Medicines Development for Global Health

2022–2023

Annual Report

Medicines Development for Global Health acknowledges the Yalukit Willam Peoples of the Boon Wurrung, the First Peoples of Country on which the company's headquarters stands. We pay our respects to all the world's First Peoples, to their ancestors and Elders, and to our shared future.

Contents

From MDGH's Board Chair and Managing Director

"In all our work we look forward to the momentous achievement of a transformative new medicine and the possibility of now seeing the natural history of that disease cleaved into 'before' and 'after' approval."

Lorna Meldrum, PhD

Chair of the Board,
Medicines Development for
Global Health

Mark Sullivan, AO

Managing Director,
Medicines Development for
Global Health

Photo: Left page: *Mother and daughter Hmong, working at Vietnam rice fields on terraced in rainy season at Mu cang chai, Vietnam. [Photo credit: AdobeStock stock photo ID: 126249959].*

Welcome to our 2022 and 2023 Annual Report and thank you for your continued interest in Medicines Development for Global Health, our mission and our progress.

Although we all want to think the lock-downs and disruption from Covid-19 are now in our rear-view mirror, we know that the knock-on effects will be with us for a long time to come, and this applies as much to the timelines for developing new medicines as it does to any other worthwhile endeavour. And we also know that for the 1.7 billion people worldwide affected by neglected tropical diseases, and who we seek to serve by developing new and improved medicines, the reality is to live under the weight, fear, and disruption of disease every single day.

It has been said that the path to seeing a new medicine approved is a long series of technical, unglamourous tasks regularly punctuated by moments of exhilaration when milestones are met – a trial completes enrolment, data is published in a journal, a positive discussion with regulators. But above all we look forward to the momentous achievement of a transformative new medicine and the possibility of now seeing the natural history of that disease cleaved into 'before' and 'after' approval.

In this edition of our Annual Report, you will learn about the steady progress we have been making with our pipeline – two promising agents targeting seven diseases that together impact more than a billion people worldwide. You will read about milestones met in our development programs, and progress towards our goals in target disease areas.

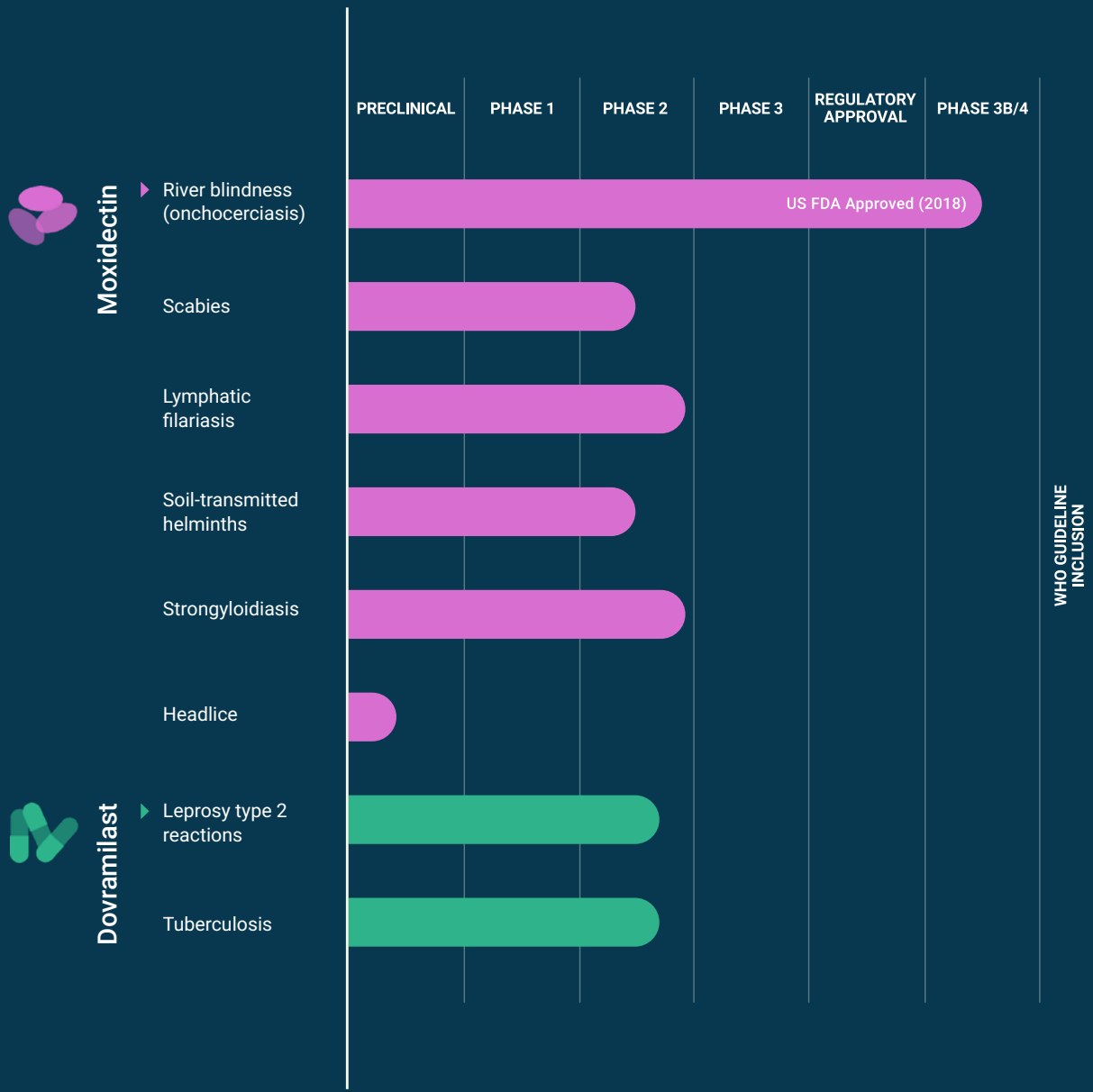
Although Medicines Development for Global Health follows the same complex pathways and same high standards for developing new medicines as large for-profit pharmaceutical companies, we don't have a cast of thousands with which to do it. In 2023 we reached 23 full-time employees, and we continue to rely upon our supporters, collaborators from within the global health community who share our vision. In this issue of our Annual Report we want to share with you some of their voices.

