Leading Group Task Force on Innovative Financing on Health
Paris 14 6 2011

Joris Vandeputte
Background

• Classical Funding Poverty related diseases: Grants by Government Money, EU, Gates, others......

• Financial crisis put extreme pressure on all sources

• Basic research, discovery – access to existing tools: relatively OK

• Translational research: urgent need to think differently

• Translational research = translation of knowledge into globally accessible products

• TBVI has several promising vaccine candidates in its portfolio
The case of TB vaccines: TBVI

- **Existing BCG**: 90 years old, safety **insufficient**, not protective enough for pulmonary TB

- **Hence:**
  - almost 2 million deaths, thousands in the EU, + 10 million new cases yearly
  - one third of world population latent carrier = source TB
  - huge economic cost = 0,52 % GNI yearly
  - worrying also in Europe: MDR, XDR
  - cost: treatment alone: near 10 Bn worldwide, 2 Bn € Europe alone yearly
Potential impact of vaccination on TB control (D. Young & C. Dye, Cell, 124, 2006)
TBVI: portfolio and opportunities

- Consortium of 40 European Research Institutes
- Objective: develop **globally accessible vaccines** for TB: active and safe
- Portfolio 39 vaccine candidates, **19 well advanced**
- Candidates showed advantages over BCG
- Portfolio allows **selection** of best candidates
- If funded now: can select the best candidates to bring at least two vaccines to the market by 2020, if not: risk of total loss!
Particularities of translational research innovative vaccines for TB

- **Long term:** 10 years at least
- Markets in LDC’s and emerging countries
- Market perception was bad
- Existing funding systems aim either basic research or access to existing products/services
- **Expensive:** Pre-phase I 2 million €, Phase I 2.5 million €, Phase II: 35 Million €, Phase III: 160 million €
What can be financed, what not?

<table>
<thead>
<tr>
<th>Discovery/Preclinical</th>
<th>Pre-phase I</th>
<th>Phase I</th>
<th>Phase IIa</th>
<th>Phase IIb</th>
<th>Phase III</th>
</tr>
</thead>
</table>

- Classical instrum (grants)
- Critical financing gap: class instr do not work
- Cl. instruments could come in if crit. fin. gap filled and proved success
Questions frequently posed

• Decision makers:
  – Where to find money in Financial crisis?
  – Which problem will this solve in my backyard?
  – Can you propose a solution, business case?

• New business model:
  – Where will financial effort lead to?
  – Is there a market?
  – Is there a return on investment?
Basics of TBVI’s finance plan 1

• Change paradigm: investment case
• Compromise state budget control and 3% GNI innovation commitment (EU 2020)
• Societal advantages for society
• TB a major threat for mankind, MDR, XDR, Poverty reduction
• Vaccines a cost/benefit human success story
• Hook in the EU: Innovation EU 2020 Flagship initiative, EU 2020 programme Barroso/ TB elimination by 2050
Basics of TBVI’s finance plan 2

- Finance pre-clinical and clinical development (Pre-phase I, phase I, phase II, phase III) to fill the critical financing gap of 560 Mio €, 10 years
- Bring two vaccines to market
- System: raise the money needed at the EIB, under state guarantee, and pay back only with exits (selling of projects) or royalties on sales

Real interest decision makers for global win win approach LDC, emergent, developed
THE INNOVATIVE FUNDING PLAN IN SHORT
How will it work?

• Step wise approach: proposals need approval for funding
• 11 are already ready for funding, 8 more to come
• Contract between TBVI and partners, with conditions such as global access and exit or royalty to pay to TBVI
• TBVI pays back the loan
How will it work: Decision Making

• **Representation** of Guaranteeing parties and EIB and other stakeholders

• **Independent decision** process: persons independent from the projects

• **Transparency**

• Selection on **technically and scientifically** fixed gating criteria and **affordability** for LDC’s
Do funded partners take any risk?

• Technically: their normal risk
• Financially: no.
• Successful partners (= vaccine candidate is on the market) only pay back AFTER they cashed:
  – when they made added value by exit
  – or by royalties
This plan offers

- **Stability** of funding over 10 years
- **Quick start of development and translation** of best candidates into globally accessible vaccines=
  portfolio effect
- **Simplification** of funding
- **Responsibility** to guaranteeing parties to justify choices
- **Minimal or no risk** for governments since no cash and repay foreseen
- **Value creation** of done investment (est. 250 M €)
INVESTMENT MEETS SOCIETAL CHALLENGES

• SAVE 2 million lives the earliest possible
• 0,52 % growth if TB eliminated
• Avoid human dramas for millions
• Finish ticking of a sanitary Time Bomb
• Virtuous circle translating knowledge into innovation generating new knowledge & innovation
• Added value for North and South trough strengthened North/South South/North, South/ South collaborations
CONCLUSION

• Make a **business case** of translation research projects

• **Two fat birds with one stone**: poverty reduction through TB elimination and added value through translation of knowledge into innovative vaccines