The uncertainty about the success of any vaccine candidate under evaluation determines the need to keep the pipeline of TB vaccine development well filled.

‘Let’s give time to the time: in order for the glass to overflow, first it has to be filled.’
Antonio Machado

The Choir
Eduardo Roca Salazar (Choco)
Oil on canvas; 90 × 110cm
INTRODUCTION

The health and economic burdens that TB places on patients and health systems across the globe are considerable, and the current tools and methods to control the disease, while valuable, are in need of improvement and have not abolished the impact of the disease. The World Health Organization (WHO) estimates that one-third of the world’s population is infected with TB and 1.7 million people die from the disease each year (1). Modeling studies suggest that TB imposes considerable economic costs, particularly in high-burden, developing countries. Directly Observed Therapy – Short course (DOTS), the primary method of control, has been shown to be an effective treatment measure for TB disease, in terms of both health impact and cost, but DOTS alone would not be sufficient to achieve global TB elimination (2). Another control measure, Bacille Calmette-Guérin (BCG) vaccine, is effective in protecting against serious forms of childhood TB, such as miliary TB and tuberculous meningitis, when given to infants at birth. However, the protective efficacy of infant BCG vaccination against adult pulmonary TB is considered unreliable and inadequate to help control the global TB epidemic (3-7). New and more effective TB vaccines could have the potential to be highly beneficial and cost-effective measures for disease control (8). Accordingly, the development of new improved TB vaccines is a promising approach to significantly reduce the health and economic impact of TB.

APPROACHES TO VACCINE DEVELOPMENT

In 2010, the Stop TB Partnership reviewed and revised its Global Plan to Stop TB for 2011-2015. This is a comprehensive plan toward the elimination of TB by 2050, with elimination defined as less than one case per million people per year. The plan outlines a set of enhanced control measures and targets for the research and development of new, more effective technologies, including the development of a safe, effective and affordable TB vaccine, which has the potential for a significant public health impact (9).
Researchers have identified a number of approaches to vaccine development. First, BCG could be replaced by a similar, but improved vaccine to be given to infants at birth (10). WHO currently recommends against the administration of BCG to HIV-infected infants, related to concerns over the risk of BCG disease in these infants (11). A modified BCG or live attenuated vaccine that is safer and more effective presents one target for development. Second, a new TB vaccine could be introduced into a heterologous prime-boost regimen following vaccination of infants with BCG or an improved replacement for BCG, or in adolescents and adults previously primed with BCG. Because nearly 80% of newborns worldwide are inoculated with BCG as a prime, a new booster vaccine, to be given later to infants or young children and again in adolescence, could enhance immunity to TB and increase protective efficacy against the disease. Finally, a post-infection or immunotherapeutic vaccine, administered during or after treatment of individuals with latent or active TB, may decrease the incidence of active disease or relapse, or reduce the duration and improve the outcome of chemotherapy.

**DRIVERS AND BARRIERS TO TB VACCINE DEVELOPMENT**

There are a number of scientific and clinical hurdles on the path to the development and licensure of a new TB vaccine (12). For example, it is not known whether the animal models used to test vaccines sufficiently mimic the immune response and TB disease in humans to predict the efficacy of vaccines from preclinical studies. Similarly, the natural immune response to MTB infection which protects most people from progressing to TB disease is not well understood. Also research has not identified correlates of protection from vaccination that could give clues to a protective immune response to TB from investigational vaccines. Consequently, the best scientific approaches to vaccine development may not become clear until after the evaluation of data from successful clinical trials. To conduct these clinical trials, a number of other barriers must be overcome. As accurate TB diagnosis is difficult for the identification of TB in infants, it is challenging to establish endpoints for trials that test new vaccines in this population. Furthermore, there is a shortage of sites with the capacity to conduct large scale Phase IIb and III trials and a large gap in funding for the conduct of such trials (9). These trials are required to evaluate human safety and protection on a scale sufficient to support TB vaccine development and licensure.
Epidemiological modeling studies suggest that vaccines with modest efficacy have the potential to reduce the TB burden over time, and economic studies show that such vaccines are likely to be cost-effective [13-18]. Perhaps more importantly, it appears that there is demand for a better TB vaccine among high level decision-makers in endemic countries. A 2010 survey of such individuals in eight TB high-burden countries reports that a new, improved TB vaccine that is more efficacious than current BCG is likely to be adopted in these countries within a few years of its licensure [19]. It is likely that the development of new, improved TB vaccines, in combination with other measures, specifically new drugs and diagnostics, will be a highly effective strategy to minimize the current serious global impact of TB.

