

# Impact investing: Developing a drug to help eradicate River Blindness



## The objective of impact investing is to simultaneously deliver both financial and societal returns.

These two criteria are not conflicting but are both demanding. The financial targets are not token but competitive, market rate returns. The societal objectives require a demonstration of clear, intentional and measurable benefits.

Here we look at how our impact investment platform is contributing to tackling global health challenges in developing countries – transforming tomorrow with a new generation of innovative private market projects.

## Case study – Moxidectin

**River Blindness is the world's second leading infectious cause of blindness.** With 198 million people at risk in some of the poorest and most remote regions of the world it poses a serious public health problem and obstacle to socioeconomic development. Until recently, the main drug used to treat infections was cumbersome – requiring delivery of two doses a year for up to 15 years.

In May 2018, Medicines Development for Global Health (MDGH), a non-profit organisation in Australia dedicated to the development of affordable medicines and vaccines, received approval from the US Food and Drug

Administration (FDA) for a medication, Moxidectin, with the potential to eradicate *onchocerciasis* or River Blindness. This was only made possible with the impact investment of the Healthcare Research & Development focused fund (the Fund) featured in this case study. The Fund played a catalytic role in financing MDGH and making this treatment a reality. The Fund was financed by investors including AXA IM, which also chairs the Investor Advisory Committee. Adding to the story, the Fund's US\$13 million investment in the drug has now returned US\$60 million in gross value to the Fund\*.

*\*AXA IM, May 2019. Past performance is not a guide to future returns.*

## Social impact requirements



Starting with the overall theme of Health and Well-being, this impact investment centres on UN Sustainable Development Goal 3 – ensure healthy lives and promote well-being for all ages. Underlying this goal is a range of issues, including financial risk protection, access to quality essential healthcare services and access to safe, effective, and affordable essential medicines and vaccines. This investment programme seeks to improve the health and well-being of underserved communities at scale by targeting neglected diseases.

### Did you know?

1.6 billion people require mass or individual treatment and care for neglected tropical diseases

## The River Blindness impact challenge

**Onchocerciasis or River Blindness** is a condition caused by a parasitic worm and can cause blindness if it migrates to the eyes. Most commonly it manifests with debilitating skin rashes, lesions and itching.

Second only to trachoma as an infectious cause of blindness worldwide, the disease is transmitted by blackflies that live and breed near fast-flowing streams and rivers, mostly in remote villages located near fertile land where people rely on agriculture.

**99%**  
of infected  
people live in  
31 African  
countries

It is estimated that 198 million people are at risk in some of the poorest and most remote regions of the world. In Sub-Saharan Africa alone 20 million people are infected and 100 million are at risk.<sup>1</sup>

Until recently the main drug used to treat River Blindness was difficult to distribute and administer effectively, partly as it requires twice yearly doses for a decade or more. And although the disease affects tens of millions of people, as the world's poorest there was little financial incentive for major pharmaceutical companies to develop a better alternative. It remained a neglected disease.

### River Blindness disease cycle:

1. **Blackfly:** The infected insect takes a blood meal from a human. A pool of blood is pumped up into the fly, saliva passes into the pool, and infective *Onchocerca* larvae pass from the fly into the host's skin.
2. **Infection:** The larvae enter the host's skin tissue, where they migrate and form nodules, and slowly mature into adult worms.
3. **Proliferation:** New worms form new nodules and cluster together. Smaller male worms migrate between nodules to mate.
4. **Reproduction:** After mating, eggs form inside the female worm and develop into microfilariae. A female may produce 1,000 per day.
5. **Transport:** When the infected host is bitten by another fly, microfilariae are transferred from the host to the fly.

## The case for investment

The Fund only invests in companies developing therapeutics or diagnostics which address critical needs in low-income countries, and also have compelling financial prospects. In other words, both impact and financial returns are required. When MDGH approached the Fund in 2015 for an investment, it was clear that Moxidectin was a promising therapy for onchocerciasis, but the financial returns required the promise of the FDA's little-known Priority Review Voucher (PRV) program.

