New TB Vaccine Candidate Enters Phase IIb Proof-of-Concept Trial in South Africa

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Vaccine Candidate is the most clinically advanced of a new generation of vaccines under development to combat the TB epidemic

OXFORD, England, ROCKVILLE, Md. & CAPE TOWN, South Africa, Apr 22, 2009 (BUSINESS WIRE) -- The Aeras Global TB Vaccine Foundation, the Oxford-Emergent Tuberculosis Consortium Ltd. ("the Consortium"), Isis Innovation Ltd., the Wellcome Trust and the University of Cape Town (UCT) announce today the start of a Phase IIb proof-of-concept clinical trial of a promising new TB vaccine developed at the University of Oxford called MVA85A/AERAS-485. The study will be conducted by the South African Tuberculosis Vaccine Initiative (SATVI) of UCT in the Western Cape Region from its study site 100 km from Cape Town in Worcester, South Africa. This study, which has been approved by the Medicines Control Council of South Africa, will test MVA85A/AERAS-485 in approximately 2,784 children under one year of age, all of whom have received Bacille Calmette-Guerin (BCG) at birth. It is expected that the trial will generate important safety, immunogenicity and preliminary efficacy data about the vaccine candidate. This is the first proof-of-concept trial of a new preventive TB vaccine in infants in more than 80 years.

Tuberculosis kills 1.8 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. New vaccines are urgently needed as part of the global response to TB. BCG is currently the only available vaccine against TB. BCG, which is administered to infants throughout the developing world and in certain countries in the developed world, provides some protection against pediatric TB. However, BCG provides only variable protection against pulmonary tuberculosis, which accounts for most of the worldwide disease burden.

"The world desperately needs new and better approaches to combat TB," said Dr. Marcos Espinal, Executive Secretary of the Stop TB Partnership. "The advancement of a new TB vaccine candidate to this stage is an exciting development for all of us who seek to end this terrible epidemic."

This new vaccine candidate is intended to augment the response of T-cells already stimulated by the BCG vaccine. Previous clinical trials of the vaccine in adults have demonstrated consistently high cellular immune responses in those who received the MVA85A/AERAS-485 vaccine candidate following vaccination with BCG.

"The search for a new TB vaccine is a complex and challenging process requiring a broad commitment, and we are pleased to be collaborating with so many dedicated and talented researchers on this important effort," said Jerald C. Sadoff, MD, President & CEO of the Aeras Global TB Vaccine Foundation. "There is still a long road ahead, but this marks an important milestone toward the goal of a more effective TB vaccine."

The Aeras Global TB Vaccine Foundation is working with the Consortium to develop MVA85A/AERAS-485 with additional funding from the Wellcome Trust. 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 by Isis Innovation, the University's technology transfer company to the Oxford-Emergent TB Consortium in July 2008. The vaccine has been awarded orphan drug status by the European Medicines Agency (EMEA) and is the most clinically advanced of a new generation of tuberculosis vaccine candidates.

"We believe this is the most exciting advance in the field of TB vaccines for over 80 years," said Dr Helen McShane of the Jenner Institute, University of Oxford, "and is a testament to the commitment shown by the partners and funders involved. We have shown that this vaccine is safe and stimulates strong immune responses. This trial will hopefully show that the vaccine can protect people from getting TB and enable the global community to begin to control this devastating disease."

Professor Gregory Hussey, Director of SATVI, says that the announcement of this study brings a message of hope: "We are testing the vaccine in an area burdened by one of the highest incidence rates of TB in the world, in a community most likely to benefit from its success. The study strengthens our commitment to stop TB."

"This marks an important milestone in what we believe is an extraordinary opportunity to prevent tuberculosis, which is a major global health crisis. Emergent is proud to join such distinguished partners as we make progress in the fight against one of the world's deadliest diseases," said Fuad El-Hibri, Chairman and Chief Executive Officer at Emergent BioSolutions.

