AERAS

Tuberculosis Market Assessment; a case for investment in R&D

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New Sense of Urgency

Urgent need for new preventative vaccines

Tuberculosis epidemic in the 21st century:

$8 billion a year for TB treatment and care in low and middle income countries alone

We know TB has mutated and evolved

- XDR diagnosed in 77 countries
- Total drug resistant disease reported in India, Iran and Italy
- MDR-TB prevalence will increase by 150% by 2036 without changes to DOTS or DOTS+ (Sze-chuan Suen, 2012. (SMDM))

WIRED

"India Reports Completely Drug-Resistant TB"

BBC

"Drug-Resistant TB Rising in UK"

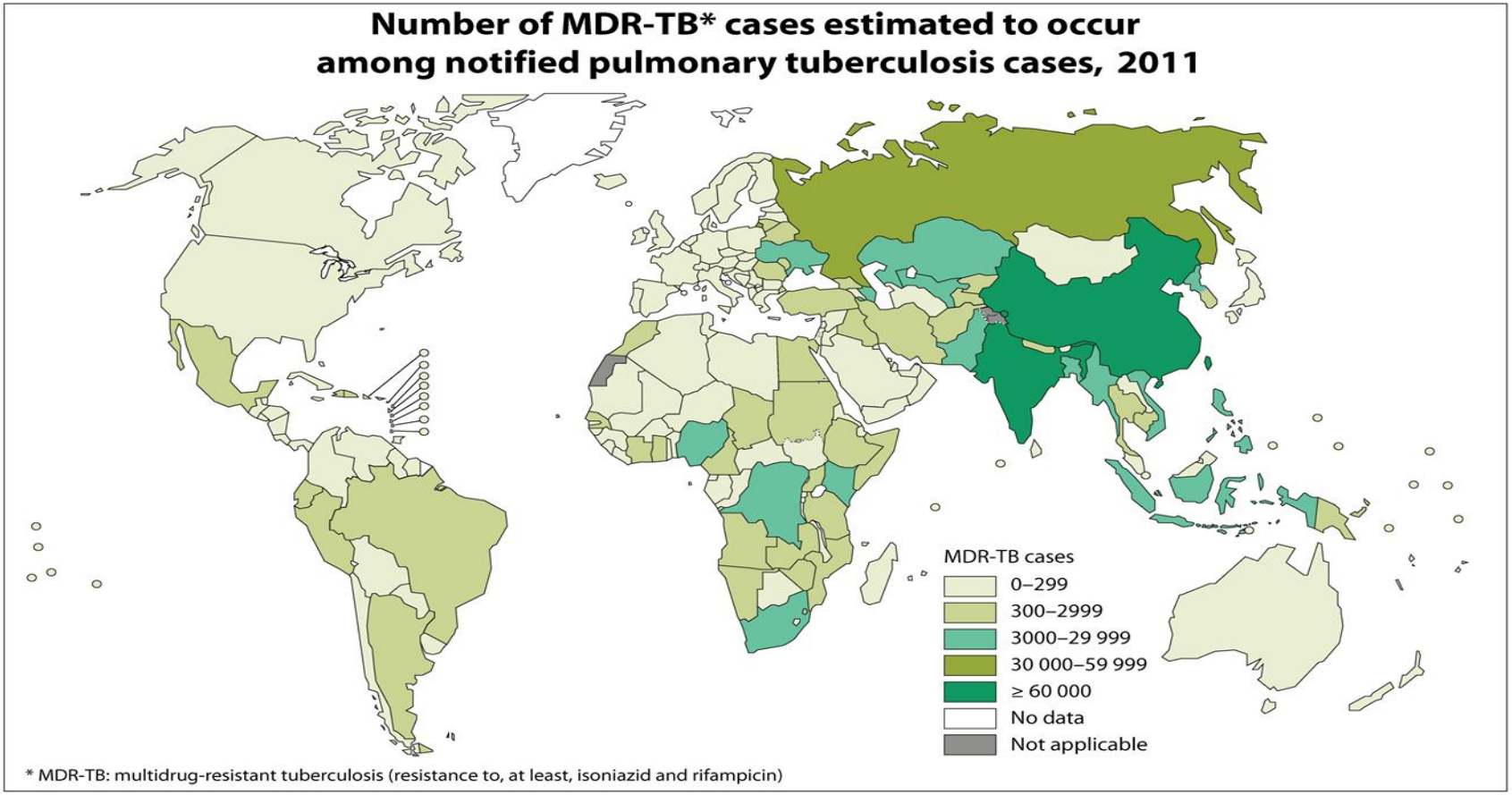
The NEW ENGLAND JOURNAL of MEDICINE

"China has a serious epidemic of drug-resistant tuberculosis."

