AERAS

TUBERCULOSIS VACCINE DEVELOPMENT

The United Nations endorsed a new set of Sustainable Development Goals in September 2015, to guide international efforts to fight poverty. A core component of these goals is the target to end the tuberculosis (TB) epidemic by 2030, which can only be achieved if new tools, including improved TB vaccines, are developed.

A NEW TB VACCINE IS THE BEST HOPE – AND A COST-EFFECTIVE STRATEGY – FOR ENDING THE TB EPIDEMIC

- The estimated cost of developing a safe, cost-effective TB vaccine is about US $1 billion over the next 10-15 years.
- According to the World Health Organization, it will cost about US $8 billion a year to respond to the TB epidemic in low- and middle-income countries with current tools, and these costs will only rise as the challenge of TB drug resistance continues to worsen.
- Considering the annual economic toll of TB, the relative cost to develop a new TB vaccine is nominal given the potential to eliminate TB as a public health problem.

HISTORY AND PROGRESS (2000-2015)

- The current BCG (Bacille Calmette-Guerin) vaccine dates back to the 1920s and is only moderately effective in preventing severe TB in infants and young children. It does not adequately protect adolescents and adults, who are most at risk for developing and spreading TB.
- Substantial progress has been made to develop new TB vaccines with 13 vaccine candidates now in the global TB vaccine clinical pipeline and a growing preclinical pipeline.
- Globally acceptable criteria for selecting, assessing and advancing only the most promising vaccine candidates through the research and development pipeline have been introduced which will help reduce the burden on governments and donors by ensuring that only the most promising products are developed.

PROGRESS IN 2015

Exciting vaccine candidates are advancing:

- A novel proof of concept trial, evaluating the ability of the Sanofi candidate, H4, to prevent sustained infection (POI) in adolescents in a high-burden setting is underway, with results expected late 2016. POI is a new innovative study design that can shorten the duration and reduce costs of identifying effective vaccines.
- A major, late-stage clinical trial for a GSK vaccine candidate called M72 has completed enrollment, and results are expected in late 2018.
- Two subunit vaccines, H56 and ID93, have been shown to be safe and immunogenic in Phase 1 studies.
- An attenuated *M. tuberculosis* vaccine candidate developed in Europe, MTBVAC, demonstrated safety and a good immune response in European adults, advancing into a trial to learn about safety and immunogenicity in South African infants, a key target population.
- Serum Institute of India (SII) has advanced a vaccine candidate called VPM1002, a modified BCG, into late-stage clinical testing in infants, to examine its safety and efficacy compared to standard BCG.

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THERE HAS BEEN A SIGNIFICANT IMPROVEMENT IN UNDERSTANDING OF TB

Developing an improved TB vaccine is challenging, but scientific evidence indicates that it is possible, and progress is being made:

- For the first time in decades, basic information on safety and immune responses to a variety of first-generation TB vaccine candidates is available, demonstrating that some candidates can boost protection in animal models, compared to BCG alone.
- Novel animal models of natural transmission are being developed that can facilitate the testing of new candidates.
- We have shown that conducting biological endpoints and efficacy trials are feasible, safe, and meaningful.
- Modern molecular techniques are being used to attempt to develop a safe, predictive TB human challenge model, which would revolutionize the field of early clinical vaccine assessment.
- New trial designs are being implemented to test (1) whether novel vaccines or the use of BCG re-vaccination can prevent TB infection (as opposed to disease) and (2) whether a vaccine can prevent relapse and/or reinfection following successful treatment of TB disease.

THE WAY FORWARD

TB vaccine research requires novel and bold approaches, the best science, and a sustained commitment from communities, governments, policy makers, civil society, industry and academia.

- Focus resources on solving the toughest scientific challenges.
- Foster innovation through collaboration with public and private partners around the world.
- Support innovation and new researchers to diversify and replenish the preclinical pipeline.
- Develop and implement novel clinical trial designs to streamline vaccine development.
- Only advance the most promising vaccine candidates using harmonized, stringent and objective criteria.
- Build long-term political and financial commitment.

ABOUT AERAS

Aeras is a non-profit Product Development Partnership (PDP) advancing the development of new TB vaccines for the world. Aeras receives support from governments and organizations, including the Bill & Melinda Gates Foundation, the US National Institute of Allergy and Infectious Diseases and National Institutes of Health, UK Department for International Development, the Global Health Initiative Technology Fund, and pharmaceutical organizations.

AERAS | Advancing Tuberculosis Vaccines for the World

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