CMC Biologics Enters into Agreement with the University of Copenhagen for Development and Clinical Manufacture of Placental Malaria Vaccine

Unique production platform produces complex proteins more cost-effectively
to address a global health priority with no current effective cure

Copenhagen, Denmark / Seattle, WA USA – December 3, 2013 – CMC Biologics, known for its technical excellence in process development and cGMP manufacture of protein therapeutics, announced that earlier this year it entered into an agreement with the University of Copenhagen for process development and cGMP clinical production of VAR2CSA for a placental malaria vaccine.

The project is focused on developing a novel prophylactic vaccine designed to protect women against malaria during pregnancy. In 2003 Professor Ali Salanti and others at University of Copenhagen discovered the antigen VAR2CSA, which enable parasite accumulation in the placenta. The VAR2CSA molecule, developed by the University of Copenhagen, has the potential to significantly reduce the effects of the parasite. The vaccine attempts not to eliminate the infection, but to eliminate the disease. There are now collaborations with many groups around the world that enabled the preclinical development of the vaccine, and now clinical development.

The vaccine antigen will be produced using ExpreS^{2}ion Biotechnologies' proprietary insect cell-based recombinant protein expression platform, ExpreS^2. The ExpreS^2 platform is well suited for novel and flexible production modalities, allowing for more cost-effective processes. ExpreS^{2}ion Biotechnologies is a partner of the University of Copenhagen in placental malaria vaccine development.

"Through collaborations like this, we have the opportunity to make a real difference in a disease with major global health implications by helping to take the program into human clinical trials," said Gustavo Mahler, Global Chief Operations Officer of CMC Biologics. "We are supportive of the committed research conducted by the University of Copenhagen and its collaborators, and pleased to be selected for this next phase of clinical development."

CMC Biologics will employ its technical expertise and experience in Process Development and cGMP manufacturing of Biopharmaceuticals in developing the vaccine and will provide cGMP grade clinical material for the upcoming clinical trials.

“This is the first clinical trial using parasite antigens that causes severe disease syndromes and we believe CMC Biologics’ experience and technical leadership will help us to reach our clinical milestones,” said Professor Thor G. Theander from the Centre for Medical Parasitology at the University of Copenhagen. “We are pleased to be entering into clinical studies to determine potential safety and efficacy of a vaccine which has the potential to help pregnant women and their unborn children.”

Placental malaria

Women, who have acquired immunity against malaria during childhood, nevertheless become susceptible to malaria again during their first pregnancies. Parasites accumulate in the placenta, where a combination of altered blood flow and expression of chondroitin sulphate A (CSA) provides a new niche for parasites to sequester. Malaria in pregnant women thus constitutes a major public health problem, manifesting as severe disease, anemia in the mother, impaired fetal development, low birth weight or spontaneous abortion.

Placental malaria (PM) has been estimated by the WHO to be responsible for 20,000 maternal and 200,000 infant deaths annually. This constitutes a major burden on the national health budgets in the endemic countries and developing an effective vaccine is a national as well as a global priority. Fortunately, women can acquire immunity against PM, and in malaria endemic areas. This relatively fast development of protection has raised the hope that a vaccine for PM can be developed.

About CMC Biologics

CMC Biologics is a dedicated contract biopharmaceutical manufacturing and development organization with facilities in Copenhagen, Denmark and Seattle, Washington, USA. CMC Biologics specializes in custom services for scale up and cGMP manufacture of protein-based therapeutics for preclinical, clinical trials, and in-market production. The Company’s fully integrated services includes cell line development using its proprietary CHEF1® system, process and formulation development, and comprehensive analytical testing. CMC Biologics has fully segregated microbial fermentation and cell culture suites and offers stirred tank and perfusion production processes. To learn more, visit www.cmcbio.com.

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