### The FDA Priority Review Voucher program (PRV)

The PRV was set up to motivate more treatments for neglected and rare diseases and also speed the approval of potential blockbuster therapies. A developer of a treatment for a neglected or orphan disease receives a voucher for priority review from the FDA to be used with a product of its choice or sold to another developer.

### Moxidectin's promise

Moxidectin demonstrated a long half-life and the ability to kill both adult worms and microfilariae of onchocerciasis. This holds the promise of allowing less frequent dosing to eliminate the disease.

### Financial potential

While onchocerciasis affects millions of people, they are the world's poorest and there is no financial promise in treating the disease. Fortunately, the FDA identified specific neglected diseases to be tackled, including onchocerciasis and they undertook to issue developers a voucher for a priority review if a new drug receives approval for a disease on this target list.

A priority review means an FDA decision within six months, compared to 10 or more for a regular review. Furthermore, the voucher can be sold, the major pharmaceutical and biotechnology companies place tremendous value in an expedited timeline to market. In the case of Moxidectin, the sale of the voucher became the basis for the financial investment.

<sup>1</sup> <https://www.who.int/news-room/fact-sheets/detail/onchocerciasis>

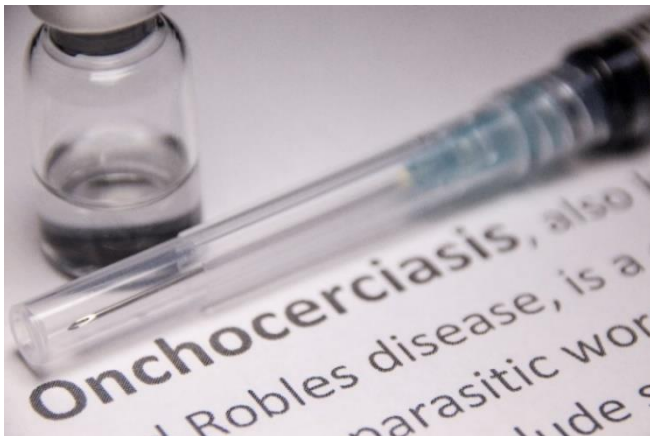
### **Moxidectin background**

Moxidectin was originally developed by Wyeth in the United States. Pfizer then acquired Wyeth and activities were placed on hold. The World Health Organization (WHO), however, wanted to see the drug developed and financed initial Phase III studies in Africa. WHO was not able to finance all studies to completion and the drug was not developed further. MDGH approached WHO in 2014 to determine the cost to finish development of Moxidectin. MDGH then licensed the rights to Moxidectin with the requirement of raising US\$10 million.

### **The Fund's Investment - more than capital**

The Fund invested US\$13 million into the development of Moxidectin in 2015. In a unique structure, the Fund financed the activities led by MDGH, a non-profit organisation in Australia. The Fund and MDGH agreed to share proceeds from a PRV sale in a pre-determined manner that included setting aside US\$20 million for additional research on Moxidectin and distribution of the drug to those who need it.

The Fund's managing partner, who has invested in and operated companies that have received FDA approval or clearance for 15 products, took an active role in the development of Moxidectin, including manufacturing assessments, FDA meeting preparation and attendance, and operational issues with MDGH and consultants.



### **Delivering on the dual objective - positive impact and financial returns**

FDA approval and a PRV were received in June 2018. In May 2019, MDGH sold its PRV to an undisclosed buyer. The proceeds of the sale generated over US\$60 million in gross return value to the Fund (a 4.6x multiple)<sup>2</sup>.

But this is not the end of the story. The Fund retains a stake in a new adjacent company, and will continue to work with MDGH to make sure Moxidectin gets to the people who need it and to continue researching Moxidectin for its efficacy in other conditions such as scabies and head lice.

**The Moxidectin story, with its promising positive impact and realised investment returns, is a prime example that impact investing can deliver on both fronts.**

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<sup>2</sup> Source: AXA IM. Past performance is not a guide to future returns. The investment examples are intended for purposes of discussion of the strategy and no representation is made that these examples are past or current recommendations, that they should be bought or sold, nor whether they were successful or not.

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