We could not have succeeded in gaining United States Food and Drug Administration approval for moxidectin for onchocerciasis, nor continued our quest to gain acceptance by the World Health Organization for inclusion of moxidectin in treatment guidelines for onchocerciasis without the tireless efforts and dedication of our staff; the guidance and wise counsel of researchers, investigators, collaborators, and regulatory authorities; and the generosity of funders.

Please read more for the latest information about our work and, as always, we invite you to join us and help support Medicines Development for Global Health in its ongoing development efforts.

Pipeline

We continued to make significant progress in the development of our pipeline. Our active portfolio comprises of two important medicines, moxidectin and dovramilast, which are under investigation for seven different neglected diseases, that collectively impact the health of more than a billion people worldwide, invariably in some of the most disadvantaged communities on earth.



Moxidectin

Moxidectin was approved for the treatment of river blindness (onchocerciasis) in people aged 12 and older, in 2018, and since then Medicines Development for Global Health has been undertaking the work necessary to achieve World Health Organization guideline and essential medicine listing inclusion.

In addition to river blindness, we continue with clinical evaluations of moxidectin for the treatment of lymphatic filariasis, scabies, soil-transmitted helminths and strongyloidiasis. Moxidectin holds the potential to be one of the most important global health medicines in history.

Moxidectin is an oral broad-spectrum anti-parasitic medicine that works by binding to glutamate-gated chloride channels in the nerves and muscle cells of parasites.

Dovramilast

Dovramilast is under investigation for its potential to replace thalidomide and steroid therapy for the treatment of leprosy type 2 reaction. These existing therapies have detrimental side effects. In addition, through partnerships with the Aurum Institute, dovramilast is under investigation as an adjunct treatment for tuberculosis, where its anti-inflammatory action may lead to a reduction in lung tissue damage.

Our pipeline is grounded in two inviolable principles: sponsored studies are conducted to the exacting standards of the most stringent regulatory authorities (such as the United States Food and Drug Administration); and we are committed to the development of our pipeline to serve the needs of underserved populations who are at risk of these devastating – but treatable – conditions.

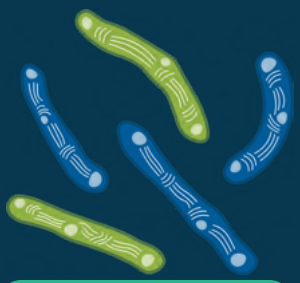
Dovramilast is a phosphodiesterase type 4 (PDE-4) inhibitor from the same class of medicine as Otezla® (apremilast), a well-known treatment of psoriasis marketed by Amgen. Dovramilast modifies the body's immune response to infection. At the end of 2023, dovramilast was awarded Orphan Drug Designation by the FDA for leprosy type 2 reaction. The name dovramilast was adopted in 2023 – it was formerly designated CC-11050 as well as AMG 634.

