
Successful completion of Phase I and initiation of Phase IIa clinical trial of a universal malaria vaccine produced in Expres²

Horsholm, Denmark, July 5, 2017 – Today, Expres²ion Biotech Holding AB announces that the Jenner Institute of the University of Oxford, a licensee of the fully owned subsidiary Expres²ion Biotechnologies ApS (“Expres²ion”), initiates recruiting for a Phase IIa clinical trial following a successful Phase I safety study of its new blood stage malaria vaccine. The Phase IIa trial will assess safety, immunogenicity and efficacy of the blood-stage malaria vaccine, which is produced in Expres²ion’s proprietary platform, Expres². Malaria is causing more than 400,000 deaths annually, and the vaccine addresses a global market estimated by The Boston Consulting Group to be in the size of up to \$400M per year.

New vaccine could provide universal protection against the most dangerous form of malaria

The new *P. falciparum* malaria vaccine, RH5.1, which now enters a Phase IIa clinical trial is a novel, recombinant malaria antigen developed at the Jenner Institute based on recombinant RH5.1 protein produced in Expres²ion’s Expres² platform. RH5.1 is 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 vaccine is intended to be a universal *P. falciparum* malaria vaccine, which works by blocking the red blood cell invasion and thus the progression of the disease.

Successful phase I demonstrated safety

The present study is funded by Leidos Inc (“Leidos”) as part of Leidos’ prime contract with the United States Agency for International Development (USAID) for the development and testing of malaria vaccines. The successfully completed part of the Phase I study assessed the safety of the vaccine and the immune response, as well as the optimal dosing regimen of the vaccine.

Initiation of recruitment for phase IIa determining vaccine efficacy against malaria challenge

The Phase IIa study will address how effective the vaccine is at preventing malaria. This is done by comparing individuals given the optimal dose of the vaccine to subjects who have not received the vaccine, when challenged with malaria parasites. The Phase IIa study is expected to run for at least one year.

Malaria killed nearly half a million in 2015

Malaria is a major global health problem with 3.2 billion people living at risk of malaria infection. In 2015, malaria was thought to have caused 429,000 deaths, most of which (70%) occurred in children under five years old (WHO, 2016, <http://www.who.int/malaria/media/world-malaria-report-2016/en/>). Currently, there is no generally approved vaccine available for malaria, which means that there is a great need for a safe, effective malaria vaccine.

Despite the urgent medical need for an effective malaria vaccine, no vaccine has yet achieved satisfactory protection against the disease. In a malaria market assessment study by the Boston Consulting Group sponsored by the Malaria Vaccine Initiative, the malaria vaccine demand was estimated to be translated into a global market value of up to \$400M per year.

CEO Dr. Steen Klynsner comments

“We are very pleased to note that the blood stage malaria vaccine has passed the Phase I safety study and will now proceed into the planned Phase II clinical efficacy study. We are proud of having delivered enabling technology for this exciting project and we now look forward to see the results which are expected in late 2018.”

Expres²ion Biotech Holding AB
Press Release, 2017-07-05

About the Jenner Institute and the University of Oxford

The 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. The 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 Expres²ion.

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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. The subsidiary has developed a unique platform technology, Expres², enabling cost effective development and robust production of complex proteins for new vaccines and diagnostics for e.g. Malaria and Zika. Since founded in 2010, the company has used its patented Expres² platform to produce more than 200 proteins in collaborations with research institutions and biopharmaceutical companies, with a superior efficiency and success rate.