**VACCINES IN THE PIPELINE**

To assist with tracking activity and progress in TB vaccine research and development, the Stop TB Partnership Working Group on New TB Vaccines publishes an inventory of new vaccines at various stages of development. This listing is updated annually with information collected from vaccine developers, and can be found at the homepage of the Vaccines Working Group of the Stop TB Partnership website: http://www.stoptb.org/wg/new_vaccines/.

Significant progress has been made toward the goal to develop new, more effective vaccines as set out by the Partnership, as shown in Table 5.15.1. The global portfolio of candidates targets a variety of different patient populations, and includes priming candidates, boosting candidates, and those intended for post-infection, immunotherapeutic use. It also includes a range of scientific approaches to vaccine development, including recombinant live bacterial, viral vectored subunits, recombinant protein subunits, and whole cell inactivated or disrupted candidates. As of 2012, seventeen candidates had entered the clinic with two candidates, Oxford MVA85A/AERAS-485 and AERAS-402/Crucell Ad35, in Phase IIb proof-of-concept trials. Results published in 2013 of the MVA-85A trial showed safety but failed to show efficacy in infants who had received BCG (43); the AERAS-402 trial was also modified in 2013 to a large safety trial without expansion to determine efficacy. Six more candidates, M72, VPM 1002, Hybrid-1+IC31, Hybrid 56 +IC3, RUTI, and SSI HyVac 4/AERAS-404 are in Phase II trials. Six candidates are currently in Phase I safety trials, including AdAg85A, MTBVAC, SSI Hybrid-I+CAF01, and ID93+GLA-SE. Five candidates, rBCG30, AERAS 422, *M. vaccae*, *Mw*, and *M. smegmatis*, have completed either Phase I or beyond Phase I trials. Beyond those vaccines in clinical
trials, there are many other candidates that are in the discovery and preclinical stages of development, including DNA and other vaccine types, which utilize different scientific approaches to those seen in the clinic.

In the following table, TB vaccine candidates are presented in three categories:

Candidates Tested in Clinical Trials-2011 (Section I): TB vaccine candidates that are in clinical studies. Certain candidates that have been in clinical studies but are not currently in clinical trials are listed as ‘completed.’

Candidates in Preclinical Studies & GMP-2011 (Section II): TB vaccine candidates that as of 2011 are not yet in clinical trials, but have been manufactured under good manufacturing practice (GMP) for clinical use and/or have undergone some advanced preclinical testing that meets regulatory standards.

Next Generation Candidates- 2011 (Section III): TB vaccine candidates that are in the discovery, research and development stage with some preclinical testing performed to show that they may confer protection and become product candidates.

Vaccine candidates are further divided into specific Vaccine Types: Recombinant Live; Viral Vectored; Recombinant Protein; Whole Cell Inactivated or Disrupted or Other and a brief description is provided. The Table lists vaccines intended to be used as a Prime (P) or Booster (B) vaccine, as a Post-infection vaccine (PI) or in immunotherapy (IT).

The information on vaccine candidates was provided and updated by the vaccine developers unless otherwise indicated. In cases where an update regarding a previously listed vaccine candidate was not received in 2011, the 2010 listing was retained.
### TABLE 5.15.1 Tuberculosis vaccine candidates – 2011

