Data from Historic Phase IIb Clinical Trial for Tuberculosis Vaccine Candidate MVA85A Published in The Lancet

February 4, 2013

- *Vaccine candidate was generally well tolerated, meeting the study's primary objective of safety*
- *Vaccine candidate did not provide statistically-significant protection in preventing TB disease in infants previously vaccinated with BCG*

LONDON--(BUSINESS WIRE)--Feb. 4, 2013-- Data were published in *The Lancet* today from a Phase IIb clinical trial evaluating the safety and efficacy of MVA85A in preventing tuberculosis (TB) in infants. MVA85A is a TB vaccine candidate designed to boost immune responses already primed by the Bacille Calmette-Guérin (BCG) vaccine, the currently licensed and widely used TB vaccine.

Data show that a single dose of MVA85A is not sufficient to confer statistically significant protection against TB disease or infection in infants who had been vaccinated at birth with BCG. There were 32 cases of TB disease in the infants that received BCG + MVA85A compared with 39 cases of disease among those receiving BCG + placebo. Non-significant vaccine efficacy was measured at 17.3% (95% CI -31·9% to 48·2%) at study completion. The vaccine candidate also did not provide statistically significant protection from infection with *Mycobacterium tuberculosis*, the bacterium that causes TB, which was a secondary efficacy endpoint.

"Although the results of this first efficacy trial of a new TB vaccine are not what we had hoped for, further analysis of the data should reveal a great deal about how the body's immune system protects against TB and what is necessary to develop an effective vaccine," said senior author Prof. Helen McShane, a Wellcome Trust Senior Clinical Research Fellow at the University of Oxford and the original developer of the vaccine. "The results from this study should let us know far more about the type and level of immune response required, and that will boost future efforts to develop an effective TB vaccine by Oxford and other researchers throughout the world. The difficulty of this task is one reason why there has not been a new TB vaccine since BCG was developed more than 90 years ago, but one is still urgently needed and I'm not about to give up now."

MVA85A is the first novel, preventive TB vaccine candidate since BCG to complete a Phase IIb safety and efficacy study.

The study was successful in that the vaccine was well tolerated, there was no evidence of any harm to the trial participants, and it gave a clear answer. This study also showed it is possible to conduct a large infant efficacy clinical trial in an area of high TB incidence with robust endpoints for detecting disease, something that is expected to greatly benefit future testing of TB vaccine candidates.

Funding for this clinical trial was provided by Aeras, a nonprofit biotech with a social mission to develop TB vaccines, The Wellcome Trust, and the Oxford-Emergent Tuberculosis Consortium (OETC), a joint venture between the University of Oxford and Emergent BioSolutions. This Phase IIb study was sponsored by Aeras and conducted by the University of Cape Town's South African Tuberculosis Vaccine Initiative (SATVI). The vaccine was originally developed and investigated by the University of Oxford.

It is anticipated that further analysis of the data and samples collected will be conducted for information that may be helpful for the development of new vaccine candidates. For example, blood samples will be used to identify markers that can predict whether a child will develop TB disease in the future. These biomarkers are termed "correlates of risk" and may substantially aid the development of new vaccines and contribute to different trial designs in the future.

To access the manuscript abstract as published in *The Lancet*, please visit: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)60177-4/abstract.

Partner Quotes

Aeras: "Vaccine development is an incredibly difficult undertaking, and the scientific community has only become fully engaged in the development of TB vaccines in the last decade," said Tom Evans, MD, Aeras interim CEO. "Because of the urgency to control the global TB epidemic, and despite these trial results, we remain steadfast in our belief that an improved TB vaccine will be developed and represents the best hope for eliminating the disease. The valuable scientific understanding gained from this trial will provide crucial information for the robust global portfolio of more than a dozen other TB vaccines undergoing clinical testing, a number that was unimaginable a decade ago."

Emergent: "While we are clearly disappointed in the results announced today, this study does demonstrate that a large-scale clinical trial testing a vaccine in infants can be designed and run efficiently, adhering to the highest standards of good clinical trial practices in a setting with a high TB burden," said Dr. Steve Chatfield, EVP and president of the biosciences division at Emergent BioSolutions, and chairman of the Oxford-Emergent Tuberculosis Consortium. "We are proud to have been part of this broad international collaboration that brought together academic, product development, manufacturing, and clinical trial expertise in an effort to make a positive impact on global health."

OETC: "Completion of the study has been a significant achievement by the MVA85A development partners and demonstrates the advantages of collaboration through a public-private partnership model to address global public health challenges," said Dr. Jacqui Shea, general manager of OETC. "While MVA85A has not met its efficacy goal, this study should enable the TB vaccine community to better understand the immune response against

TB and help to design future efficacy studies."

SATVI: "We are proud to have completed the first efficacy trial of a new TB vaccine in 90 years, and believe the results will guide the TB vaccine field in the future," said Prof. Willem Hanekom, director of the South African TB Vaccine Initiative (SATVI). "The TB epidemic in our country is devastating – half a million South Africans develop the disease every year. Prevention by an effective vaccine would be the best way to get the epidemic under control. With this goal in mind, our group will continue to test multiple new vaccine candidates in the Worcester area. We are very grateful for the commitment of the local community in this effort."

