January 2015 – June 2019

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, also refer to the www.TBvacpathway.org.

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/

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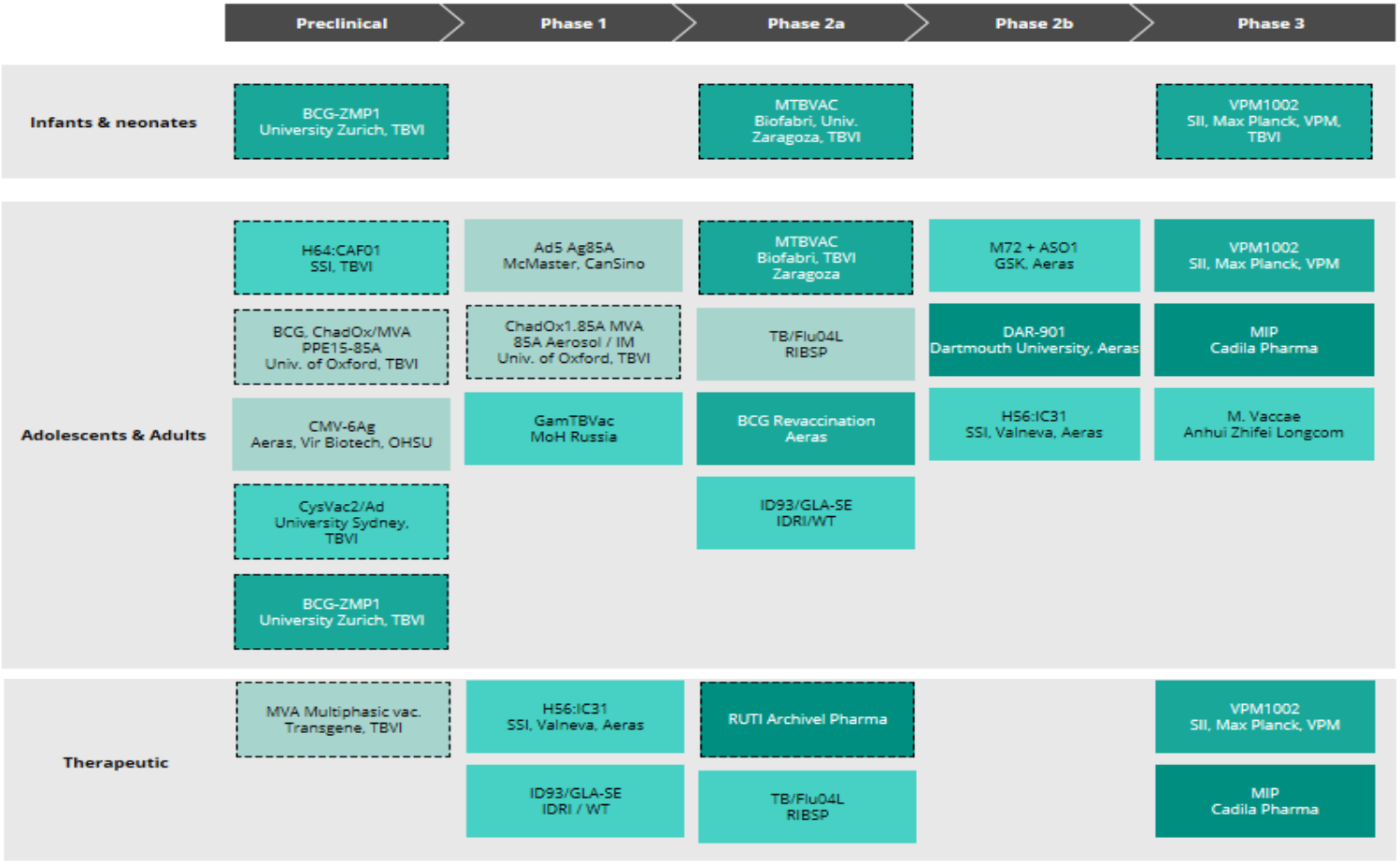
TBVAC2020 Key achievements 2015 - 2019

Discovery to diversifying the TB vaccine pipeline:

- 44 different novel vaccine concept and formulations tested to provide safety, immunogenicity and efficacy data
- 28 novel and different TB vaccine approaches have been developed and tested *in vivo*.
- 12 innovative vaccine approaches are currently in development
- 6 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)



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

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Knowledge sharing

- 124 publications in 28 scientific journals
- >175 presentations (posters and talks) at scientific meetings and conferences

Knowledge exchange

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

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