#### SECTION I: Candidates Tested in Clinical Trials

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Products</th>
<th>Product description</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Status as of 2011</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recombinant Live</strong></td>
<td>VPM 1002</td>
<td><em>rBCG</em> Prague strain expressing listeriolysin and carries a urease deletion mutation</td>
<td>Max Planck, Vakzine Projekt Management GmbH, TBVI</td>
<td>☐ ☐</td>
<td>Phase II</td>
<td>[10, 20–23]</td>
</tr>
<tr>
<td></td>
<td>rBCG30</td>
<td><em>rBCG</em> Tice strain expressing 30 kDa MTB antigen 85B; phase I completed in U.S.</td>
<td>UCLA, NIH, NIAID, Aeras</td>
<td>☐</td>
<td>Phase I [completed]</td>
<td>[24–28]</td>
</tr>
<tr>
<td></td>
<td>AERAS-422</td>
<td>Recombinant BCG expressing mutated PfoA and overexpressing antigens 85A, 85B, and Rv3407</td>
<td>Aeras</td>
<td>☐</td>
<td>Phase I [completed]</td>
<td>[29–31]</td>
</tr>
<tr>
<td></td>
<td>MTBVAC [ΔphoP, Δfad D26]</td>
<td>Live vaccine based on attenuation of MTB by stable inactivation by deletion of phoP and fad D26 genes</td>
<td>University of Zaragoza, Institute Pasteur, BIOFABRI, TBVI</td>
<td>☐</td>
<td>Phase I</td>
<td>[32–36]</td>
</tr>
<tr>
<td><strong>Viral Vectored</strong></td>
<td>Oxford MVA85A / AERAS-485</td>
<td>Modified vaccinia Ankara vector expressing Mtb antigen 85A</td>
<td>Oxford Emergent Tuberculosis Consortium (OETC), Aeras, EDCTP, Wellcome Trust</td>
<td>☐ [B] [IT]</td>
<td>Phase IIb</td>
<td>[37–43]</td>
</tr>
<tr>
<td></td>
<td>AERAS-402/ Crucell Ad35</td>
<td>Replication-deficient adenovirus 35 vector expressing MTB antigens 85A, 85B, and Rv3407</td>
<td>Crucell, Aeras, EDCTP, NIH</td>
<td>☐</td>
<td>Phase IIb</td>
<td>[29-30,44–46]</td>
</tr>
<tr>
<td></td>
<td>AdAg85A</td>
<td>Replication-deficient adenovirus 5 vector expressing MTB antigen 85A</td>
<td>McMaster University</td>
<td>☐ ☐</td>
<td>Phase I</td>
<td>[47–51]</td>
</tr>
<tr>
<td><strong>Recombinant Protein</strong></td>
<td>M72 + AS01</td>
<td>Recombinant protein composed of a fusion of MTB antigens Rv1196 and Rv0125 &amp; adjuvant AS01</td>
<td>GSK, Aeras</td>
<td>☐ [B]</td>
<td>Phase II</td>
<td>[52–55]</td>
</tr>
</tbody>
</table>
### TABLE 5.15.1 Tuberculosis vaccine candidates – 2011

#### SECTION I: Candidates Tested in Clinical Trials

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Products</th>
<th>Product description</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Status as of 2011</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hybrid-I+IC31</td>
<td>Adjuvanted recombinant protein composed of MTB antigens 85B and ESAT-6</td>
<td>Statens Serum Institute (SSI), TBVI, EDCTP, Intercell</td>
<td></td>
<td>P</td>
<td>Phase II</td>
<td>[56–60]</td>
</tr>
<tr>
<td>Hybrid-I+CAF01</td>
<td>Adjuvanted recombinant protein composed of MTB antigens 85B and ESAT-6</td>
<td>SSI, TBVI</td>
<td></td>
<td>P</td>
<td>Phase I</td>
<td>[56,59,61–63]</td>
</tr>
<tr>
<td>HyVac 4/ AERAS-404, +IC31</td>
<td>Adjuvanted recombinant protein composed of a fusion of MTB antigens 85B and TB10.4</td>
<td>SSI, Sanofi-Pasteur, Aeras, Intercell</td>
<td></td>
<td>B</td>
<td>Phase I</td>
<td>[64–67]</td>
</tr>
<tr>
<td>Hybrid 56 + IC31</td>
<td>Adjuvanted recombinant protein composed of MTB antigens 85B, ESAT-6 and Rv2660</td>
<td>SSI, Aeras, Intercell</td>
<td></td>
<td>P</td>
<td>Phase IIa</td>
<td>[68–69]</td>
</tr>
<tr>
<td>ID93 in GLA- SE adjuvant</td>
<td>Subunit fusion protein composed of 4 MTB antigens</td>
<td>Infectious Disease Research Institute</td>
<td></td>
<td>B</td>
<td>Phase I</td>
<td>[70–71]</td>
</tr>
<tr>
<td>Whole Cell, Inactivated or Disrupted</td>
<td>M. vaccae, Inactivated whole cell non-TB mycobacterium; phase III in BCG-primed HIV+ population completed; reformulation pending</td>
<td>NIH, Immodulon</td>
<td></td>
<td>P</td>
<td>Phase III [completed]</td>
<td>[72–76]</td>
</tr>
<tr>
<td></td>
<td>Mw [M. indicus pranii (MIP)], Whole cell saprophytic non-TB mycobacterium</td>
<td>Department of Biotechnology (Ministry of Science &amp; Technology, Government of India), M/s. Cadila Pharmaceuticals Ltd.</td>
<td></td>
<td>IT</td>
<td>Phase III [completed]</td>
<td>[77–79]</td>
</tr>
</tbody>
</table>
### SECTION I: Candidates Tested in Clinical Trials