abc NEWS

"WHO Warns of Untreatable TB"

We have the data and the evidence



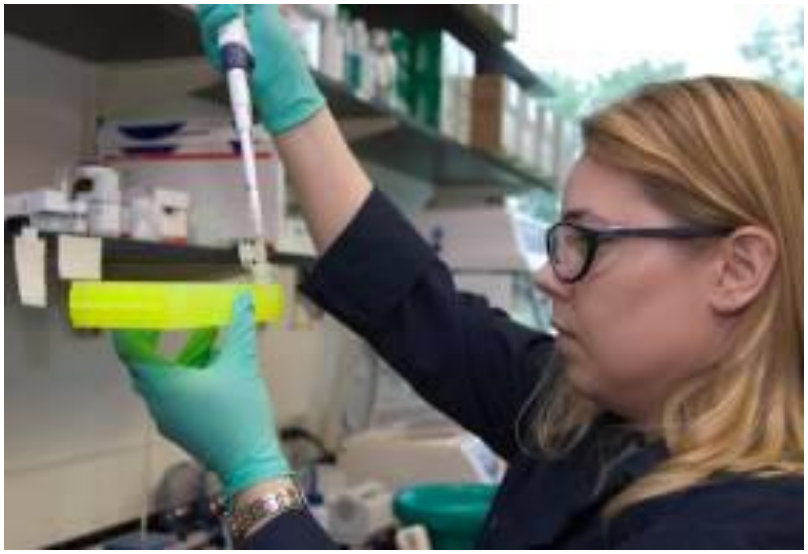
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Source: *Global Tuberculosis Report 2012*. WHO, 2012.

World Health Organization

TB VACCINE DEVELOPMENT 2013-2014

Strategies for TB Vaccine Development



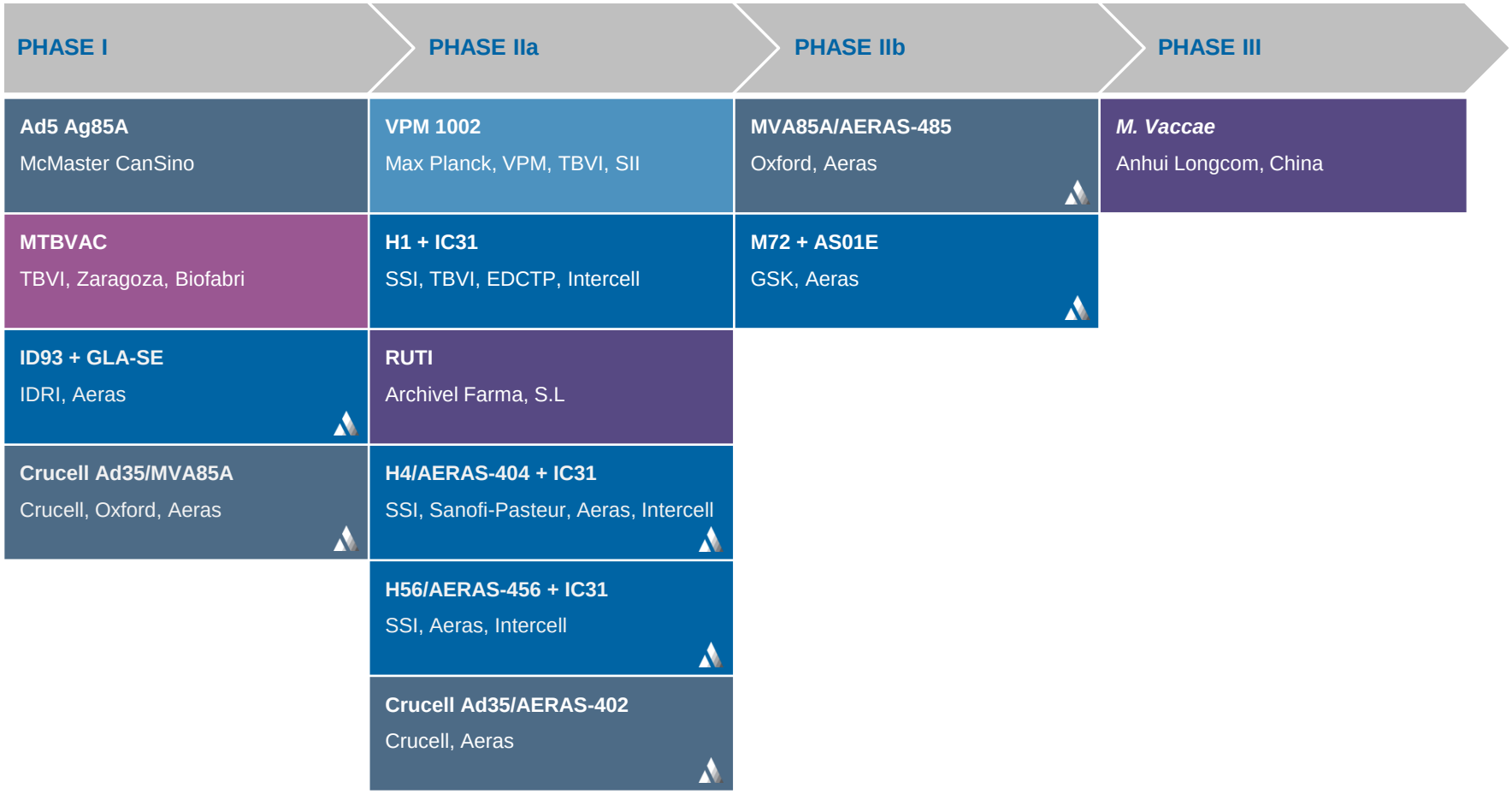
Preventive Vaccines: Prime-Boost Regimen

