A Better Tuberculosis Vaccine: Aeras and Vanderbilt University

Tuberculosis (TB) is a contagious disease caused by the bacterium *Mycobacterium tuberculosis*. Approximately two billion people (one-third of the world's population) are infected. A TB infection causes active disease in only about five to ten percent of these individuals. The remaining individuals have latent disease that causes no obvious symptoms and cannot be passed on to others. The disease can become active when the immune system is weakened (most commonly when individuals contract HIV/AIDS). TB caused an estimated 1.7 million deaths in 2004 with the highest number of deaths occurring in Africa.

In 1921, BCG (Bacille Calmette-Guerin), the current TB vaccine, was developed using *Mycobacterium bovis,* a bacterium related to *M. tuberculosis*.[1] However, epidemiological evidence indicates that the effectiveness of BCG diminishes over a person's lifetime. In addition, the current TB treatment regimen is complicated. It requires patients to take as many as four different drugs for at least six months. Of even greater concern, a multi-drug-resistant strain of the bacterium is emerging. Therefore, an improved TB vaccine would be highly valuable in the effort to stop TB.

The Aeras Global Vaccine Foundation (Aeras)[2] was founded in 1997 with the mission to develop and to ensure access to new, effective TB vaccines. Aeras adheres to an industrial model of vaccine development, having created a pipeline of lead and back-up TB vaccine candidates. These include vaccines for initial vaccination and boosters for infants and adolescents. Aeras is also developing vaccines to protect against the activation of latent infections and second-generation technologies with improved product profiles. Aeras has established infrastructure for both preclinical development and clinical trials. They have recently opened a manufacturing facility in Maryland that is capable of providing 150 million annual vaccine doses by 2010. The Bill and Melinda Gates Foundation[3] recently awarded Aeras a grant of US$82.9 million to develop a new TB vaccine. Aeras's goal is to obtain regulatory approval for a new vaccine regimen in seven to ten years.

On May 4, 2006, Aeras and Vanderbilt University[4] announced an exclusive license agreement for a TB vaccine based on technology developed at Vanderbilt. The technology enhances the ability of the BCG vaccine to trigger immune system responses. Under the agreement, Aeras will use the technology to modify the BCG vaccine and will guide the new vaccine through clinical trials. The license agreement grants Aeras exclusive rights for developing a TB vaccine. If a successful vaccine results from the use of this technology, then Aeras will manufacture the new vaccine at its facility in Rockville, Maryland. Vanderbilt retains rights to the technology as a delivery system for other uses. This could potentially include new vaccines or immunotherapies against other diseases from HIV and malaria to cancer.

The Vanderbilt technology, called pro-apoptotic BCG, is designed to weaken the BCG virus. It is a version of BCG with genetic modifications designed to inhibit the bacterium's ability to stop the programmed cell death of a patient's immune cells. These modifications are likely to result in a vaccine that provides

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better, longer-lasting protection against TB and may prevent progression to active TB among people with compromised immune systems.

PARTNERS

The Gates Foundation awarded funding to Aeras Global TB Vaccine Foundation, a product development partnership, to develop the TB vaccine. Vanderbilt University developed the technology upon which the new vaccine will be based.

PROGRESS, CURRENT STATUS, AND GOALS

The goal of the project is to develop a new TB vaccine and conduct clinical trials to secure regulatory approval. Aeras has established test sites for the vaccine near Bangalore, India, and Cape Town, South Africa. Aeras's goal is to obtain regulatory approval for a new vaccine regimen in seven to ten years (with either the pro-apoptotic BCG or another candidate).

DEALS

Vanderbilt University granted Aeras an exclusive license in the TB field of use. Vanderbilt retains rights in other fields. The license is royalty bearing (including stacking terms) and stipulates milestone payments. Patent costs are paid by Aeras. ■

For further information, please contact:

AERAS GLOBAL TB VACCINE FOUNDATION, *Rita Khanna, Ph.D., J.D., Legal Counsel, Aeras Global TB Vaccine Foundation, 7500 Old Georgetown Road, Suite 800, Bethesda, MD 20814, U.S.A. rkhanna@aeras.org*

VANDERBILT UNIVERSITY, *Christopher D. McKinney, Director, Vanderbilt University Office of Technology Transfer and Enterprise Development, 1207 17th Avenue South, Suite 105, Nashville, TN 37212, U.S.A. chris.mckinney@vanderbilt.edu*

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1 See, for example, www.metrokc.gov/health/tb/bcg-vaccine.htm.

2 Aeras Global TB Vaccine Foundation. www.aeras.org.

3 Bill and Melinda Gates Foundation. www.gatesfoundation.org.

4 Vanderbilt University Office of Technology Transfer and Enterprise Development. www.vanderbilt.edu/technology_transfer.