



4 February 2014

Foreign Affairs, Defence and Trade Committee
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

Attention: Foreign Affairs, Defence and Trade Committee:

Australian government support for tuberculosis research and development under the Medical Research Strategy

I am writing on behalf of the Global Alliance for TB Drug Development (TB Alliance), a product development partnership (PDP) dedicated to the discovery and development of better, faster-acting drugs for tuberculosis (TB). The Australian government's critical investment of \$2.5 million in the TB Alliance through the Medical Research Strategy in 2012-2013 has been instrumental in accelerating the development of lifesaving new therapies to tackle TB, while fostering important scientific collaborations that link Australian researchers to the global R&D pipeline.

The Asia Pacific region is home to almost 50% of TB cases in the world.¹ The increasingly obsolete tools used to treat TB have contributed to an alarming rise in drug-resistant disease with a profound health and economic impact in advanced and developing economies alike. In high burden countries, the cost of TB is astronomical— projected at more than US \$23 billion a year in India alone,² while even in low burden settings, TB's financial toll is profound, costing European nations almost €6 billion each year.³ Existing treatments for multi-drug-resistant (MDR) and extensively drug-resistant TB (XDR-TB) are toxic, can take more than 2 years to complete, and— as recent cases of XDR-TB in Queensland have evidenced— can cost health systems up to \$1 million *per patient* to deliver.⁴ Given the complexity, cost, duration, and toxicity of current treatments, only 10% of MDR-TB cases successfully complete therapy— leaving the spread of this deadly, and incredibly mobile, disease unchecked.⁵

With the Australian government's support in 2012-2013 through AusAID's Medical Research Strategy, TB Alliance has made ground-breaking progress in advancing its portfolio of improved TB treatments, with anticipated near-term impact in Australia and across the Asia Pacific region.

Key progress includes:

- Completing clinical development for the first new, treatment-shortening regimen for drug-sensitive TB in 4 decades. (Top-line results forthcoming in 1Q2014)

¹ WHO. 2013. *Global TB Report, 2013*. Geneva: WHO.

² Government of India. (2011) *TB India 2011: Revised National TB Control Program Annual Status Report*.

³ Kelland, Kate. 2013. Tuberculosis "time bomb" costs Europe billions of euros a year, Thu Aug 15, 2013.

⁴ Kirby, Tony. Extensively-drug-resistant TB hovers at Australia's door. *Medical Journal of Australia*. 2013; 198 (7): 355.

⁵ WHO. 2013. *Global TB Report, 2013*. Geneva: WHO.



- Advancing the PaMZ (PA-824, moxifloxacin, and pyrazinamide) regimen for both drug-sensitive and multi-drug resistant TB (MDR-TB) to pivotal Phase 3 development. If successful, this regimen will shorten treatment duration by 75% and reduce treatment costs by up to 90% for some forms of MDR-TB, making MDR-TB treatment affordable and scalable for the first time in history.
- Closing gaps in access to appropriate treatments for pediatric TB through a new program to catalyze the manufacture and commercialization of WHO recommended pediatric TB formulations.
- Identifying a once-a-day, oral, 3 month universal regimen for all forms of TB, including XDR-TB, in preclinical models.
- Collaborating with National TB Programs and local partners in countries such as Indonesia and Vietnam to begin planning for introduction of the new anticipated drug sensitive regimens.

TB Alliance partners with dozens of private sector and academic partners, including Griffith University in Brisbane, in order to drive innovation for this otherwise neglected disease. Together with partners, we are poised to deliver 7 improved TB treatments to market within the next 2 years, at a fraction of the cost of conventional R&D approaches.

While constituting a relatively small proportion of Australia's overall aid commitments, the \$2.5 million in funding provided to the TB Alliance under the Medical Research Strategy has been critical in accelerating the delivery of TB treatments with the potential to dramatically reduce health system costs—within Australia and globally— while saving millions of lives. In a context in which treating just a few drug-resistant patients can cost health systems millions of dollars, investment in improved, shortened, and affordable TB treatments reflects tremendous value for money. We urge the Australian government to continue its important investment in TB drug research and development in 2014-2015 and beyond to ensure that the critical progress that has been made is not derailed.

Sincerely,

Melvin Spigelman, MD

President and Chief Executive Officer,
Global Alliance for TB Drug Development