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Products</th>
<th>Product description</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Status as of 2011</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>RUTI</td>
<td>Fragmented MTB cells</td>
<td>Archivel Farma, S.I.</td>
<td>B PI IT</td>
<td>Phase II</td>
<td>[80–84]</td>
<td></td>
</tr>
<tr>
<td>M. smegmatis¹</td>
<td>Whole cell extract; phase I completed in China</td>
<td>–</td>
<td>B PI IT</td>
<td>Phase I [completed]</td>
<td>–</td>
<td></td>
</tr>
</tbody>
</table>

¹Candidate information communicated by the Wuhan Institute of Biological Products.

### SECTION II: Candidates in Preclinical Studies & GMP- 2011

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Products</th>
<th>Product description</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombinant Live</td>
<td>MTB [ΔleuCD ΔpanCD ΔsecA2]</td>
<td>Non-replicating, MTB strain auxotrophic for leucine and pantothenate; attenuated for secA2</td>
<td>Albert Einstein College of Medicine</td>
<td>B PI IT</td>
<td>[85–86]</td>
</tr>
<tr>
<td>Recombinant Protein</td>
<td>HBHA</td>
<td>Naturally methylated 21-kDa purified protein from M. bovis BCG</td>
<td>Institute Pasteur of Lille, INSERM, TBVI, Aeras</td>
<td>B PI IT</td>
<td>[87–91]</td>
</tr>
<tr>
<td>Other</td>
<td>HG85A</td>
<td>DNA vaccines—Ag85A</td>
<td>Shanghai H&amp;G Biotech</td>
<td>B IT</td>
<td>[92–96]</td>
</tr>
<tr>
<td></td>
<td>Hsp DNA vaccine</td>
<td>Codon-optimized heat shock protein from M. leprae, a Cpg island</td>
<td>Sequella, Shanghai Public Health Clinical Center</td>
<td>B</td>
<td>[97–99]</td>
</tr>
</tbody>
</table>
### SECTION III: Next Generation Candidates – 2011

