care and education that encompass laboratory science, international field studies, clinical care and country-wide programs of disease control.

Jenner Institute and the University of Oxford
Jenner Institute is a research partnership between the University of Oxford and the Pirbright Institute focused on the development of vaccines against major global diseases. University of Oxford's Medical Sciences Division is one of the largest biomedical research centres in Europe. The University is rated as the best in the world and it has one of the largest clinical trial portfolios in the UK and great expertise in taking discoveries from the laboratory into the clinic.

Certified Advisor
Sedermera Fondkommission is appointed as Certified Adviser for ExpreS^{2}ion.

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This press release contains information that ExpreS^{2}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 October 24, 2018.

About ExpreS^{2}ion
ExpreS^{2}ion Biotechnologies ApS is the fully owned Danish subsidiary of Sweden-based ExpreS^{2}ion Biotech Holding AB with company registration number 559033-3729. The subsidiary holds a unique proprietary platform, ExpreS^2, made for fast and efficient development and robust production of complex proteins with focus on new vaccines, immune therapy and diagnostics. Since founded in 2010, the company has produced more than 250 proteins and 35 virus-like particles (VLPs) for and in collaboration with leading research institutions and companies, demonstrating superior efficiency and success rates. In addition, ExpreS^{2}ion develops novel vaccines based on a ground-breaking VLP platform through its Danish joint venture AdaptVac ApS, founded in 2017.

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1850 - Efficacy of the Novel *Plasmodium falciparum* Blood-stage Vaccine RH5.1/AS01B in a Phase I/IIa Clinical Trial

October 31, 2018, 12:00 PM - 1:45 PM

Authors

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Disclosures

A.M. Minassian: None.

Abstract

The development of an effective blood-stage malaria vaccine holds significant promise for reducing the morbidity and mortality associated with clinical malaria. The reticulocyte-binding protein homologue 5 (RH5) is the most promising blood-stage *P. falciparum* candidate antigen to date. It is essential for erythrocyte invasion and has shown *in vivo* efficacy in non-human primates. Protection was strongly correlated with anti-RH5 serum IgG antibody concentration and *in vitro* functional growth inhibition activity (GIA). We have shown the recombinant protein RH5.1 delivered with GSK's adjuvant AS01B to be safe and immunogenic in a dose-escalating Phase Ia study in healthy UK adults (NCT02927145, unpublished). Here we report on the promising immunogenicity of the fractional dose group from the Phase Ia trial, where 12 volunteers received 2x 50 µg of RH5.1/ AS01B 4 weeks apart, followed by a delayed 10 µg dose 6 months later. We then present data on vaccine efficacy, assessed using a blood-stage controlled human malaria infection (CHMI) model against both primary and secondary homologous *Plasmodium falciparum* 3D7 clone challenge. 30 healthy malaria-naïve UK volunteers were recruited into this CHMI study. 15 received 3x 10 µg doses of RH5.1/ AS01B (4 weeks apart) and then received an intravenous injection of parasitized red blood cells in parallel with 15 control volunteers. Impact of the vaccine on qPCR-derived parasite multiplication rate (PMR) was the primary efficacy endpoint. 9 of these vaccinees and 8 controls have since undergone a second homologous CHMI to assess durability of immunity, compared to a third group of 6 new malaria-naïve controls. Results of both the first and second *P. falciparum* blood-stage challenges will be presented.