

# **TBVI: Translating science into products through innovative funding**

**A contribution to a healthier world and an innovative Europe by developing new TB vaccines**

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## Summary

In the past 10 years European researchers have made tremendous progress in the development of urgently needed new, safer and more effective vaccines against tuberculosis (TB). Important investments by the EU and EU member states in several successive European Union (EU) funded framework programmes have resulted in 39 promising TB vaccine candidates at different stages of development. These vaccine candidates have been developed in collaboration between 40 European universities, research institutes and companies that since 2008 have been united in an independent non-profit organisation called TuBerculosis Vaccine Initiative (TBVI).

The usual funding mechanisms through industry and via risk capital are unfortunately insufficient to realise the full development of new vaccines for tuberculosis. The reasons are twofold: Firstly, tuberculosis is a complex disease; it will take long term investment before the first vaccines are launched. Secondly, the market for TB vaccines has been perceived as being of little significance. Nevertheless, recent scientific progress has been tremendous with 11 new promising vaccines in clinical development and a first efficacy trial in men on-going. In addition, market studies show that the market potential is real and significantly better than initially perceived. Furthermore, the European knowledge and advancements gained in previous research projects are at risk of being lost because of a financing gap in translating these innovations into usable products; a true brain and technology drain. TBVI calculated this critical financing gap at €560 million: the amount of money needed to bring the first, most advanced vaccine(s) to the market by the end of this decade.

To close this gap, TBVI has developed a new funding model, allowing governments and industries to invest in these promising vaccine developments. European governments or agencies are asked to provide guarantees that allow the stepwise uptake of money from financial institutions to support stage specific development of the vaccine portfolio. This loan will be repaid through exit fees and profits of the final vaccines. The new funding model will initiate a positive cycle of innovation, taking into account the current difficult financial situation of countries. In the plan, states are not asked to provide any cash but the investment does contribute to the European goal to invest 3% of Gross National Income (GNI) into innovation.

### **In short, the plan includes:**

- A financial guarantee of a maximum of €560 million by national governments or EU institutions to raise the funds from financial institutions needed to lead the first vaccine candidates to the market.
- Step-by-step uptake of debt with financial institutions, e.g. European Investment Bank, upon stage-specific development and assessment of the most promising vaccine candidates in the portfolio.
- Pay back of this debt through interim exit values during the developing process or royalties on sales.
- 2 vaccines ready for the market by 2020.
- An affordable price of the developed vaccines for the least developed countries.

### **The benefits of this innovative funding model:**

1. **Economic benefits:** Vaccines will prevent and significantly save the spending on TB treatment. The current burden is over €2 billion per year spent on TB treatment in Europe alone. According

to the World Bank, the total cost of tuberculosis – globally causing almost 2 million deaths annually - is 0.52% of the world's GNI.

2. **Direct return:** Market analysis shows a wide demand for new, safer and more effective tuberculosis vaccines. The potential market is several hundred millions of doses per year with a reasonable to good profitability rate.

3. **Societal returns:** New, more efficient vaccines against tuberculosis will save millions of lives: in South East Asia alone, mass vaccination would save 14.5 million lives between launch and 2050. Vaccination will improve the health and wealth in particular of the populations of the least developed, high TB burden countries, thus contributing to poverty reduction. These vaccines will also contribute to the global goal of elimination of TB by 2050 (Stop TB Partnership at WHO).

4. **Health of EU citizens:** The vaccines will give Europe the preventive tools to protect its citizens from the threat of tuberculosis, including the growing threat of drug-resistant strains.

5. **EU 2020 agenda:** TBVI's funding model strongly supports the EU 2020 agenda as it stimulates EU research and development and helps the EU stay competitive in the world economy. It will strongly support its industry, SMEs as well as international companies, to adapt to the new global knowledge-based economy. Developing new vaccines will strengthen Europe's knowledge-based economy, with an added value of creating 1200 jobs and related activities, and confirm the EU as worldwide leader in vaccines.

6. **Expanding knowledge and stimulating innovation:** TBVI represents a strong European consortium of over 40 universities, research institutes and companies. A consortium that has generated a wealth of knowledge, thanks to indispensable funding through governments and framework programmes. TBVI's research partners are globally recognised as the best in their field. Translating this knowledge into vaccines stimulates the European *I-conomy* (Innovation economy) and it will ensure that money already invested is not lost. This innovative way of funding might be an example to many other innovation projects in the *I-conomy*, and is totally in line with the 'European 2020 Flagship Initiative Innovation Union'.

7. **Budget:** This funding model offers a solution to governments and governmental agencies that are squeezed between budget austerity and the commitment to support the knowledge-based economy and to increase health and wealth in the world.

8. **High probability of success:** Developing 39 vaccines in one portfolio has several benefits. For example, the vaccine candidates will be compared and evaluated according to strict criteria. Furthermore, improvements from different developers can be combined so new vaccine strategies can be developed. This ensures that only the best vaccine candidates will be selected and the chances of developing two vaccines ready for the market around 2020 are real.