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Products</th>
<th>Product description</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recombinant Live</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HG856-BCG</td>
<td>rBCG overexpressing chimeric ESAT-6/Ag85A DNA fusion protein</td>
<td>Shanghai Public Health Clinical Center</td>
<td></td>
<td>[B] [P] [IT]</td>
<td>[100]</td>
</tr>
<tr>
<td>IKEPLUS M. smegmatis with ESX-3 deletion/ complementation</td>
<td>Live M. smegmatis with deletion of ESX-3 encoding locus and complementation with MTB locus</td>
<td>Albert Einstein College of Medicine, Aeras</td>
<td></td>
<td>[B]</td>
<td>[101]</td>
</tr>
<tr>
<td>paBCG</td>
<td>BCG with reduced activity of anti-apoptotic microbial enzymes including SodA, GlnA1, thioredoxin, and thioredoxin reductase</td>
<td>Vanderbilt University</td>
<td></td>
<td>[P]</td>
<td>[102]</td>
</tr>
<tr>
<td>Proapoptotic rBCG</td>
<td>Recombinant BCG expressing mutated PfoA and including mutations shown at AECOM to induce macrophage apoptosis</td>
<td>Aeras, Albert Einstein College of Medicine</td>
<td></td>
<td>[P]</td>
<td>–</td>
</tr>
<tr>
<td>rBCG(mbtB)30</td>
<td>rBCG with limited replication overexpressing the 30 kDa MTB Antigen 85B</td>
<td>UCLA, NIH, NIAID</td>
<td></td>
<td>[P]</td>
<td>[103]</td>
</tr>
<tr>
<td>rBCG T+B</td>
<td>rBCG and M. smegmatis expressing multiple T and B epitopes of MTB</td>
<td>Finlay Institute, Universiti Sains Malaysia</td>
<td></td>
<td>[B] [P]</td>
<td>[104–106]</td>
</tr>
<tr>
<td>rM. smegmatis T+B</td>
<td>rBCG38</td>
<td>Universidad Nacional Autónoma de México</td>
<td></td>
<td>[B]</td>
<td>[107–110]</td>
</tr>
<tr>
<td>rBCG38</td>
<td>rBCG Tice strain overexpress the 38 kDa protein</td>
<td>Universidad Nacional Autónoma de México</td>
<td></td>
<td>[B]</td>
<td>–</td>
</tr>
<tr>
<td>Type of Vaccine</td>
<td>Products</td>
<td>Product description</td>
<td>Sponsor</td>
<td>Indication</td>
<td>Citations</td>
</tr>
<tr>
<td>----------------</td>
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<td>-----------</td>
</tr>
<tr>
<td>rBCGMex38</td>
<td>rBCG  Mexico strain overexpress the 38 kDa protein</td>
<td>Universidad Nacional Autónoma de Mexico</td>
<td></td>
<td></td>
<td>[109, 111–113]</td>
</tr>
<tr>
<td>rM.microti30</td>
<td>rM.microti strain overexpress the 30 or 38kDa protein</td>
<td>Universidad Nacional Autónoma de Mexico</td>
<td></td>
<td></td>
<td>[27, 114–115]</td>
</tr>
<tr>
<td>rM.microti38</td>
<td>rM.microti strain overexpress the 30 or 38kDa protein</td>
<td>Universidad Nacional Autónoma de Mexico</td>
<td></td>
<td></td>
<td>[27, 114–115]</td>
</tr>
<tr>
<td>Streptomyces live vector</td>
<td>Recombinant streptomyces expressing multiple T and B epitopes from M.tb</td>
<td>Finlay Institute, Institute of Pharmacy and Food, Cuba</td>
<td></td>
<td></td>
<td>[105–106,116]</td>
</tr>
<tr>
<td>rBCG85C</td>
<td>rBCG overexpressing antigen 85C of M. tuberculosis</td>
<td>University of Delhi South Campus and Department of Biotechnology, Government of India</td>
<td></td>
<td></td>
<td>[117]</td>
</tr>
<tr>
<td>Disruption of the SapM locus</td>
<td>Recombinant M. bovis BCG in which the SapM locus has been disrupted</td>
<td>FWO-Ghent University-VIB</td>
<td></td>
<td></td>
<td>[118]</td>
</tr>
<tr>
<td>BCG zmp 1</td>
<td>BCG zmp 1 deletion mutant</td>
<td>University of Zurich, TBVI</td>
<td></td>
<td></td>
<td>[119–121]</td>
</tr>
<tr>
<td>Recombinant Protein</td>
<td>Latency fusion proteins</td>
<td>Recombinant fusion proteins composed of antigens 85A-85B-Rv3407, Rv3407-Rv1733c-Rv2626c, Rv0867c-Rv-1884-Rv2389c</td>
<td>Aeras</td>
<td></td>
<td>–</td>
</tr>
</tbody>
</table>
### SECTION III: Next Generation Candidates – 2011

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Products</th>
<th>Product description</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>r30</td>
<td>r30kDa MTB Ag85B protein purified from rM. Smegmatis</td>
<td>UCLA, NIH, NIAID</td>
<td>[24–28]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R32Kda (recombinant 85A)</td>
<td>Purified recombinant 85A protein from BCG</td>
<td>Bhagawan Mahavir Medical Research Center, LEPRA Society- Blue Peter Research Centre</td>
<td>[122–126]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viral Vectored</td>
<td>Recombinant LCMV</td>
<td>Recombinant lymphocytic choriomeningitis virus expressing Ag85A, Ag85B, or Ag85B-ESAT6</td>
<td>University of Geneva</td>
<td>[127–128]</td>
<td></td>
</tr>
<tr>
<td>rhPIV2-Ag85B</td>
<td>Replication-deficient human parainfluenza type 2 virus expressing Ag85B</td>
<td>National Institute of Biomedical Innovation, Japan; Japan BCG Laboratory</td>
<td>[129]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>LIP1 Ac2SGL sulfoglycolipid</td>
<td>Ac2SGL/PIM2 in DDA/TDB</td>
<td>Centre National de la Recherche Scientifique (CNRS), TBVI</td>
<td>[130–132]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LIP2 SL37 (synthetic) sulfoglycolipid</td>
<td>SL37/PIM2 in DDA/TDB</td>
<td>CNRS, TBVI</td>
<td>[133–134]</td>
<td></td>
</tr>
</tbody>
</table>
## SECTION III: Next Generation Candidates – 2011

