Urgent Need for Global Investment in TB Vaccines

Stop TB Partnership Board Meeting
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Chief Executive Officer
Aeras
Vaccines: An Extraordinary Track Record

“A more effective vaccine would be the single most powerful tool to reduce the incidence of TB.”
— The Bill & Melinda Gates Foundation

**Measles Stats**
- 2000 – 853,480 cases\(^1\)
- 2012 – 226,722 cases\(^2\)
73.5% decline worldwide between 2000–2012, after global increase in immunization

**Smallpox Stats**
- 1950s – 50,000,000 cases every year\(^3\)
- 1980 – 0 cases\(^4\)
100% reduction (eradicated)

**Polio Stats**
- 1988 – 350,000 estimated cases
- 2013 – 406 reported cases
99% decrease since the launch of the Global Polio Eradication Initiative in 1988\(^5\)
We need a more effective vaccine than BCG
Global Strategies

All rely on new tools, including better:

- Vaccines
- Drugs
- Diagnostics

UN Sustainable Development Goals

WHO’s End TB Strategy

Global Plan to End TB 2016-2020
We will not meet our goals and end the TB epidemic without new, more effective vaccines.

Source: WHO Health Assembly 2014
New Effective TB Vaccines are Achievable

- 14 vaccine candidates in the global TB vaccine clinical pipeline, a growing preclinical pipeline and new tools
- Understand more about the human immune response to TB & risks for developing TB disease
- Recent data from human trials show potential for new vaccination strategies and hope for new vaccines (Ph 2 Study with BCG/H4:IC31)
  - Additional data coming this summer adding to the growing pool of new knowledge (Ph2 Study M72)
- Novel clinical trial designs opening up new paths to get answers faster and more cost effectively
Global Clinical Pipeline

Information on candidates in clinical development is self-reported by vaccine sponsors, coordinated by the Working Group on New TB Vaccines and updated February 2018.
Severe Economic Impact of TB Disease

- Annual global cost of TB is $18.9B
  - $6.9B = cost of prevention, diagnosis and treatment\(^1\)
  - $12B = economic impact (lost productivity, wages)\(^2\)
- Still not identifying and treating 1/3 of population with TB disease
- Global use of a new, more protective TB vaccine would be a far more cost effective solution

Sources: 1. WHO. Global TB Report 2017; 2. WHO. Trade, foreign policy, diplomacy and health; Tuberculosis Control
Antimicrobial Resistance: TB is one of top 3 AMR Threats

- WHO estimates ~490K new cases of AMR TB in 2016
  - Only ¼ of these were detected & reported
  - 4.1% of all new TB cases in 2016
- Cost of care is higher due to longer-lasting illnesses, more tests & costlier Rx drugs
  - Only 54% of AMR patients were successfully treated in 2016
- Cost implications if AMR is not controlled:
  - US $100T by 2050 if AMR is not controlled
  - 10M lives lost per year, 2.5M from TB

Source: WHO Antimicrobial Resistance Fact Sheet, January 2018
Global Under Investment in TB R&D

- TB is #1 Infectious Disease Killer in the World
- A minimum of US $2B per year is needed for all TB R&D, but from 2005-2015, funding has never exceeded $0.7B per year
- TB vaccine R&D investment in 2016 was only ~13% of all TB R&D (US $95M vs $726M)
- 3 funders provided 74% of all global funding for TB vaccine R&D in 2016
  - Diversification and expansion is critical

Source: TAG 2017 report “The Ascent Begins”
TB vaccine research is severely underfunded

We cannot afford to *not* invest.

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<tr>
<th>Number of Deaths in 2016</th>
<th>AMOUNT OF RESEARCH &amp; DEVELOPMENT INVESTMENT</th>
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<td>TB 1.7 Million</td>
<td>$95.4 Million</td>
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<td>HIV 1 Million</td>
<td>$894 Million</td>
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<tr>
<td>Ebola 11,310</td>
<td>$244.6 Million (from start of outbreak)</td>
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Sources:
- http://www.who.int/mediacentre/factsheets/fs104/en/
- http://www.treatmentactiongroup.org/tbrd2017
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5112007/
What Would it Take to Succeed?

With $1 Billion US we could:

• Accelerate development activities that could impact epidemic
• Attract new researchers to the field
• Accelerate scientific progress and innovation
  – Identify immune correlates of protection
  – Investigate better strategies for use of BCG
  – Confirm predictability of POI trials to prevent disease
  – Advance pipeline candidates toward licensure
  – Further develop tools such as CHIM and refine animal models
The Cost of Inaction

Delaying investing in new tools by just five years could result in a tremendous human and economic toll

By 2030, it would mean:

• 8.4M new cases
• 1.4M more deaths
• US $5.3B more in treatment costs
• US $181B in lost productivity

Source: The Global Plan to End TB 2016-2020
### Summary

**Urgent need for TB Vaccine R&D**

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<tr>
<th>CHALLENGES</th>
<th>HOW TO ADDRESS</th>
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<td>1. Severe under-investment in vaccine R&amp;D</td>
<td>Make new vaccines a key piece of any strategy to end TB</td>
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<td>2. Lack of awareness that new TB vaccines are essential to stop the epidemic within target timelines</td>
<td>Ensure innovation, investment and inclusion</td>
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AERAS | Advancing Tuberculosis Vaccines for the World  
StopTB Partnership | Working Group on New TB Vaccines  
TBVI
Requests for the Stop TB Partnership Board

• To ensure the inclusion of the WGNV and partners in the preparation work leading to the UN HLM

• To advocate for the inclusion of vaccines specifically within the UN HLM political declaration
Thank You