



The Global Alliance for TB Drug Development (TB Alliance)

The Product Development Partnership III Fund

Tuberculosis (TB) is the leading infectious disease killer globally

Each year, 9 million people are infected with TB, of which 1.5 million people eventually die. Nearly all TB cases and deaths occur in the developing world and those afflicted everywhere are mostly the poorest and most vulnerable. Especially women and children are uniquely impacted by the disease as TB is the third most deadly killer of women of child-bearing age. Each year, one million children get sick with TB and approximately 10 million children are orphaned by the disease. TB is also the leading cause of death among people living with HIV; one in four deaths of people with HIV is due to TB. Despite the massive threat of TB, treatment is wholly inadequate. The length and complexity of treatment has resulted in widespread drug-resistant TB. Treating drug-resistant TB is ineffective, toxic, and prohibitively expensive.

TB Alliance aims to develop an affordable “universal” treatment regimen for TB

TB Alliance’s mission is to dramatically impact the tuberculosis pandemic by developing new, faster-acting and affordable TB treatments that are available to those who need them. The ultimate vision of the organization is to develop an ultra-short “universal” treatment that can cure all forms of TB. During the period 2016-2020, TB Alliance plans to make considerable progress toward this

vision by introducing new combination treatments (also called “regimens”) that would shorten and improve treatment for drug-sensitive and some forms of drug-resistant TB as well as advance at least three new drugs into human studies.

Today, treatment for drug-sensitive TB takes a minimum of six months with four drugs and treatment for drug-resistant TB can take two years, or even longer, with the potential for a dozen or more pills and injections. In the period 2016-2020, among other programs, TB Alliance plans to create a shorter and better regimen by introducing a new four-month regimen for drug-sensitive TB and a new six-month regimen for many people with multi drug-resistant (MDR-TB). This will be the first significant improvement to the standard of care in drug-sensitive TB in more than 40 years and the first treatment shortening and simplification for MDR-TB treatment ever. At the same time, TB Alliance is optimistic that a novel approach initiated in 2015 to test the first new treatment for extensively drug-resistant (XDR-TB) – where today, few patients survive -- will be successful and at a minimum lead to a new six to nine month all-oral drug regimen for people with no other options. Product Development Partnerships (PDP) amplify impact TB Alliance brings together drug trial sponsors to develop the best TB drug regimens, regardless of which drug happens to belong to which sponsor. This collaboration forges partnerships among

pharmaceutical companies and other drug developers, regulatory agencies, and non-profits to support advances in regulatory science, the development of infrastructure, and other progress needed to facilitate the development and availability of new TB treatments. This approach shortens the time it takes to introduce impactful TB drug regimens by decades and significantly reduces costs. Such a consortium would not have been possible without a PDP such as TB Alliance.

TB Alliance catalyzed the TB drug development field by drawing in industry, non-profit partners, and communities affected by TB as well as marshalling resources to develop and advance new TB treatment regimens. Cost-sharing approaches are also piloted in South Africa, China, and Brazil, accelerating development in these high-burden countries as well as adding funding, expertise, and infrastructure. TB Alliance's strategy for manufacturing partnerships is important to create sustainability and to engage the private sector in a key and expensive part of the product development cycle. Earlier funding by the Netherlands Ministry of Foreign Affairs (MoFA).

Previous funding by the Netherlands Ministry of Foreign Affairs

TB Alliance is now poised to advance promising drug combinations into the last stages of testing before they can be made globally available. This is only possible because of previous support from the Netherlands Ministry of Foreign Affairs, which helped ensure that

novel drugs from new drug classes are now available. MoFA's previous investment has also laid the groundwork to allow TB Alliance to bring one or more new drug candidates into preclinical development per year. This ensures a more promising pipeline for the future of TB treatment.

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| Total budget lead applicant (5 years) | € 162,992,718 |
| Contribution by the Netherlands Ministry of Foreign Affairs | € 15,300,000 |

Key partners TB Alliance

TB Alliance was founded as a response to a global declaration signed by over 100 public and private entities, many of which are now organized in the TB Alliance Stakeholder Association. TB Alliance operates on a virtual model, maximizing the use of partner capacity in both developed and developing countries with high TB burden. TB Alliance works with industry (e.g. Janssen, Mylan, GSK and Sanofi), civil society (e.g. KNCV-TB and Artsen Zonder Grenzen), patient representatives, academia, and of course WHO.

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The Product Development Partnerships III Fund of the Ministry of Foreign Affairs

The Product Development Partnerships III Fund (PDP III) contributes to innovation in the areas of healthcare products and technologies specifically aimed at diseases and conditions related to poverty and sexual and reproductive health and rights (SRHR). The fund focuses on the development and availability of affordable, effective medicines, vaccines, diagnostics and innovative products for neglected diseases and conditions, with a view to combating poverty and inequality. The Ministry of Foreign Affairs therefore supports PDPs, which are public-private partnerships set up to accelerate the development and availability of products which are unlikely to attract private investment while in development.