New Horizons for TB Vaccine Research

IJmuiden, 10 February 2015

Line MATTHIESSEN, MD, PhD
Head of Unit - 'Fighting infectious diseases and global epidemics',
Health Directorate
Directorate-General for Research and Innovation
European Commission
EU leadership in TB vaccine R&D

- 75% of the global TB vaccine portfolio either originates in Europe or is being developed in partnership with European public or private organizations.
- Europe is the world’s biggest manufacturer of vaccines.
- EC, Dutch and British governments represent 3 of the top 5 global donors.
- EC has invested more than €34M in TB preclinical research 2000-2013.
- EC has invested via EDCTP more than €42M towards site preparedness, capacity building and support for TB clinical trial in Africa.
- EU invested via Horizon 2020 € 26,2 M in TB preclinical research in 2014.

"Horizon 2020, and particularly EDCTP-2, will be a new journey that will open more avenues for collaboration between Africa, Europe and the rest of the world to address global health challenges such as tuberculosis."

3rd Global Forum on TB Vaccines, March, 2013 (video address)
Vaccine R&I in infectious diseases
FP7 HEALTH cooperation programme
Total: 43 projects, EU budget EUR 234m

EC contribution per infectious diseases area (million EUR)

- AMR: 25.49 (11%)
- PRD: 82.67 (35%)
- EE: 41.50 (18%)
- NID: 42.37 (18%)
- Multiple diseases: 42.18 (18%)

Number of projects per infectious diseases area

- AMR: 5
- PRD: 16
- EE: 10
- NID: 9
- Multiple diseases: 3

AMR: Antimicrobial resistance
EE: Emerging epidemics
NID: Neglected infectious diseases
PRD: Poverty-related diseases
Multiple diseases: cross-infectious diseases area
EU support in vaccine R&I: strategy

Discovery | Preclinical | Phase I | Phase II/III | Regulatory | Vaccine

Implementation modalities
- Small/Large collaborative projects
- EDCTP clinical trials program

IMI - precompetitive technology, bottlenecks, few vaccine projects
- Translational research
- Clinical capacity

BioVacSafe, Advance
Horizon 2020: Societal challenges: Health, Demographic change and wellbeing
TB vaccine research projects

**TBVAC2020**
Advancing novel an promising TB vaccine candidates from discovery to preclinical and early clinical development

- 40 partners
- Total EU Budget: €18.2 million
- Project start: January 2015
- Duration: 4 years

**EMI-TB**
Eliciting mucosal immunity in tuberculosis

- 14 partners
- Total EU Budget: €8.0 million
- Project start: January 2015
- Duration: 4 years
HORIZON 2020

VACCINE RESEARCH AND INNOVATION LANDSCAPE

- Health, Demographic Change And Wellbeing
- Food, Security, Sustainable Agriculture, Marine and Maritime Research and the Bioeconomy
TB will not be eliminated by 2050 without breakthroughs from the R&D pipeline

Today TB incidence >100x higher than elimination target for 2050

Current rate of decline - 2%/yr (globally)

China, Cambodia -4%/yr (the best observed nowadays)

W Europe after WWII - 10%/yr (Historical example)

Elimination target:<1 / million / yr -20%/yr
... and WHO goal to eliminate TB by 2050 unlikely to be met without a new, effective vaccine to interrupt transmission

Source: WHO report - Global strategy and targets for tuberculosis prevention, care and control after 2015
New TB vaccines offer opportunity for global health impact and market potential

Avert millions of new TB cases and save lives

New TB vaccine could contribute to a significant decline in TB incidence
• Substantial decline needed to achieve WHO goals

Support meaningful financial returns

Economic studies indicate market potential for TB vaccines in high and middle income countries
• Opportunity for innovative financing such as loans, equity, procurement in later stages of development

Opportunity to bring together traditional funding and new, innovative financing to support sustainable TB Vx development

Source: WHO Global Tuberculosis Report 2013
How do we increase the likelihood of success, of being able to introduce efficient TB vaccines by 2025?
Global TB Vaccine Partnership (GTBVP) aims to achieve two complementary objectives

1. Increase the likelihood of successful and cost-efficient TB vaccine development by building alignment around global portfolio priorities
   - Ensure funds are spent efficiently and channeled to the most promising clinical candidates, minimizing duplication of effort and making investment in TB vaccine development more attractive

2. Promote and facilitate access to sustained financing for priorities
   - Create a mechanism to facilitate greater alignment among current funders, and attract new and innovative funding to support TB vaccine development in later stages

We are seeking your input on **how we can work better together** to achieve these objectives
GLOBAL TUBERCULOSIS VACCINE PARTNERSHIP (GTBVP)  
"Moving towards Tuberculosis Vaccine Global Portfolio Management "  
Barcelona 27th October 2014

'The Barcelona process': Working groups to develop position papers:

WG1: Experimental medicine. Tasked with assessing and agreeing on operational and scientific strategy in executing an experimental medicine paradigm within the GTBVP.

WG2: Portfolio management. Tasked with developing a scientific consensus on the operational characteristics of a portfolio management process that can implement both classical product development strategies as well as hypothesis driven experimental medicine approaches.

Consultation process. Results to be discussed in a major TB conference 2015.
Thank you for your attention!

Find out more: www.ec.europa/research/horizon2020