The Aeras Global TB Vaccine Foundation is a non-profit organization working as a Product Development Partnership to develop new tuberculosis vaccines and ensure that they are distributed to all who need them around the world. Aeras collaborates with academia, industry, foundations and governments to develop new TB vaccine candidates and delivery systems, manufacture vaccines at low cost and establish intellectual property rights to assure their future availability and affordability. Aeras' major funders are the Bill & Melinda Gates Foundation, the Netherlands Ministry of Foreign Affairs, the Danish International Development Agency, the Research Council of Norway and the U.S. Centers for Disease Control and Prevention. Aeras operates a state-of-the-art manufacturing and laboratory facility in Rockville, Maryland, USA and has an office in Cape Town, South Africa. www.aeras.org

Emergent BioSolutions Inc. is a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and therapeutics that assist the body's immune system to prevent or treat disease. Emergent's marketed product, BioThrax(R) (Anthrax Vaccine Adsorbed), is the only vaccine licensed by the U.S. Food and Drug Administration for the prevention of anthrax. Emergent's development pipeline includes programs focused on anthrax, botulism, tuberculosis, typhoid, hepatitis B and chlamydia. Additional information may be found at www.emergentbiosolutions.com.

Isis Innovation Ltd is the University of Oxford's technology company and manages the University's intellectual property portfolio, working with

University researchers on identifying, protecting and marketing technologies through licensing, spin-out company formation and material sales. Isis files on average one new patent application each week, has concluded over 400 technology licensing agreements, and established 62 new spin-out companies from Oxford. Isis also manages Oxford University Consulting (OUC), which arranges consulting services providing clients access to the world-class expertise of the University's academics to enhance innovative capability. Last year OUC arranged over 100 consulting deals. Isis has established a separate business division, Isis Enterprise, offering consulting expertise and advice in technology transfer and open innovation to university, government and industrial clients around the world. Isis was founded in 1987 and is today one of the world's leading technology transfer and innovation management companies.

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

The South African Tuberculosis Vaccine Initiative is located in the Institute of Infectious Disease and Molecular Medicine at the University of Cape Town (UCT). Since 1999, with funding largely from the Aeras Global TB Vaccine Foundation, SATVI has developed the capacity to conduct registration standard vaccine trials at a site in Worcester, where rates of tuberculosis are amongst the highest in the world. SATVI has a state of the art immunology laboratory where it conducts cutting edge basic science research aimed at better understanding the human immune response to tuberculosis and to tuberculosis vaccines. SATVI has also conducted a number of very large field trials and epidemiological cohort studies, which are necessary to test the efficacy of new tuberculosis vaccines. www.satvi.uct.za

The University of Oxford's Medical Sciences Division is one of the largest biomedical research centers in Europe. It represents almost one-third of Oxford University's income and expenditure, and two-thirds of its external research income. Oxford's world-renowned global health program is a leader in the fight against infectious diseases (such as malaria, HIV/AIDS, tuberculosis and avian flu) and other prevalent diseases (such as cancer, stroke, heart disease and diabetes).

Key to its success is a long-standing network of dedicated Wellcome Trust-funded research units in Asia (Thailand, Laos and Vietnam) and Kenya, and work at the MRC Unit in The Gambia. Long-term studies of patients around the world are supported by basic science at Oxford and have led to many exciting developments, including potential vaccines for tuberculosis, malaria and HIV, which are in clinical trials. www.medsci.ox.ac.uk

Wellcome Trust is the largest charity in the UK. Its mission is to fund innovative biomedical research in the UK and internationally, spending around £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing. www.wellcome.ac.uk

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Aeras Global TB Vaccine Foundation
Annmarie Leadman
Director, Communications
+1 240-599-3018
aleadman@aeras.org
or
Emergent BioSolutions
Tracey Schmitt
Vice President, Corporate Communications
+1 301-795-1847
Mobile +1 240-938-0314
schmittT@ebsi.com
or
Oxford-Emergent Tuberculosis Consortium, Ltd.
Dr. Jacqui Shea
General Manager
+44 118 944 3316
Mobile +44 779 863 1215
Sheaj@ebsi.com
or
University of Oxford
Jonathan Wood
Press Officer
Medical Sciences
+44 (0)1865 280530
jonathan.wood@admin.ox.ac.uk
or
South African Tuberculosis Vaccine Initiative
Linda Rhoda
Communications Manager
+27 21 406 7621
Linda.rhoda@uct.ac.za
or
Wellcome Trust
Michael Regnier
Media Officer
+44 (0) 20 7611 7262
M.Regnier@wellcome.ac.uk