

\*\*\*\*Updated November 2014\*\*\*\*

## MarketVIEW: Tuberculosis vaccines

<b>Product Name</b>	:	<b>MarketVIEW:</b> Tuberculosis vaccines
<b>Description</b>	:	Vaccine commercial opportunity analysis
<b>Contents</b>	:	Executive presentation + forecast model
<b>Therapeutic Area</b>	:	Endemic/developing world vaccines
<b>Publication date</b>	:	November 2014
<b>Catalogue No</b>	:	VAMV021

## Background

*Mycobacterium tuberculosis (M.tb)* currently infects around one-third of the world's population. Although the majority of infections are latent and asymptomatic, between 5-10% of individuals develop active disease, which is both contagious and able to cause severe morbidity and death. Most of M.tb infections occur in sub-Saharan Africa where co-infection with HIV is a significant contributor to disease burden.

The BCG vaccine has been widely adopted by greater than 100 countries with high coverage to protect against systemic TB in children. However, the vaccine does not prevent or eliminate Mtb infection, especially later in life. In many countries with high and rising TB incidence rates – BCG has failed to control the epidemic. Vaccine manufacturers and academic groups are currently investigating new TB vaccines which could either replace BCG or boost its effect. The most advanced candidates in development are Oxford University (OU/Aeras) MVA85A and M72 + AS01E (GSK Biologicals).

This **MarketVIEW** product is a comprehensive MS Excel-based model + summary presentation which forecasts the potential commercial value of a novel TB vaccines (all mechanisms of action) across global markets to 2035. The model contains value (\$ m) and volume (mio doses) predictions for high and low TB burden countries in the infants (<1yrs), children, adolescents and adult target groups. Differing TB vaccine profiles and related issues such as differential pricing are also discussed.

## Methodology

**VacZine Analytics** has closely monitored all significant source material pertaining to tuberculosis vaccines. Example, secondary source materials used are literature articles, government websites/databases, medical bodies and associations, conference proceedings and previously analyses (where publically available). Previously published research by **VacZine Analytics** in field of endemic vaccines has also been utilised. **\*\*\*See Bibliography for exact sources.**

### PRODUCT CONTENTS:

**Published November 2014 (CAT No: VAMV021)**

\*\*\*\*This product is composed of a summary presentation

Author's note

Contents

Executive Summary

Key commercial model outputs

TB vaccines (all types) combined sales (\$m), 2015-35 [Hi case]

TB vaccines: available market per vaccine type (\$m) to 2035 [Hi case]

TB volume (vaccinees), by target population, 2015-35 [Hi case]

TB vaccines: available market per competitor (\$m) to 2035 [Base case]

TB vaccine sales (\$m), by country (base case), 2030

TB vaccine sales (\$m), by target population and country, 2030

TB vaccines: commercial model assumptions

The role of new TB vaccines

New TB vaccines: mechanisms overview

Pre-exposure (prime) vaccines - infants

Pre-exposure (prime-boost) vaccines - infants/adolescents

Post-exposure (prime-boost) vaccines - adults

Therapeutic vaccines

Populations/vaccines modelled

Market categorization

Country model inputs: vaccine adoption, coverage and pricing

Detailed country assumptions

TB disease trends and dynamics

TB incidence rates by country, 2013

Estimated number of incident TB cases (all forms), 2013

Global disability-adjusted life years (DALYs) per 100,000 population, 2012

BCG vaccination: overview

BCG vaccination policy by country

TB vaccine pipeline overview

Comment on TB vaccine candidates

MVA85A (AERAS-485)

Ad35/MVA85A combination

M72 (GSK Biologicals)

H4 (AERAS-404)

H56 (AERAS-456)

ID93

**Continued....**

VPM1002  
MTBVAC  
Ad5Ag85A  
Whole-cell or fragmented mycobacteria vaccines  
Launch timings  
Bibliography  
About **VacZine Analytics**

**PAGES: 52 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form**

**Contents – MS Excel forecast presentation**

Title sheet  
Chart summary  
Value summary by country (2030)  
Market share/competitors  
Value summary  
Vaccinees summary  
Country models =>  
China  
India  
Indonesia  
Bangladesh  
Pakistan  
Philippines  
Brazil  
Russia  
South Korea  
South Africa  
Other (UMI or HI)  
Other (LI or LMI)  
Other LATAM  
Sub-Saharan Africa  
Pricing  
Country-based data  
Forecast TB incidence  
GAVI countries  
BCG vaccine schedule  
Births  
12 yrs  
13 to 15 yrs  
Adults  
Clinical trials  
Charts  
Income group  
Backpage

**37 worksheets - interconnected**

## BIBLIOGRAPHY:

1. WHO. Global tuberculosis report 2014. Available at: [http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/). Accessed: published November 2014
2. WHO. Tuberculosis data. Available at: <http://www.who.int/tb/country/data/download/en/>. Accessed: published November 2014
3. WHO. Global Health Observatory (GHO). DALYs by region, 2012. Available at: [http://www.who.int/gho/mortality\\_burden\\_disease/daly\\_rates/en/](http://www.who.int/gho/mortality_burden_disease/daly_rates/en/). Accessed: published November 2014.
4. Trunz BB et al. Effect of BCG vaccination on childhood tuberculous meningitis and miliary tuberculosis worldwide: a meta-analysis and assessment of cost-effectiveness. *Lancet*. 2006 Apr 8;367(9517):1173-80.
5. Hesseling AC et al. The risk of disseminated Bacille Calmette-Guerin (BCG) disease in HIV-infected children. *Vaccine*. 2007 Jan 2;25(1):14-8.
6. Zwerling A et al. The BCG World Atlas: a database of global BCG vaccination policies and practices. *PLoS Med*. 2011 Mar;8(3):e1001012.
7. Aeras. Global Pipeline of TB Vaccine Candidates. Available at: <http://www.aeras.org/pages/portfolio-approach>. Accessed: published November 2014.
8. Aeras. Clinical Portfolio. Available at: <http://www.aeras.org/candidates>. Accessed: published November 2014
9. Tameris MD et al. Safety and efficacy of MVA85A, a new tuberculosis vaccine, in infants previously vaccinated with BCG: a randomised, placebo-controlled phase 2b trial. *Lancet*. 2013 Mar 23;381(9871):1021-8.
10. WHO Questions and Answers on Tuberculosis Vaccines. 4 February 2013. Available at: <http://www.who.int/tb/vaccinesfaqs/en/>. Accessed: published November 2014
11. Montagnani C et al. Vaccine against tuberculosis: what's new? *BMC Infect Dis*. 2014;14 Suppl 1:S2.
12. Prevention of infection study underway in South Africa. Available at: <http://www.aeras.org/pressreleases/>. Accessed: published November 2014.
13. TB vaccine report. Available at: <http://www.pipelinereport.org/2014/tb-vaccine>. Accessed: published November 2014
14. Frick. M. The Tuberculosis Vaccines Pipeline. June 2013. Available at: <http://www.pipelinereport.org/2013/tb-vaccine>. Accessed: published November 2014.  
Weiner J 3rd et al. Recent advances towards tuberculosis control: vaccines and biomarkers. *J Intern Med*. 2014 May;275(5):467-80