



## All-Party Parliamentary Group on Global Tuberculosis

**Chairs: Andrew George MP  
Nick Herbert MP  
Julie Morgan MP**

**Minutes from meeting with Dr. Jerald C. Sadoff,  
President and CEO of Aeras Global TB Vaccine Foundation**

**Wednesday 16 May 2007**

**Speaker:** Dr. Jerald C. Sadoff

**Participants:** Andrew George MP (Chair)  
Ann Cryer MP  
Jeremy Hunt MP  
Julie Morgan MP  
David Burrowe MP  
Baroness Lindsay Northover  
Veronica Karunde-Rogers  
Becky Owens, Aeras  
Derek Bodell, Global Health Strategies  
Gavin Bryce, Action for Global Health  
Louise Holly, RESULTS UK  
Bénédicte Piton, RESULTS UK

### **Welcome**

Andrew George MP (AG) welcomed Dr. Jerald C. Sadoff (JS), President and CEO of Aeras Global TB Vaccine Foundation and thanked him for the opportunity to learn more about Aeras' work and mission.

As one of three co-chairs of the APPG on TB and chairman of the meeting, AG noted that the APPG's *Agenda for Action* recognises the need for greater research and development into new TB control tools and the importance of a new TB vaccine. AG invited participants to introduce themselves before asking JS to proceed with his presentation.

### **Presentation by Jerald C. Sadoff**

#### **Introduction**

JS described the Aeras Global TB Vaccine Foundation as an international, non-profit product development partnership (PDP). He explained that Aeras' mission was to develop new, more effective TB vaccines and ensure their availability to all who need them, aiming at creating a new TB vaccine in 7 – 9 years.

JS recalled the following key facts:

- In 2005, there were 1.6 million deaths and 8.8 million new cases of TB
- 2 billion people were infected with latent TB
- One third of people living with HIV/AIDS are co-infected with TB, with the highest burden in Sub-Saharan Africa and Southeast Asia.

- TB accelerates the progression of HIV into AIDS and is the leading cause of death of HIV positive people.

He also highlighted the progression of MDR-TB and XDR-TB (i.e. resistant to the most common first line drugs and at least two classes of second line drugs) worldwide. A new TB vaccine could ultimately protect people from MDR and XDR as well as standard forms of TB.

He then emphasized that, although it reduces the risk of severe pediatric TB disease, the current BCG vaccine had proved an unreliable protection against adult pulmonary TB, which accounts for most TB worldwide.

Furthermore, despite wide use, BCG has had no apparent impact on the growing global TB epidemic and is not known to protect against latent TB.

### **The crucial need for a new vaccine**

With the development of new forms of TB and as there has been no new TB vaccine in 86 years since the BCG vaccine was created, it is crucial that increased efforts should put into research into new TB vaccines.

TB will not be eliminated without a new vaccine.

A new TB vaccine could potentially:

- Achieve global TB control in 15-20 years, if it is 50-70% better than BCG and used in conjunction with better drugs and diagnostics
- Minimise TB as a global threat by 2050

### **New research financing mechanisms**

JS distinguished between the existing new research financing mechanisms:

- Non-profit Product Development Partnership or PDPs (“push mechanisms”)
  - They provide resources for “translational research” (lab to clinical trial)
  - They perform preclinical technical assessments and clinical development of new products
  - They increase Net Present Values for low margin markets
- Advance Market Commitments or AMC (“pull mechanisms”)
  - Donors commit to buying vaccine when it is developed
  - This guarantees return on investments for successful product
  - 1st AMC for pneumococcal disease is worth \$1.5 billion; an AMC for TB is also needed

### **Barriers for industry**

JS recalled that, although the need for TB vaccines was greatest in the developing world, new vaccines are generally licensed for the industrialised world first and made available to developing countries 10 to 20 years later.

Aeras is committed to developing new TB vaccines which can be licensed for use in the developing world as soon as possible.

Pharmaceutical companies are reluctant to invest in new TB vaccine research because of scientific uncertainty, the uncertain return on investment, the lack of vaccine development capacity and the opportunity costs (low margin TB vaccine vs. high margin “lifestyle” drug).

## **How Aeras works**

Aeras aims at developing TB vaccines and ensuring full availability and access to all who need them.

One of Aeras’ main objectives is to offer at least one new TB vaccine regimen for infants and one for adolescents within 7-10 years.

In addition, as a Product Development Partnership, Aeras endeavours to focus global TB vaccine efforts by working with industry, academia, philanthropy and government to develop vaccines and conduct clinical trials and developing vaccines in its own lab and manufacturing plant.

Aeras ensures its partners receive support for preclinical development, epidemiology and field site preparation and support for clinical trials. In return, Aeras receives partner involvement in disease with developing country markets, product development and production support as well as the guarantee of affordable access to developing world.

Aeras conducts its clinical trials in high TB burden countries/regions. It currently works in field sites in South Africa and India, is developing sites in Kenya and Uganda with the European and Developing Countries Clinical Trials Partnership (EDCTP) and is seeking additional field sites in Asia (China, Viet Nam or Indonesia).

It also builds local health care/research capacity and contributes to building human capacity and local research profession thanks to its Professional Development Programme.

## **Aeras’ current projects**

Research on six different vaccine candidates is currently being carried out. All candidate vaccines induce enhanced protection compared to BCG in animal models and cellular immune responses in humans or non-human-primates.

## **UK’s commitment to global health**

JS acknowledged the UK as a key donor to the Global Fund to Fight Aids, TB and Malaria and the Stop TB Partnership, as well as a global leader in recognition and support of PDPs for neglected diseases.

The British government is committed to reaching UN goal of 0.7% of national income dedicated to foreign aid by 2013 and supports AMC for pneumococcal vaccines.

DFID is also serving as chair of PDP Funders Group.

## **Funding Gap for TB Vaccine Development**

A total of US \$3.641 billion are needed to fund TB vaccine development between 2006 and 2015, with discovery and translational research, clinical trials and manufacturing scale-up being the most under-funded development phases.

At present, there is a US \$1.5 billion funding gap (US \$2.1 billion expected to be available).

Aeras needs to raise US \$20 million annually until 2010 with funding needs increasing to US \$30 million per year after 2010 for phase 3 trials.

Additional contributions from major country donors such as the UK are crucial to the continuation of Aeras' research projects. Aeras is currently looking for donors to fund the trials of its six candidate vaccines.

### **Aeras TB Vaccine Development Needs**

Aeras needs support in order to:

- Advance development of multiple lead and back-up vaccine candidates
- Build capacity and support research in developing countries
- Manufacture and scale up vaccines
- Ensure access for developing countries