AERAS℠

GLOBAL TB VACCINE FOUNDATION

Global TB Epidemic*

- *In 2007, 9.27 million people became sick with TB and 1.8 million people died from the disease*
- *Half a million people suffered from multi-drug resistant TB (MDR-TB)*
- *25% of TB deaths were HIV-related*

TB in South Africa*

- *461,000 people, including 336,000 people living with HIV (73%), developed TB in South Africa in 2007*
- *112,000 people in South Africa died of TB in 2007, including 94,000 people who were infected with HIV*
- *South Africa reports the highest rates of multi-drug resistant and extensively drug-resistant TB (M/XDR-TB) in the region*

Ongoing TB Vaccine Research in South Africa

- *Phase IIb safety & efficacy, MVA85A / AERAS-485, BCG-vaccinated infants*
- *Phase II safety & efficacy of AERAS-402/Crucell Ad35 in adults with HIV*
- *Phase II safety, AERAS-402 / Crucell Ad35, BCG-vaccinated adults with a history of pulmonary TB*
- *Phase I safety, MVA85A/AERAS-485, BCG-vaccinated adults with TB and/or HIV infection*
- *Phase I safety, SSI HyVac 4 (AERAS-404), BCG-vaccinated healthy adults*
- *Phase I safety, AERAS-402/Crucell Ad35, BCG-vaccinated infants*
- *Phase I safety, GSK M72, BCG-vaccinated adults*
- *Phase Ia safety, VPM1002, [target population]*

This trial is sponsored by Vakzine Project Management and the TuBerculosis Vaccine Initiative (TBVI)

** 2007, World Health Organization Global Tuberculosis Control 2009*

"We cannot win the battle against AIDS if we do not also fight TB. TB is too often a death sentence for people with AIDS."

- Nelson Mandela

Tuberculosis – A Global Epidemic

Tuberculosis (TB) is an airborne, infectious disease caused by bacteria which primarily affect the lungs. TB is a leading infectious disease killer and the leading cause of death for people living with HIV in Africa. The deadly relationship between TB and HIV, as well as the emergence of increasingly drug-resistant forms of TB, has created a pandemic that is even more severe and complex than it was when the World Health Organization (WHO) declared TB a global health emergency in 1993. In fact, today more people are suffering from TB than ever before. Without new tools and increased resources to fight TB, it would take more than a thousand years to eliminate the disease.

TB/HIV

HIV is the greatest risk factor for developing tuberculosis because its effect on the immune system makes people infected with HIV more susceptible to TB disease. The number of people who get sick with TB each year has more than doubled in countries with high HIV prevalence in the past 15 years.

The Global Plan to Stop TB

The Stop TB Partnership was established in 1998 as a network of international organizations, countries, donors, governmental and non-governmental organizations, and individuals working to eliminate TB as a public health problem by 2050 (<1 case per million population). The Stop TB Partnership's Global Plan to Stop TB 2006 - 2015 sets out the actions and funding needed over a ten-year period to accelerate progress toward that goal, and calls for universal access to diagnosis and treatment and the development of new tools to fight TB, including new diagnostics, drugs, and vaccines.

TB Vaccine Development – Transforming the Approach to Tuberculosis

An expanding cadre of researchers throughout the world is working to develop TB vaccines that are safe and effective against all forms of TB – including multi-drug resistant and extensively-drug resistant TB (M/XDR-TB) – for people of all ages, including people living with HIV. With sufficient resources and positive results from current clinical trials, we anticipate a new TB vaccine could be available by 2020.

The TB Vaccine Trial Sites Network (TBVACSIN)

The countries hardest hit by tuberculosis are playing a critical role in conducting TB vaccine clinical trials. Through the Tuberculosis Vaccine Trial Sites Network (TBVACSIN), TB vaccine clinical trial researchers are creating state-of-the-art TB research laboratories and infrastructure and learning from each others' experiences to conduct clinical research to the highest international scientific and ethical standards. Through TBVACSIN, clinical trial sites in South Africa, Kenya, Uganda, and Mozambique were recently awarded a grant from the European & Developing Countries Clinical Trials Partnership to conduct a multi-site trial of a new TB vaccine.