Scabies

River blindness

7 diseases

Lymphatic filariasis



Leprosy type 2 reaction

OUR IMPACT

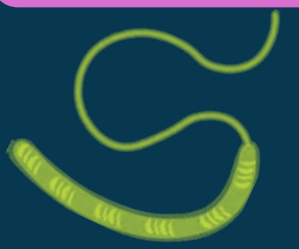
1.7B+

people suffer from neglected tropical diseases worldwide

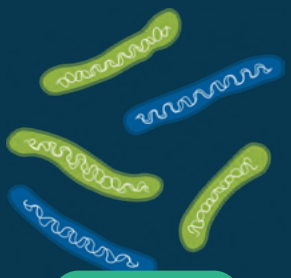
2 molecules

- Moxidectin
- Dovramilast

Soil transmitted helminthiasis



Stronglyloidiasis



Tuberculosis

13 clincal site locations:

(active or recently completed)

Professor John Reeder

Director, Special Programme for Research and Training in Tropical Diseases (TDR)

Professor John Reeder has been a critical supporter of moxidectin to realize its potential as a treatment for river blindness for many years. When Pfizer withdrew as co-development partner, the search for a suitable partner began. Under his leadership, the TDR and Medicines Development for Global Health collaboration took shape.

There have been many significant challenges – and uncharted territory – along the way, and he freely acknowledges the difficulties the team faced. "You do what you have to at the time, but when you look back and start writing it all down you realise it was quite a struggle, and it could have easily gone wrong at any point."

Challenges stretched from navigating the legalities of ownership, to the complications of conducting clinical trials in resource-poor settings, to negotiating with the United States Food and Drug Administration to gain product registration. And on top of that, Professor Reeder understood that this would be a costly venture and would need innovative financing approaches. Importantly for Professor Reeder, "Financing for this project would need to drive the product forward to be able to reach those who need it the most, at the lowest possible cost."

Moxidectin was approved by the United States Food and Drug Administration for the treatment of river blindness in people aged 12 and older in June 2018, a joint success for TDR and Medicines Development for Global Health.

Photo: *Moxidectin 2mg tablets. [Headshot photo credit: Prof. John Reeder].*

> **"This was a true partnership. It couldn't have happened without this, this moment in time when the right partners got together: TDR and Medicines Development for Global Health."**

But as Professor Reeder tells it, that was simply the beginning. One of the aspects of the moxidectin story that excites him most is that it has shown how public money could be put to use to take a veterinary product and see its potential for human use for those most in need emerge. "The important thing is this is one of those diseases that affects the poorest of the poor, those who really are outside the healthcare system. And the fact that we've been able to bring to reality the first drug for river blindness for 30 years is exciting."

Moxidectin in onchocerciasis

ABOUT RIVER BLINDNESS

River blindness (also known as onchocerciasis) is a neglected tropical disease caused by the parasitic worm *Onchocerca volvulus*, which is transmitted to humans via bites from infected black flies. The resulting infection can lead to severely debilitating and disfiguring skin conditions, visual impairment and even blindness. More than 200 million people are at risk of infection and almost all infected people live in 31 African countries. River blindness elimination programs rely on the public health strategy known as mass drug administration or community directed treatment, in which the whole population in endemic areas are treated, regardless of disease status. Ivermectin is the current standard of care for treating river blindness and has been donated in endemic areas for over 30 years. Despite this, there are still many areas where prevalence is high, and elimination of disease transmission is a long way off which is why new medicines, like moxidectin, are required.

31

African countries are where the majority of infected people live

65

key onchocerciasis and NTD stakeholder meetings attended

10+

invitations to speak to key audiences

2

manuscripts submitted for publication

PROJECT SPECIALIST PROFILE

Mupenzi Mumbere MD

Senior Clinical Project Manager, Medicines Development for Global Health

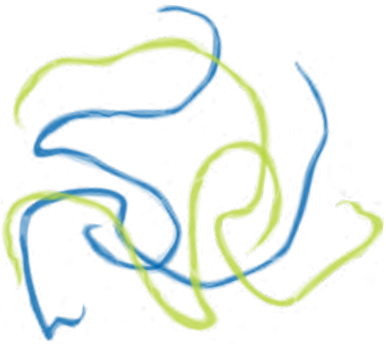
[Headshot photo credit: Mupenzi Mumbere, MD]

Dr Mupenzi Mumbere was initially exposed to moxidectin as an Investigator for the original Phase 3 trial of moxidectin vs ivermectin, which demonstrated the superiority of moxidectin at reducing skin microfilarial load[2]. Today, he works for Medicines Development for Global Health from his office in the Democratic Republic of Congo, as senior clinical project manager supporting the two Phase 3b/4 trials: the repeat dose study (MDGH-MOX-3001), which recently completed enrolment, and the large safety study (MDGH-MOX-3002), designed to evaluate the "real world" use of moxidectin in typical river blindness and lymphatic filariasis-endemic community settings. This study provided Mupenzi with a new challenge working as part of the MDGH study Sponsor team – supporting the set up of a second study site in Cote d'Ivoire. He describes it as "a period of intense work, fortunately rewarded by positive outcomes."