- Improve the prime - recombinant BCG (rBCG) or live *Mtb* vaccine
- Develop novel booster vaccines to extend and enhance immune protection

Immunotherapeutic Vaccines: Boost

- Prevent relapse or reinfection following treatment
- Shorten the course of chemotherapy

The Global Pipeline of TB Candidates 2013



TB Vaccine Development: Highlights for 2013-2014

- Phase IIb trial of a new vaccine candidate, M72, to begin enrolment
- Potential to expand to new countries to conduct clinical trials
- New scientific partnerships and collaborations –focus on enabling biomarker and correlate discovery
- Implementation of innovative trial designs – immunotherapy; prevention of infection

TB Market Assessment

The Economic Impacts of TB

FAMILY

TB primarily strikes down working-age adults

COUNTRIES

TB costs the global economy an estimated $1Billion each day

TB is reaching deep into the emerging economies, for example, for China estimated to be up to $1.182 Trillion from 2006-2015

BUSINESS SECTOR

Annual cost to the South African mining sector is over $880 million

GROWING COST OF DRUG-RESISTANT TB

Cost of treatment for MDR - $12,462 per patient in highest burden countries and $250,000 in the U.S.

Hospitalization for one XDR patient - $483,000 in the U.S.

Aeras methodology to estimate the market for new TB vaccines

1. Defined the global market:

- Disease burden
- TB Incidence by country
- Contact rate of infection
- Impact of HIV status

2. Assessed the global market on 3 levels:

- **Product level**:
  - generic TB target product profiles for infants , adolescents & adults were developed
- **Geographic level:**
  Global market segmented into World Bank classifications;
  - High income
  - Middle income
  - Low income
- **Time level:**
  - 10 yr. market revenue horizon
  - 20-30 yr. health impact

3. Vetted data and assumptions with partners:

- Academia
- TBVI
- WHO
- Industry experts:
  - GSK
  - Crucell
  - SSI
  - SII
  - Sanofi Pasteur

