New Tuberculosis Vaccine Enters Phase IIb Proof-of-Concept Trial in People Living with HIV in Senegal and South Africa

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Vaccine candidate is the most clinically advanced of a new generation of vaccines under development to combat TB and the TB/HIV co-epidemic

ROCKVILLE, Md. & LONDON, Aug 11, 2011 (BUSINESS WIRE) --

Aeras and the Oxford-Emergent Tuberculosis Consortium (OETC) announce today the start of a Phase IIb proof-of-concept efficacy trial of a new investigational tuberculosis (TB) vaccine that involves people living with the human immunodeficiency virus (HIV). The trial will be conducted at research sites in Senegal and South Africa with primary funding support from the European and Developing Countries Clinical Trials Partnership (EDCTP).

TB is a leading cause of death for people infected with HIV and the second leading infectious disease killer in the world. This is the first proof-of-concept efficacy trial in people infected with HIV using MVA85A, which is being developed by OETC (a joint venture between the University of Oxford and Emergent BioSolutions) and Aeras. It is expected that the trial will generate important safety, immunogenicity and efficacy data about this vaccine.

The trial will test the vaccine candidate in approximately 1,400 adults ages 18-50 who are infected with HIV. The study will be led by the UK Medical Research Council in The Gambia, Aeras, and the University of Oxford, and conducted at two sites by the University of Cape Town (UCT) Institute of Infectious Disease and Molecular Medicine in Khayelitsha, South Africa and Laboratoire de Bacteriologie-Virologie du Centre Hospitalier Universitaire Aristide Le Dantec in Dakar, Senegal. This follows the first proof-of-concept clinical trial of the same candidate TB vaccine, which recently reached full enrollment with almost 3,000 infant participants in South Africa.

"Clinical trials of new vaccines against tuberculosis must be an urgent priority on our agenda, as too many lives are lost to TB, especially among people living with HIV," said Member of the European Parliament Michael Cashman. "I recently visited a clinical trial site of this vaccine candidate in infants in South Africa, and I was impressed with the progress. I am anxious to see a new TB vaccine licensed, and I am proud that European Union Member States are investing in this critically-important work."

Professor Charles Mgone, Executive Director of EDCTP, said, "The TB and HIV co-epidemic is devastating, requiring a concerted global response. EDCTP in partnership with Aeras, Oxford-Emergent Tuberculosis Consortium and others is committed to accelerate research and development of this promising vaccine against tuberculosis by co-financing the clinical trial as an essential part in its evaluation."

Tuberculosis kills 1.7 million people per year, and more than two billion people worldwide are infected with TB - approximately one out of every three people on the planet. People infected with HIV living in countries with high TB prevalence are 20 times more likely to develop TB than those who are HIV-negative. In 2008, there were an estimated 1.4 million new cases of TB among persons with HIV infection, and TB accounted for 23 percent of AIDS-related deaths, according to the World Health Organization (WHO). The Bacille Calmette-Guérin (BCG) vaccine, the only currently-licensed vaccine against TB, is not effective in preventing adult pulmonary TB, the most common form of the disease.

"A new, more effective TB vaccine would be game-changing in international efforts to eliminate TB globally by 2050," said Jim Connolly, President and Chief Executive Officer of Aeras. "Studies have already shown that this promising vaccine has an acceptable safety profile and stimulates strong immune responses in HIV-infected individuals."

Aeras is the trial sponsor, and significant funding is provided by EDCTP, a pan-European body that supports multicenter projects which combine clinical trials, capacity building and networking. This study has been approved by the Medicines Control Council of South Africa, the South African Department of Health, and the Comité National d'Ethique pour la Recherche en Santé (CNERS) in Senegal. The Scientific Institute of Public Health (WIV-ISP) in Belgium, which first identified the antigen 85A for possible use in a vaccine candidate, is providing in-kind laboratory services for the study.

"Together with our partners, Emergent BioSolutions is proud to be leading the development of a new vaccine to defeat TB, one of the world's deadliest infectious diseases. This trial is particularly critical because of its focus on adults living with HIV. If we are successful, MVA85A will help make the dream of a world free from TB a reality," said Fuad El-Hibri, Chairman and Chief Executive Officer of Emergent BioSolutions.

"It is great to see the vaccine candidate we initially developed at Oxford University reach this stage of clinical trials," said Dr. Helen McShane, a Wellcome Trust Senior Clinical Research Fellow at the University of Oxford. "In the next few years we should begin to get results on how effective the vaccine is in protecting those who are most at risk of TB. It's our hope that this vaccine will turn out to be a powerful new weapon to combat TB in the parts of the world that need it most."

About MVA85A

The MVA85A vaccine candidate is intended to boost the response of T-cells already stimulated by the BCG vaccine. The vaccine candidate was originally developed at the University of Oxford by Dr. Helen McShane, a Wellcome Trust Senior Clinical Research Fellow, working with Dr. Sarah

Gilbert, a Reader in Vaccinology, and Professor Adrian Hill, a Wellcome Trust Principal Research Fellow. It was licensed to the Oxford-Emergent Tuberculosis Consortium by Isis Innovation, the University's technology transfer company, in July 2008. Previous clinical trials of the vaccine in adults - supported by the Wellcome Trust - in the United Kingdom, the Gambia, Senegal and South Africa have demonstrated consistently high cellular immune responses in those who received the MVA85A vaccine candidate following vaccination with BCG. To date, the vaccine has been shown to have an acceptable safety profile and has had no clinically-significant effects on viral load or CD4 count in three studies involving a total of 80 participants living with HIV in Senegal, South Africa and the UK. The vaccine has been awarded orphan drug status by the European Medicines Agency (EMA) and is the most clinically advanced of a new generation of tuberculosis vaccine candidates.

