Sustaining the Market for Child TB Treatment

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TB Alliance

Catalyzing and advancing new TB cures

• Founded in 2000
• Not-for-profit product development partnership (PDP) model
• Largest TB drug pipeline in history
• Offices in New York City, USA and Pretoria, South Africa
• Experienced drug discovery/development, regulatory, and formulation team
• Entrepreneurial, virtual approach to drug discovery and development
• ~50 employees
• Broad and diverse partnership base

We’re speeding development of shorter, simpler, safer, and affordable TB treatments
The Problem

Children with TB are the neglected of the neglected

- TB is a leading cause of death among children worldwide and children are susceptible to the most severe and fatal forms of the disease
- The market for pediatric medicines is “broken” and needs repair and requires:
  - Better estimates of how many children get TB and where they are located
  - Clarity on drug registration pathways
  - Consistency of treatment policies and practices
  - Prioritization by governments, donors, in-country stakeholders (i.e., NGOs, private sector) and drug companies
Unmet Medical Need

Not enough kids being treated – and not being treated appropriately

Goal

Increase access to correctly dosed, properly formulated, affordable, high quality pediatric TB medicines

Implementing Partner

World Health Organization

Timeline

High quality, child-friendly, properly dosed HRZ, HR and E products available by early 2016
# Three Key Outcomes

## Scope of Initiative

<table>
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<tr>
<th><strong>Market Catalyzed</strong></th>
<th><strong>Drugs Available</strong></th>
<th><strong>Uptake Influenced</strong></th>
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| • Market Research--How many patients? Where? How are they currently being treated?  
• Manufacturers’ commitments  
• Momentum and visibility | • Correct dosage & dispersible form for HRZ, HR, and E  
• Shorten gap between approval of adult products vs. pediatric products | • Global treatment guidelines adopted  
• National guidelines developed and health workers trained  
• Child TB included in NSPs and Global Fund Concept Notes  
• Funding committed for product and implementation |
Timeline for New First-Line Pediatric Formulations:

- **2013:** Project Launch
- **Q1 2014:** Initiate discussions with GDF, Global Fund, other donors
- **Q2 2014:** Three manufacturing partners secured
- **Q4 2014:** Countries quantify cases of child TB
- **Q1 2015:** Manufacturers submit for WHO PQ and local registration
- **Q2 2015:** Dosage guidelines for children <5kg
- **Q2/3 2015:** First-line FDC products available to procure through GDF and/or Importation waivers
- **Q2 2016:** All first-line products WHO pre-qualified and available in the market
Market Research Objectives & Activities

STEP-TB Project aims to achieve the following

• Gather **market data** on the existing and potential pediatric TB market to make the business case to manufacturers, donors, and governments

• Conduct **demand-side research** on
  – the size of the market (public and private),
  – current treatment practices and policies,
  – consumer and prescriber preferences

• Conduct research on the **concerns, constraints and drivers of global, national, local and private purchasers** of pediatric TB medicines

• Conduct supply-side research on the **concerns of sellers** of pediatric TB medicines
Framework for Analyzing TB Market

Finding children with TB

TOTAL CASES [Treated & Untreated]
TREATED CASES [NTP & non-NTP]
REPORTED CASES [NTP including PPM]

TOTAL POTENTIAL MARKET SIZE
PRIVATE SECTOR SALES
DIRECT NTP PROCUREMENT
GDF DISTRIBUTION
Call to Action

TB-Free Future for Children

EVERY CHILD DIAGNOSED IS TREATED FOR TB

REGULATORS
Inclusion in Trials
Clear Speedy Pathway

COUNTRIES
Quantify Child TB in Country
Implement Current Guidelines
Scale-up Contact Investigation
Fast-track Product Registration
Include Child TB in Budget and Grants

MANUFACTURERS
Optimal Products Available
Steady Supply

DONORS
Fund New Products
Encourage Use of New Products
Thank you!

For more information on childhood TB go to: tballiance.org/children