TB Vaccines Target Product Profiles

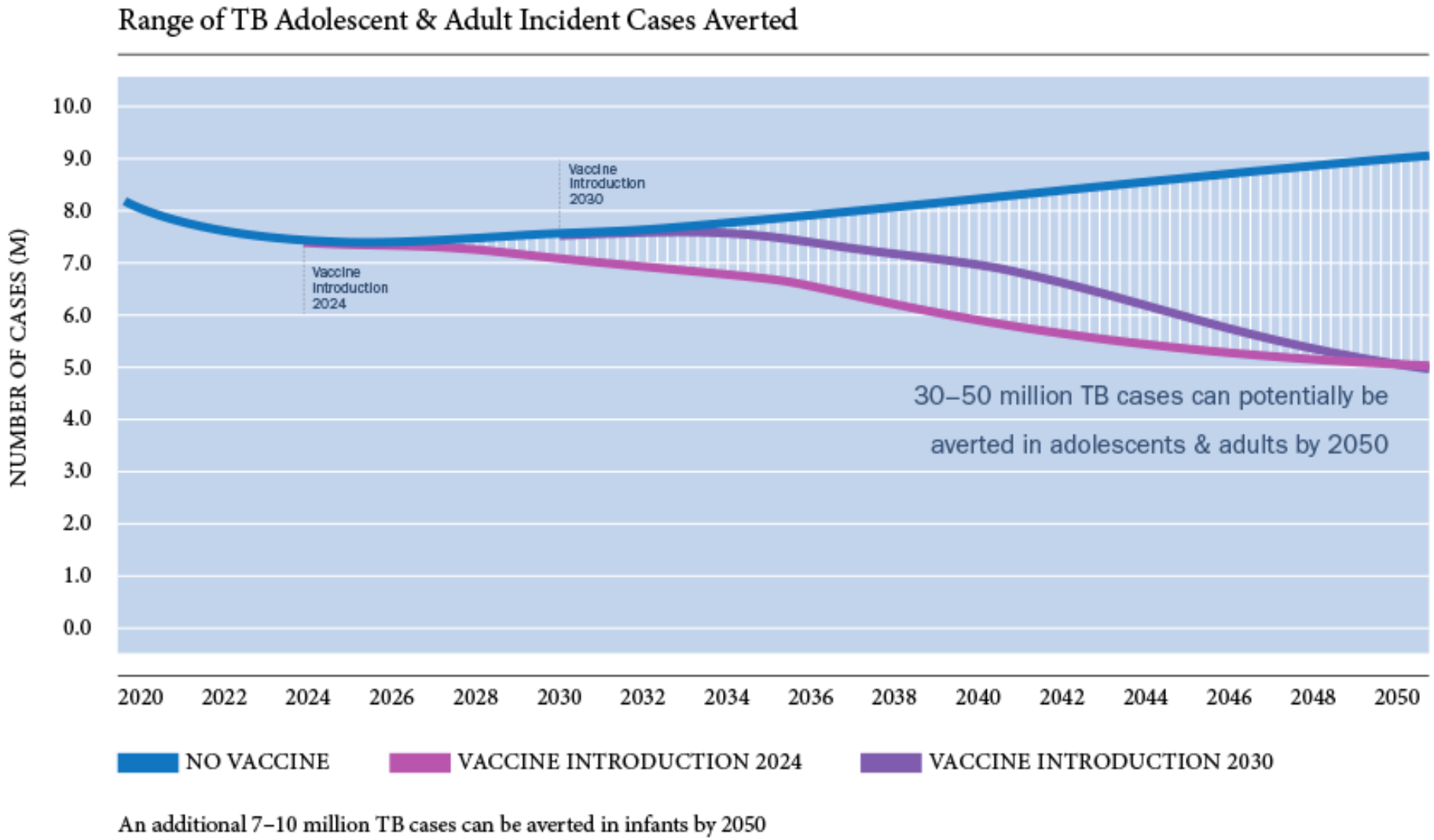
	Adolescents & Adults Vaccine	Infant Vaccine (BCG with better efficacy)
Indication	To prevent active disease	To prevent active disease
Target Population	≥ 10yo without known active TB	Newborns independent of HIV status
# Doses	2 doses	1 dose
Vaccination Strategy	Routine vaccination of 10 yo, and Mass campaigns in ≥ 11yo, every 10 yrs	Routine vaccination of newborns
Vaccination Coverage Rate Proxy	HPV coverage rate proxy for 10yo	BCG
Expected Efficacy	60% improvement in relative efficacy compared to the control arm	60% improvement in relative efficacy compared to current BCG
Expected Safety	No safety concerns	As safe as current BCG