About Aeras

Aeras is a non-profit product development organization dedicated to the development of effective vaccines and biologics to prevent TB across all age groups in an affordable and sustainable manner. Aeras has invented or supported the development of six TB vaccine candidates to date, five of which are currently undergoing Phase I and Phase II clinical testing in Africa, Asia, North America and Europe. Aeras receives funding from the Bill & Melinda Gates Foundation, other private foundations, and governments. Aeras is based in Rockville, Maryland, USA where it operates a state-of-the-art manufacturing and laboratory facility, and Cape Town, South Africa. http://www.aeras.org

About OETC

The Oxford-Emergent Tuberculosis Consortium Ltd ("OETC")is a joint venture between the University of Oxford and Emergent BioSolutions. OETC was formed with the aim of developing the MVA85A TB vaccine to meet both developed and developing country health needs.

About EDCTP

The European and Developing Countries Clinical Trials Partnership (EDCTP) was created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases (PRDs) of HIV/AIDS, tuberculosis and malaria. Currently EDCTP is a partnership between 14 European Union member states plus Norway and Switzerland with 47 sub-Saharan African countries. The aim of the programme is to accelerate the development of new or improved drugs, vaccines and microbicides against HIV/AIDS, malaria and tuberculosis through promoting the integration of national programmes of EDCTP European Member States and development of a genuine partnership with African counterparts. http://www.edctp.org

About Emergent BioSolutions Inc.

Emergent BioSolutions protects and enhances life by developing and manufacturing vaccines and therapeutics that are supplied to healthcare providers and purchasers for use in preventing and treating disease. Emergent's marketed and investigational products target infectious diseases, oncology and autoimmune disorders. Additional information about the company may be found at http://www.emergentbiosolutions.com

About Laboratoire de Bacteriologie-Virologie du Centre Hospitalier Universitaire Aristide Le Dantec

Professor Souleymane Mboup is the Laboratory Director and the Principal Investigator (PI) of this clinical trial in Senegal. The Laboratoire de Bacteriologie-Virologie Le Dantec (LBV) is working in partnership with the Infectious Disease Department of Fann Hospital led by co-PI Professor Papa Salif Sow and the CTA (Centre for Ambulatory Treatment) led by Dr. Ndèye Fatou Ngom. LBV is globally known for Professor Mboup's co-discovery ofthe HIV-2 virus with a Harvard University team. He was one of three major PIs to receive an NIH CIPRA Program award. The Laboratory is engaged in many research areas including HIV, malaria, Hepatitis B and neglected diseases. A dedicated research team has been set up to take over this challenging Phase II vaccine trial, which will be coordinated by Dr. Birahim Pierre Ndiaye, who has extensive experience managing clinical studies. http://www.hopitaldantec.org/

About the Medical Research Council

For almost 100 years, the Medical Research Council (MRC) has improved the health of people in the UK and around the world by supporting the highest quality science. The MRC invests in world-class scientists. It has produced 29 Nobel Prize winners and sustains a flourishing environment for internationally-recognised research. The MRC focuses on making an impact and provides the financial muscle and scientific expertise behind medical breakthroughs, including one of the first antibiotics penicillin, the structure of DNA and the lethal link between smoking and cancer. Today MRC-funded scientists tackle research into the major health challenges of the 21st century. MRC has units in Africa dedicated to research on infectious diseases and non-communicable diseases for such settings. Dr. Martin Ota, the Principal Investigator and Project Coordinator of this important novel TB vaccine trial, is a senior scientist from the MRC Unit The Gambia. http://www.mrc.ac.uk

About Oxford University's Medical Sciences Division

Oxford University's Medical Sciences Division is one of the largest biomedical research centres in Europe, with over 2,500 people involved in research and more than 2,800 students. It brings in around two-thirds of Oxford University's external research income. Listed by itself, that would make it the fifth largest UK university in terms of research grants and contracts. A major strength of Oxford medicine is its long-standing network of clinical research units in Asia and Africa, enabling world-leading research on malaria, TB, HIV/AIDS and flu. Oxford is also renowned for its large-scale studies into the causes and treatment of cancer, heart disease, diabetes and other common conditions. http://www.ox.ac.uk

About The Clinical Infectious Diseases Research Initiative

The Clinical Infectious Diseases Research Initiative at the University of Cape Town was established in 2008 by a Strategic Award from the Wellcome Trust of Great Britain. The Initiative is administered from the IIDMM (Institute of Infectious Diseases and Molecular Medicine) by a Steering Group under the direction of Professor Robert J Wilkinson. It supports extensive research in Infectious Diseases, and one of the objectives is to improve clinical and laboratory research facilities. This is the first adult TB vaccine clinical trial to be launched at the purpose built clinic at Site B Community Health Clinic, Khayelitsha. http://www.cidri.uct.ac.za

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, including any potential future securities offering, our expected revenue growth and

net earnings for 2011, and any other statements containing the words "believes," "expects," "anticipates," "plans," "estimates" and similar expressions, are forward-looking statements. There are a number of important factors that could cause the actual results of the Consortium or Emergent to differ materially from those indicated by such forward-looking statements, including the success of our ongoing and planned preclinical studies and clinical trials; the rate and degree of market acceptance and clinical utility of our products; the success of our ongoing and planned development programs; the timing of and our ability to obtain and maintain regulatory approvals for our other product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and other factors identified in Emergent's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 and subsequent reports filed with the SEC. The Consortium and Emergent disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

SOURCE: Emergent BioSolutions Inc.

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