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Products</th>
<th>Product description</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>HG856A</td>
<td>Chimeric DNA vaccines—ESAT-6/Ag85A; Ag85A/Ag85B</td>
<td>Shanghai H&amp;G Biotech</td>
<td>B IT</td>
<td>[100]</td>
<td></td>
</tr>
<tr>
<td>HG85 A/B</td>
<td>Chimeric DNA vaccines—Ag85A/B</td>
<td>Shanghai H&amp;G Biotech</td>
<td>B IT</td>
<td>[92–96]</td>
<td></td>
</tr>
<tr>
<td>HG856-SeV</td>
<td>Recombinant Sendai virus overexpressing chimeric ESAT-6/Ag85A protein</td>
<td>Shanghai H&amp;G Biotech</td>
<td>B</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>HVJ-Envelope/ HSP65 DNA+IL-12 DNA</td>
<td>Combination of DNA vaccines expressing mycobacterial heat-shock protein 65 &amp; IL-12</td>
<td>Osaka University</td>
<td>B PI IT</td>
<td>[135–139]</td>
<td></td>
</tr>
<tr>
<td>DNAacr</td>
<td>DNA vaccine expressing □-crystallin, a key latency associated antigen of <em>M. tuberculosis</em></td>
<td>University of Delhi South Campus and Department of Biotechnology, Government of India</td>
<td>B</td>
<td>[140]</td>
<td></td>
</tr>
<tr>
<td>rBCGacr/DNAacr</td>
<td>rBCG and DNA vaccines expressing □-crystallin of <em>M. tuberculosis</em> in a heterologous prime boost approach</td>
<td>University of Delhi South Campus and Department of Biotechnology, Government of India</td>
<td>P B</td>
<td>[141]</td>
<td></td>
</tr>
<tr>
<td>Liporale™ TB</td>
<td>Live attenuated BCG Danish Strain in a novel stable lipid matrix for oral vaccination</td>
<td>Immune Solutions Ltd.</td>
<td>P B</td>
<td>[142–146]</td>
<td></td>
</tr>
</tbody>
</table>
### SECTION III: Next Generation Candidates – 2011

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Products</th>
<th>Product description</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Citations</th>
</tr>
</thead>
</table>
| Mycobacterial liposomes and proteosomes | Liposomes from *M. smegmatis* and proteo-liposomes from BCG and *M. smegmatis* | Finlay Institute
Universiti Sains Malaysia | ![ ]() [ ]() [ ]() [ ]() [147] |
| pUMVC6/7 DNA² | DNA vaccine plasmid vectors pUMVC6 or pUMVC7 expressing Rv3872, Rv3873, Rv3874, Rv3875 or Rv3619c | Kuwait University | ![ ]() [ ]() [ ]() [148–149] |
| T-BioVax | Heat shock HspC protein antigen complexes | ImmunoBiology Ltd. | ![ ]() [ ]() [ ]() [150–151] |
| TBVax | T cell epitope-based DNA-prime/peptide boost vaccine | EpiVax, Inc. | ![ ]() [ ]() [ ]() [152–154] |
| EspC | Recombinant protein and/or viral-vectored | Imperial College London | ![ ]() [ ]() [ ]() [ ]() [155] |
| PS- conjugate | Subunit Mtb polysaccharide protein conjugate | Albert Einstein College of Medicine | ![ ]() – |

²Candidate information acquired from published literature.
Abbreviations

BCG – Bacille Calmette-Guérin
IL – Interleukin
GMP – Good Manufacturing Practices
GSK – GlaxoSmithKline Biologicals
M. bovis – *Mycobacterium bovis*
MTB – *Mycobacterium tuberculosis*
NIAID – National Institute of Allergy and Infectious Diseases
NIH – National Institutes of Health
OETC – Oxford-Emergent Tuberculosis Consortium, Ltd.
SSI – Statens Serum Institute
TBVI – Tuberculosis Vaccine Initiative
UCLA – University of California Los Angeles

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