

New TB vaccine enters clinical testing

September 23 2010

At an international gathering of TB vaccine researchers in Tallinn today, the Aeras Global TB Vaccine Foundation announced it will initiate a clinical trial of an investigational live recombinant tuberculosis vaccine to be led by researchers at Saint Louis University in St. Louis, Missouri, USA. The announcement was made at the Second Global Forum on TB Vaccine Development.

Building on more than a decade of global scientific research, Aeras scientists have engineered a new investigational vaccine, called AERAS-422, which will undergo [clinical trials](#) to evaluate its properties for interrupting TB at all stages of infection, including initial infection, latency and reactivation.

"Moving our lead in-house vaccine from the laboratory into clinical testing is an important milestone for Aeras and its partners. Finding a potential replacement for the currently available TB vaccine, which was invented almost 90 years ago, is a primary goal in our mission," said Thomas G. Evans, MD, Aeras' Chief Scientific Officer. "Based on data from pre-clinical studies, we are cautiously optimistic about the potential of this [vaccine candidate](#) to be safer and more immunogenic than the currently available vaccine."

The new vaccine, called AERAS-422, is a modernized version of the currently used TB vaccine - Bacille Calmette Guérin (BCG). BCG is widely viewed as insufficient in preventing pulmonary TB, and this trial is part of a wider global effort to develop safer and more immunogenic TB vaccines that would be effective against all forms of TB.

AERAS-422 has been modified with an endosome escape mechanism and over-expresses three key proteins: 85A, 85B and Rv3407. The bacterium that causes TB hides inside cells. Therefore, the endosome escape mechanism is designed so that the proteins will escape an internal compartment of the cell and be more efficiently presented to the immune system to elicit a greater protective response in the body.

"The TB epidemic continues to become more complex and difficult to control, especially in South Africa where resistance to available TB treatments is on the rise," said Bernard Fourie, PhD, Chief Scientific Officer of Medicine in Need and Managing Director of Mend South Africa. "The scientific community has made developing a safer and more effective TB vaccine a priority and we are pleased that there is progress in the field."

The Phase I clinical trial to test the safety of AERAS-422 will be led by Principal Investigator Daniel Hoft, MD, PhD, at Saint Louis University's Center for [Vaccine Development](#). The trial will enroll healthy adults who have never received a vaccination against [tuberculosis](#). Dr. Hoft's team will also conduct initial immunological assessments.

"The TB vaccine field has made tremendous progress over the past 10 years," said Daniel Hoft, MD, PhD, of the Center for Vaccine Development at Saint Louis University. "Not only is the start of the clinical trial of AERAS-422 another important benchmark in the search for more effective TB vaccines, it is also an opportunity to learn more about cellular immunity, a less well understood but critically important component of TB vaccine development."

Aeras is pursuing a TB vaccine development strategy based on a prime-boost approach that incorporates an initial BCG or recombinant BCG vaccination for infants at birth to be followed by a booster vaccine later in infancy to adolescence. In addition to AERAS-422, developed as a

"prime," Aeras is also supporting the clinical development of four [TB vaccine](#) candidates designed as "boosters" in the prime-boost [vaccine](#) scenario. Two have reached the Phase IIb proof of concept stage.

Provided by Aeras Global TB Vaccine Foundation

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