Conservative Case Assumptions

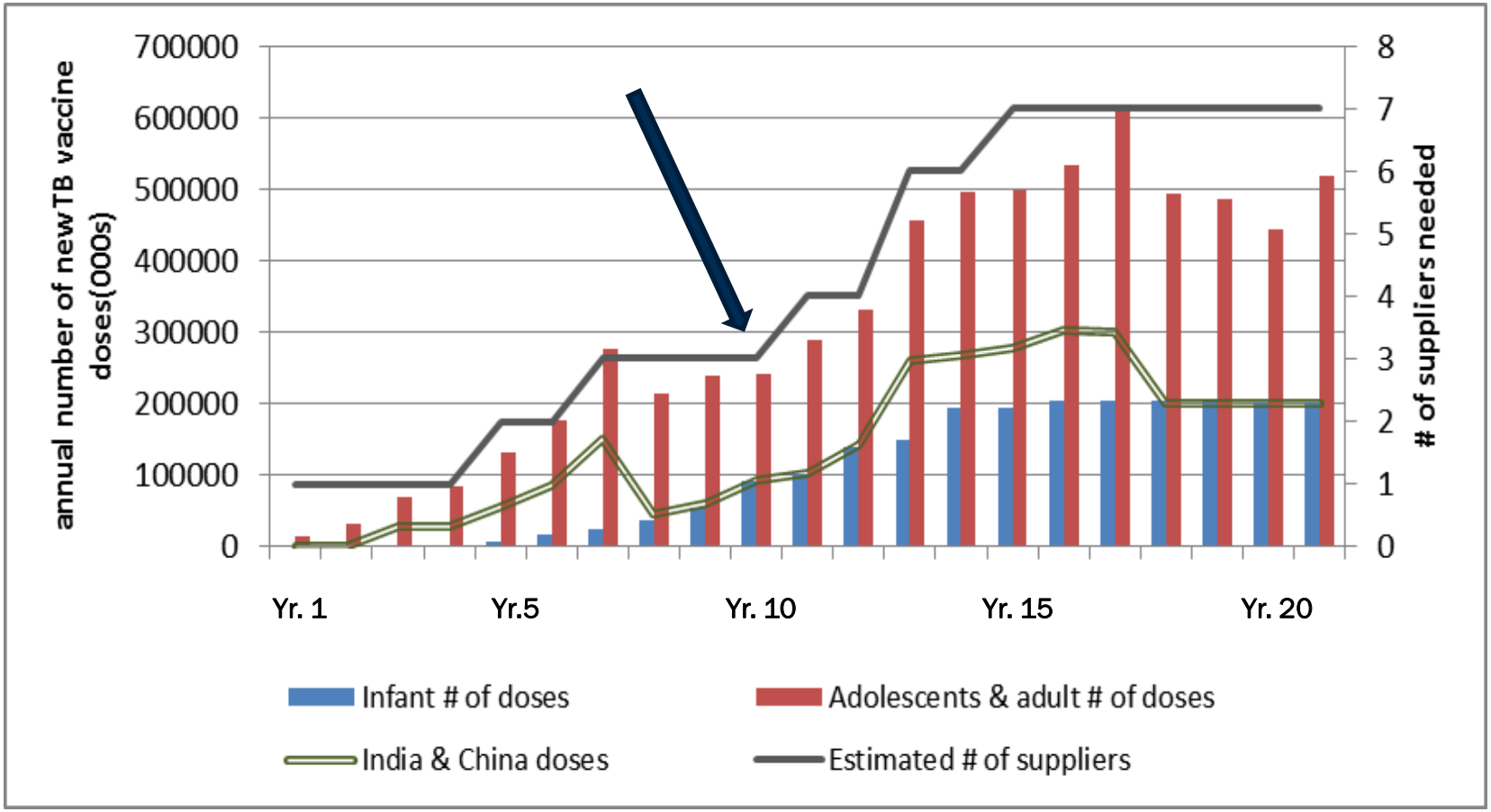
- 20% coverage rate for adolescents & adults in MICs & LICs
- 90>% coverage rate for infants in MICs & LICs
- HICs coverage rate for sub-populations only:
  - Military 90%
  - Health Care Workers 35%
  - Travelers 35%
  - Children of immigrants 10%
- Steady state vaccination – infants and 10yr. olds in school and not in school
- Mass vaccination campaigns every 10 years; adolescents 10> and adults
- First year of introduction, adolescent & adults, 2024/2030 with WHO pre-qualification; infant vaccine 2030/2033
- Country ramp up to full coverage ranges 2-6 years depending on the population of country

China and India Assumptions		
	China	India
Coverage rate	20% adolescents & adults 90%> infants	20% adolescents & adults 90%> infants
Country Ramp up to full coverage	5 years – adolescents & adults 3 years infants	10 years-adolescents & adults 3 years infants