TB Vaccine Clinical Trial Sites in South Africa

The South African Tuberculosis Vaccine Initiative's (SATVI) clinical trial site in Worcester, supported by the Aeras Global TB Vaccine Foundation and others, is the most experienced TB vaccine clinical trial site in the world. TB vaccine clinical trials are currently ongoing at the site, ranging from small safety studies to the first Phase IIb preliminary efficacy trial of a new TB vaccine in infants in 80 years. The Aurum Institute is leading Phase II safety and efficacy clinical trial of a TB vaccine in people living with HIV. Working with support from Aeras, Aurum is conducting this trial in Klerksdorp.

The Aeras Global TB Vaccine Foundation (www.aeras.org) is a global non-profit research organisation funded primarily by foundations and governments working with scientists, academic institutions, industry, foundations, and governments throughout the world to ensure the rapid development and ample distribution of affordable vaccines to eliminate TB. Aeras has partner clinical trial field sites in South Africa, Kenya, Uganda, Mozambique, Cambodia, and India. At each partner field site, Aeras supports the development of infrastructure, such as offices and laboratories, necessary for TB vaccine clinical trials. Aeras' Africa Office was established in Cape Town in May 2008 to enable the Foundation to work more closely with partner clinical trial field sites.

The South African Tuberculosis Vaccine Initiative (SATVI) (www.satvi.uct.ac.za) of the University of Cape Town (UCT) is currently the largest dedicated African TB vaccine clinical research group. Established in 2001, SATVI is conducting groundbreaking TB vaccine research at its site 120km from Cape Town in the Boland, an area with one of the highest rates of TB in the world (1400 / 100 000) in which HIV and TB are the main causes of death. It has the infrastructure and capacity to conduct large-scale TB vaccine clinical research, having conducted large-scale epidemiological TB studies in babies and teenagers as well as a Phase IV trial involving 12 000 infants. SATVI is currently testing four TB vaccine candidates, including one that has recently entered the first Phase IIb preliminary efficacy trial of a new TB vaccine in infants in more than 80 years. SATVI has cutting edge laboratory facilities based at the University of Cape Town, where it conducts immunology studies to measure the body's responses to vaccine candidates. The laboratory also focuses on understanding how our immune systems protect us against TB, which is important information for further TB vaccine development.

The University of Cape Town Lung Institute (www.lunginstitute.co.za) is located on the campus of the Faculty of Health Sciences. It provides clinical services and conducts research in the fields of respiratory medicine, tuberculosis, allergy, occupational medicine, and dermatology. Special emphases in research are epidemiology, allergy diagnostics, lung physiology, clinical pharmacology, evaluation of novel treatments, and community-based interventions for improving disease management and improving health. In association with various departments of the University, the Lung Institute provides training for students in the health professions and collaborates broadly with training and research institutions elsewhere in South Africa and abroad.

The Aurum Institute (www.auruminstitute.org) is an internationally-recognised, specialist research and health systems management organisation. Its focus is TB and HIV prevention, treatment, and care. The negative impact of the poor understanding and management of these epidemics is vast, affecting individuals, communities, and economies. The recognition of the huge advantages of controlling these diseases is Aurum's motivation. Aurum has an international reputation for its work in the fields of tuberculosis and HIV/AIDS and is the recipient of research and other grants from South African and international agencies and institutions for this work. In the field of TB in particular, Aurum is conducting a number of groundbreaking studies into the prevention of TB in gold mineworkers. This research has the potential to shift policy and practice in TB management worldwide. Aurum is based in Johannesburg, South Africa with operations throughout the country and collaborations across the globe.

Aeras Global TB Vaccine Foundation
+27 (0) 21 659 8440
info@AerasSA.org

South African Tuberculosis Vaccine Initiative
Linda Rhoda
Communications Manager
+27 21 406 6697
Linda.Rhoda@uct.ac.za

University of Cape Town Lung Institute
Eric Bateman
Professor of Respiratory Medicine
+27 21 406 6901
Eric.Bateman@uct.ac.za

The Aurum Institute
Jennifer Heslop Spencer
Communications
+27 83 778 1729
media@auruminstitute.org