



January 2015 – October 2018

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

Introduction

In the effort to eradicate tuberculosis as one of the world's most deadly diseases, novel TB vaccines will be an important part of the solution.¹

To address the unmet need for novel vaccines the Horizon2020 project TBVAC2020 aims to innovate and diversify the current TB vaccine and biomarker pipeline. To select as early as possible the most promising TB vaccine candidates, and accelerate their development portfolio management is applied by using gating and priority setting criteria.

Approach

TBVAC2020 combines creative 'bottom-up' approaches with a directive "top-down" portfolio management. The 'bottom-up' approach focuses on vaccine discovery, on new preclinical models addressing clinical challenges and on identification and characterisation of correlates of protection. While the directive "top-down" approach focuses on portfolio management to select the most promising TB vaccine candidates by their comparative evaluation using objective gating and priority setting criteria and by supporting direct, head-to head or comparative preclinical and early clinical evaluation.

This approach innovates and diversifies the existing TB vaccine and biomarker pipeline as well as accelerate the development of the most promising TB vaccine candidates through early development stages. The approach combined with the involvement of many internationally leading groups in the TB vaccine and biomarker area in TBVAC2020 fully aligns with the Global TB Vaccine Partnership (GTBVP).

General key achievements

Only 15 years ago the TB vaccines pipeline was virtually empty. Today, 22 candidate vaccines are in preclinical and clinical development globally. Of these, 14 have benefitted from the TBVAC2020 and its predecessor's collaborative research inputs.

¹ WHO Global report on TB 2018 www.who.int/tb/publications/global_report/archive/en/

TBVAC2020 Key achievements 2015 - 2018

Discovery to diversifying the TB vaccine pipeline:

- 40 different novel vaccine concept and formulations tested to provide safety, immunogenicity and efficacy data
- 22 novel and different TB vaccine approaches have been developed and tested *in vivo*.
- 11 innovative vaccine approaches are currently in development
- 7 candidates shown significant protection compared with the unvaccinated controls.

Novel concepts and strategies that will accelerate the design of next-generation vaccine candidates:

- 5 immunization strategies developed (Novel adjuvants)
- 2 innovative approaches for vaccine discovery (SWATH-MS, Elution of lipids)
- 3 novel delivery platforms viral vectors, Nano particles and Liposomes
- 1 novel route of administration (Aerosol delivery)

	Preclinical	Phase 1	Phase 2a	Phase 2b	Phase 3
Infants / neonates	BCG-ZMP1 Univ Zurich, TBVI		MTBVAC Biofabri, Univ Zaragoza, TBVI		VPM1002 SII, Max Planck, VPM, TBVI
Adolescents / adults	CysVac2/ Ad University Sydney, TBVI	Ad5 Ag85A McMaster, CanSino	H4:IC31 Sanofi Pasteur, SSI, Aeras	M72/ASO1 GSK, Aeras	VPM1002 SII, Max Planck, VPM
	BCG, ChAdOx1/MVA PPE15-85A Univ Oxford, TBVI	ChAdOx1.85A MVA 85A Univ Oxford, TBVI	BCG Revaccination Aeras	DAR-901 Darmouth, Aeras	MIP Cadila Pharma
	H64:CAF01 SSI, TBVI	MVA 85A Aerosol Univ Oxford, TBVI	MTBVAC Biofabri Univ Zaragoza TBVI, Aeras	H56:IC31 SSI, Valneva, Aeras	M. Vaccae Anhui Zhifei Longcom
	CMV-6Ag Aeras, Vir Biotech, OHSU	GamTBvac MoH Russia	TB/Flu04L RIBSP		
Therapeutic	MVA Multiphasic vac. Transgene, TBVI	H56:IC31 SSI, Valneva, Aeras	RUTI Archivel Pharma, TBVI		VPM1002 SII, Max Planck, VPM
		ID93/GLA-SE IDRI/wT	TB/Flu04L RIBSP		MIP Cadila Pharma
Live					
Wholecell					
Subunit					
Vector					

Correlates of protection

- New T cell subsets and dysfunctional B cells as biomarkers of TB disease
- Successful development and application of new biomarker assays measuring global immune and metabolic host responses as well as mycobacterial growth inhibition.
- Strong TB biomarker signatures of disease, response to tx risk, reduced risk

Knowledge sharing

- 109 publications in 28 scientific journals
- >150 presentations (posters and talks) at scientific meetings and conferences

Knowledge exchange

- 4 annual meetings
- attended by 120-160 attendees
- from 70 research institutes/ universities, industry/SMEs, funding and technical agencies, and partner organizations

Contribution to EU scientific excellence



TBVAC2020 Consortium

- Participating entities: 42, from 15 countries
- 2 Industry partners and 3 SMEs
- 248 individuals (136 females, 112 males)
- TBVI coordinator of the consortium