Potential Health Impact of New TB New Vaccines



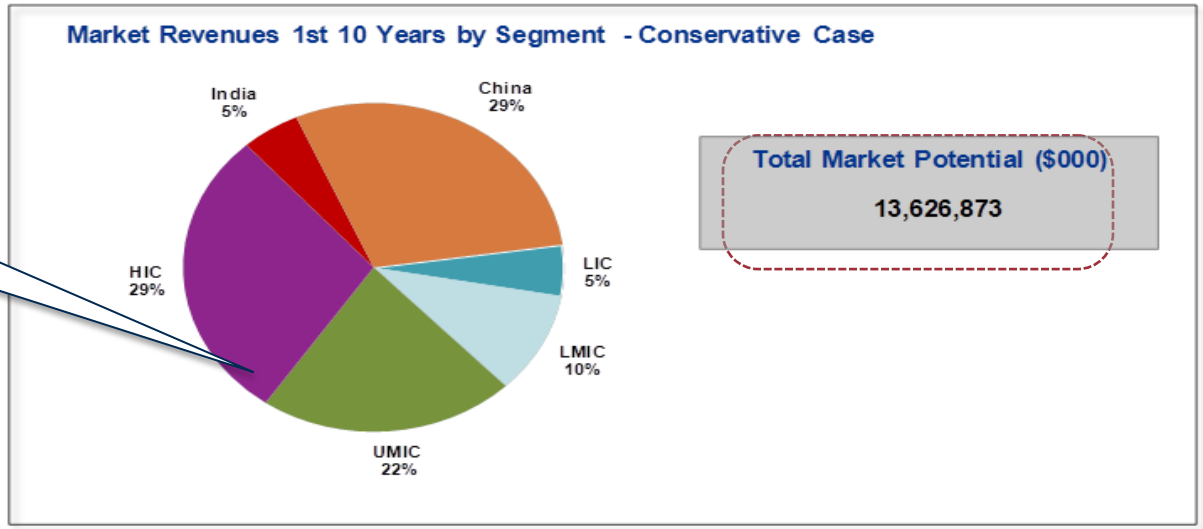
TB vaccines early estimates of global supply & demand potential



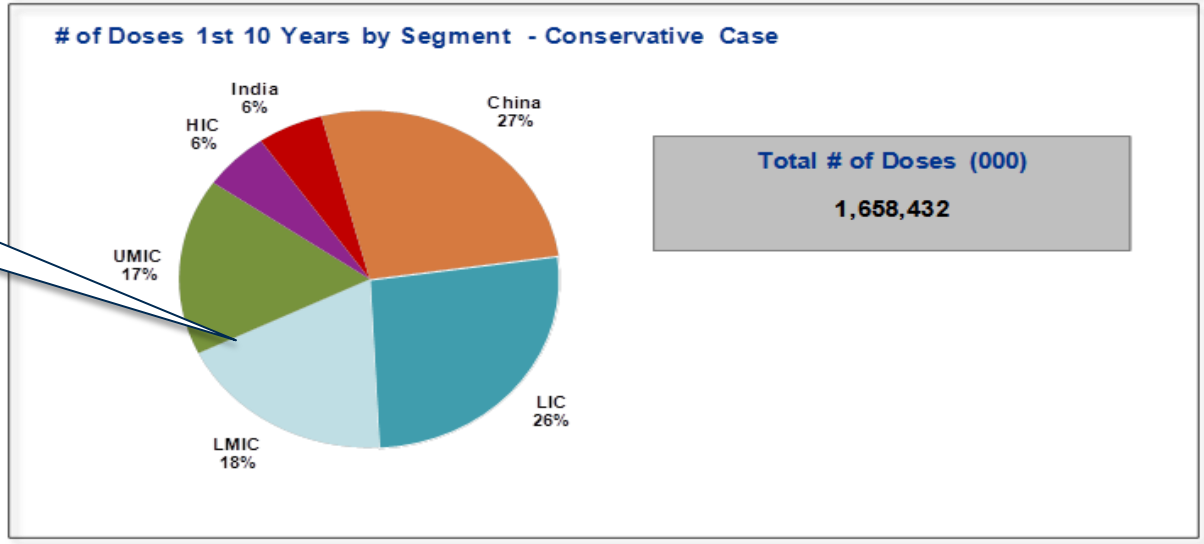
A minimum of 3 suppliers would be required to meet potential demand within 10 years after vaccine introduction (~250,000 M - 300,000 M)