Wellcome Trust: Dr. Ted Bianco, Director of Technology Transfer at the Wellcome Trust, said: "It is no mean feat to design and implement a trial of this kind and obtain a result as unequivocal as this. It is only through the difficult business of evaluating candidate vaccines in humans that we will really move forward in understanding how we might improve on BCG. I stand in admiration of the professionalism of this international team that understands the importance of well executed science, irrespective of the result one might have hoped for."

About TB Vaccine Development

BCG is the only licensed vaccine to prevent TB and it is used extensively with approximately 100 million newborns being vaccinated globally each year[1], according to the World Health Organization (WHO). While BCG can prevent severe forms of TB in some children, its widespread use in infants has failed to control the global epidemic.

Study Design

This Phase IIb study was a double blind, randomized, placebo-controlled trial investigating the safety, immunogenicity and efficacy of MVA85A in BCG-vaccinated infants.

The study, which began in 2009, was the first to evaluate MVA85A's ability to prevent TB disease following BCG vaccination. The study, in infants without TB disease or HIV infection, involved a 'prime-boost' strategy that used MVA85A to boost immune responses already primed by the BCG vaccine.

The study enrolled nearly 2,800 HIV-negative infants in the Western Cape province of South Africa. All of the infants that participated in the study received BCG at birth and then one half of the infants received a single dose of MVA85A at 4-6 months of age and the other half received a placebo (Candida skin test antigen). Approximately 93% of the infants enrolled completed the study and have been monitored for up to 37 months for any signs of TB disease. MVA85A was generally well tolerated and the vaccine had a safety profile comparable to other pediatric vaccines. The most frequent side effect observed was mild redness or swelling around the injection site following vaccination.

MVA85A is also being investigated in a Phase IIb efficacy study in people living with HIV in Senegal and South Africa, a Phase IIa study in infants born to HIV positive mothers in South Africa, and Phase I studies in the UK.

More About Tuberculosis (TB)

TB is an infectious disease that primarily affects the lungs and can be lethal if left untreated. Symptoms of TB disease can vary from person to person and by age, but may include a frequent, persistent cough (lasting three weeks or more), coughing up of blood, unexplained weight loss, decreased appetite, fatigue, fever, night sweats and chills, and chest pains.

Reference

1. World Health Organization,

   http://www.who.int/vaccine_safety/initiative/tools/BCG_Vaccine_rates_information_sheet.pdf

About Aeras

Aeras is a nonprofit biotech with a social mission, dedicated to advancing the development of new tuberculosis vaccines. In collaboration with global partners in Africa, Asia, North America and Europe, Aeras is supporting the clinical testing of six experimental vaccines as well as a robust portfolio of earlier stage candidates. Aeras receives funding from the Bill & Melinda Gates Foundation, the UK Department for International Development, and the Netherlands' Ministry of Foreign Affairs and a range of other governments. Aeras is based in Rockville, Maryland, Cape Town, South Africa, and Beijing, China.

Aeras was the regulatory sponsor for this Phase IIb clinical trial of MVA85A in infants. http://www.aeras.org/home/home.php.

About Emergent BioSolutions Inc.

Emergent BioSolutions (NYSE:EBS) is a specialty pharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats. More information is available on http://www.emergentbiosolutions.com/. Follow us on twitter: @emergentbiosolu

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 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. The University is rated the best in the world for medicine, and it is home to the UK's top-ranked medical school. From

the genetic and molecular basis of disease to the latest advances in neuroscience, Oxford is at the forefront of medical research. It has one of the largest clinical trial portfolios in the UK and great expertise in taking discoveries from the lab into the clinic. Partnerships with the local NHS Trusts enable patients to benefit from close links between medical research and healthcare delivery. A great strength of Oxford medicine is its long-standing network of clinical research units in Asia and Africa, enabling world-leading research on the most pressing global health challenges such as malaria, TB, HIV/AIDS and flu. Oxford is also renowned for its large-scale studies which examine the role of factors such as smoking, alcohol and diet on cancer, heart disease and other conditions.

MVA85A was developed at Oxford University. http://www.ox.ac.uk/

About SATVI

Established in 2001, the University of Cape Town's South African Tuberculosis Vaccine Initiative (SATVI) is the largest dedicated TB vaccine research group on the African continent. It is located within the Institute of Infectious Disease and Molecular Medicine of the University of Cape Town. Its mission is to conduct innovative, high-quality TB vaccine research in Africa and impact the global epidemic. A new, effective, affordable vaccine has the potential to save hundreds of thousands of lives worldwide. SATVI is conducting registration standard clinical trials of several novel TB vaccine candidates. It is also engaging in projects to address critical clinical, epidemiological, immunological and human genetic questions in TB vaccine development.

SATVI is conducting several studies of MVA85A, including the Phase IIb study of MVA85A in infants. http://www.satvi.uct.ac.za/

About Wellcome Trust

The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.

The Wellcome Trust is providing funding support for the development of MVA85A. http://www.wellcome.ac.uk/index.htm

Emergent 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, prospects, plans and objectives of management, and any other statements containing the words “believes”, “expects”, “anticipates”, “intends”, “plans”, “estimates” and similar expressions, are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company’s actual results 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 product candidates; our commercialization, marketing and manufacturing capabilities and strategy; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

Source: Emergent BioSolutions

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