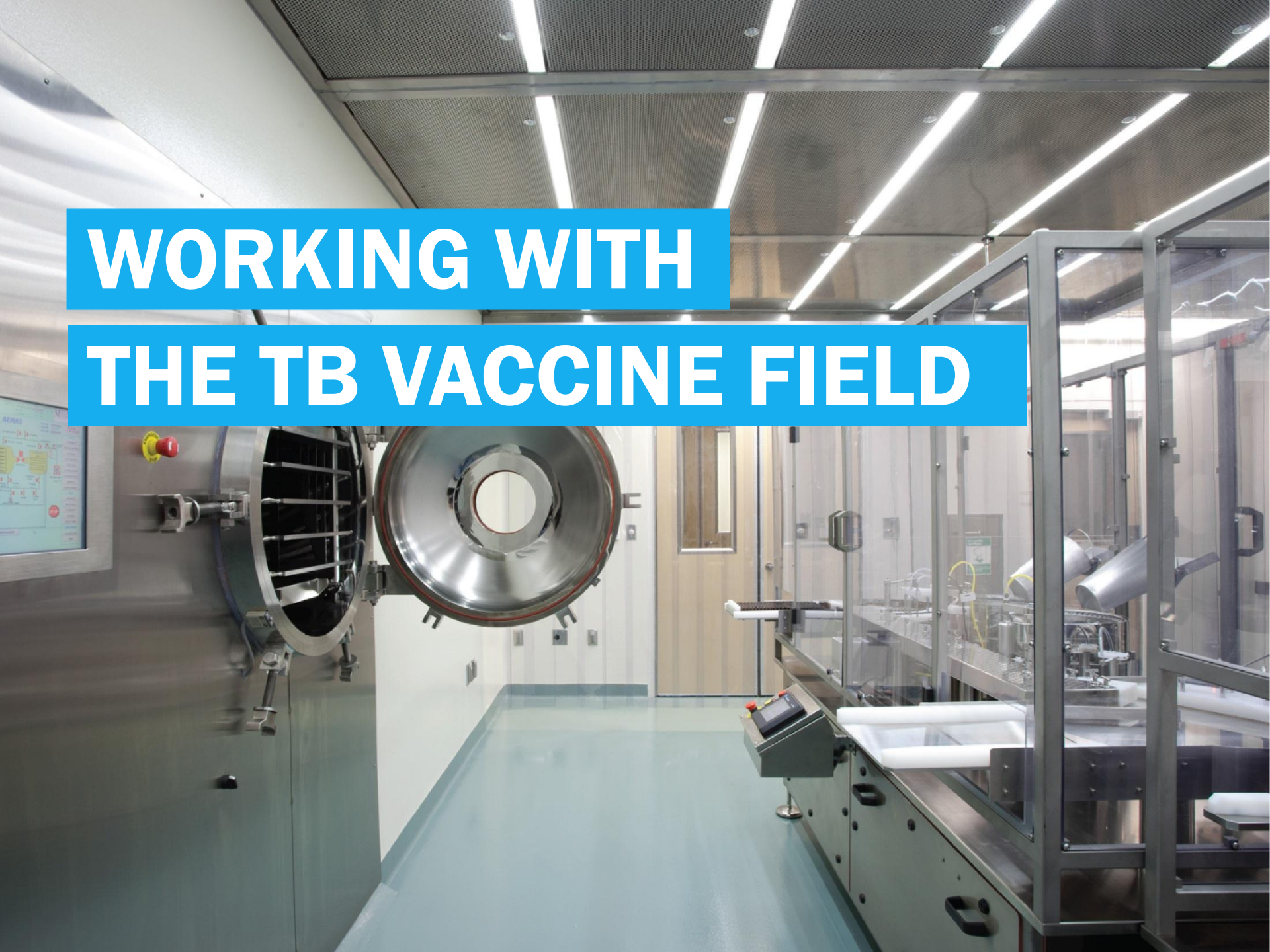
Overall market revenue potential

HICs & China dominate the market returns



MICs & China dominate the vaccine supply





WORKING WITH THE TB VACCINE FIELD

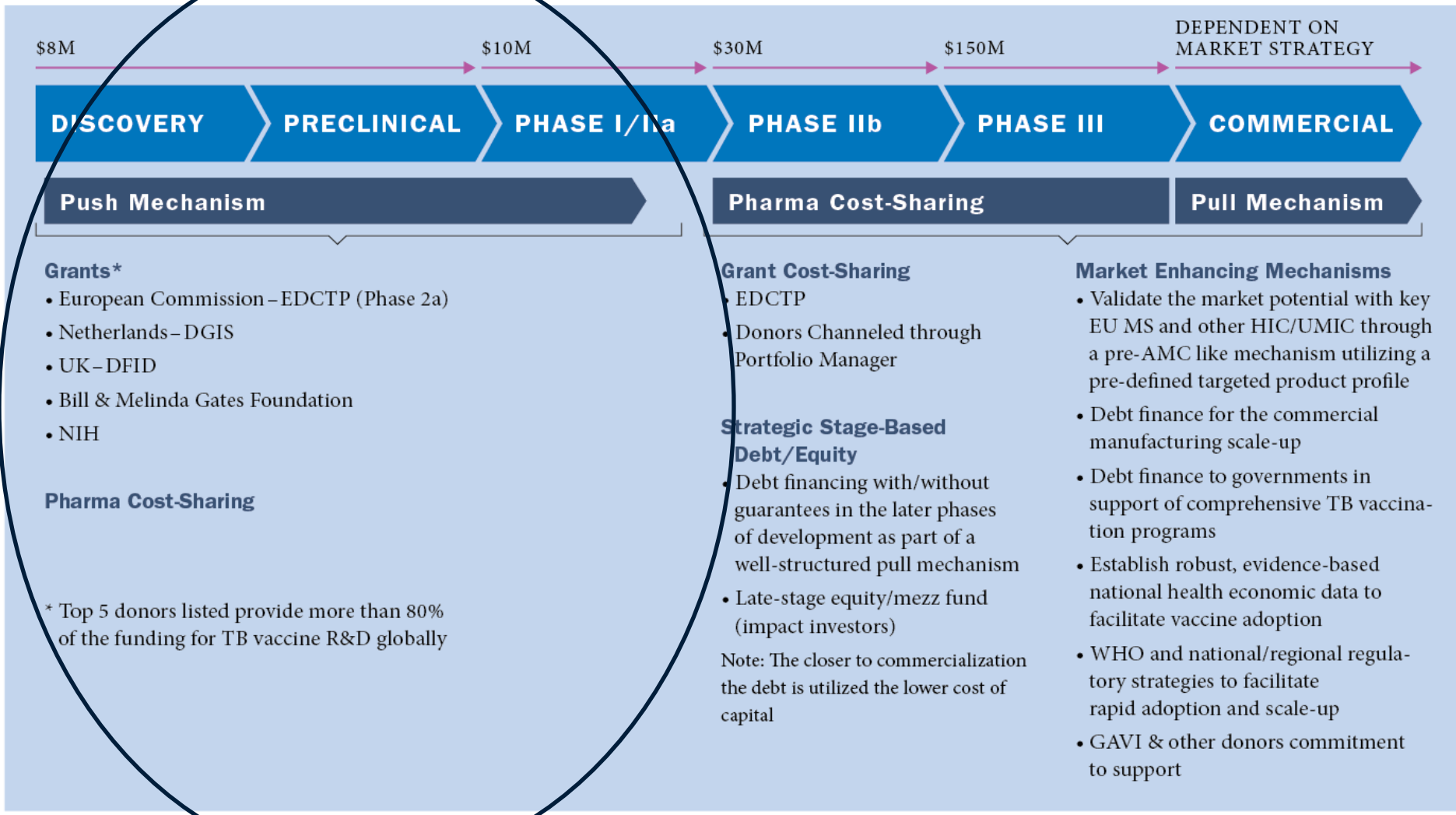
The TB Vaccine R&D Situation to Date:

So far USD $600M spent and a lot of effort to develop a number of promising TB vaccine candidates in the global portfolio

- **Funding:** Mainly through grants and by some industry for individual candidates.

- **Current Global TB vaccine portfolio:**
  - 12 clinical trials currently underway
  - More than 25 discovery leads and preclinical candidates
  - Efforts to diversify the portfolio underway
  - Lessons learnt from historical trials offer key insights into the biology of tuberculosis informing development efforts
  - Clinical trial capacity and expertise to run large-scale efficacy trials
  - Improved knowledge around biomarkers and correlates of protection informing on vaccine design and animal models

Overview of Possible Funding Solutions



Major Funders and R&D Partners

Thank you.

www.aeras.org

AERAS | Advancing Tuberculosis Vaccines for the World