> **"Working for Medicines Development for Global Health is a unique opportunity for me to contribute to the development of a medicine that will have a significant impact on the health of millions of people. It is also an excellent opportunity for me to learn from colleagues with a rich diversity of backgrounds."**

Dr Mumbere has a unique perspective on moxidectin from his work both as an Investigator and now as senior clinical project manager and is enthusiastic: "Having seen the potential of this medicine to combat river blindness better than current options, I am excited about the possibility that the world will have a medicine that will accelerate the elimination of onchocerciasis as a public health problem in countries where it is endemic."

Photo: Left page: *Fishermen on the beaches of Yongoro, Sierra Leone, West Africa. [Photo credit: AdobeStock stock photo ID: 114232833].*



In 2018, the United States Food and Drug Administration approved moxidectin for the treatment of river blindness (onchocerciasis) in people aged 12 and older. It was the first new medicine to be approved for this debilitating disease in more than 30 years. We are dedicated to seeing moxidectin delivered to the people at risk of onchocerciasis and have been working tirelessly since the approval to generate the additional data required by the World Health Organization for moxidectin's inclusion in treatment guidelines where it can help accelerate elimination of disease transmission.

One of the requirements for World Health Organization guideline inclusion is generating the evidence to support use of moxidectin in children under 12 years of age. In 2022, we completed a paediatric dose-finding study to inform selection of a dose for children aged 4 to 11 years (MDGH-MOX-1006, NCT03962062). Data from this study will be used to support an application to the United States Food and Drug Administration in 2024 for inclusion of the treatment of children from 4 years of age in the moxidectin prescribing information for river blindness. Another requirement was a larger scale "safety" study (12,500 participants) to generate real world evidence for the use of moxidectin in river blindness (MDGH-MOX-3002, NCT04311671).

PROJECT SPECIALIST PROFILE

Peya Gaye, PhD

Senior Clinical Project Manager, Medicines Development for Global Health

[Headshot photo credit: Peya Gaye, PhD]

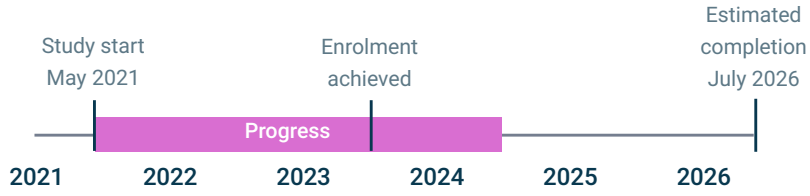
Dr Peya Gaye joined Medicines Development for Global Health in March 2023. Based in Senegal, Peya is managing the ongoing Phase 3b/4 large safety study of moxidectin in onchocerciasis (MDGH-MOX-3002). She is an international clinical research specialist with 15 years experience in the conduct of clinical trials in Europe, North America, Africa, and Asia, acting as Clinical Operations Manager, Project Manager, Investigational Product Manager and Senior Clinical Research Associate. Peya has more than 10 years of experience in the management and monitoring of clinical trials from Phase 1 to Phase 4 in different therapeutic areas including ovarian cancer, lung cancer, breast cancer, pain management, malaria, ebola virus disease, and COVID-19.

Peya has worked in both high- and low-income countries and has developed specific technical expertise to implement and manage ICH-GCP clinical trials in challenging environments. Most recently she worked on a 30-country platform trial for the World Health Organization. Peya has a PhD in Microbiological and Water Chemistry from University of Poitiers and a post-graduate diploma in Epidemiology from University of Bordeaux, both in France.

CLINICAL STUDIES

A repeat dose study in the Democratic Republic of Congo, MDGH-MOX-3001 (NCTNCT03876262):

This 320-participant Phase 3b/4 study is comparing the safety and efficacy of annual or biannual doses of moxidectin to ivermectin. The study achieved full enrolment in the middle of 2023 and will complete in 2026.

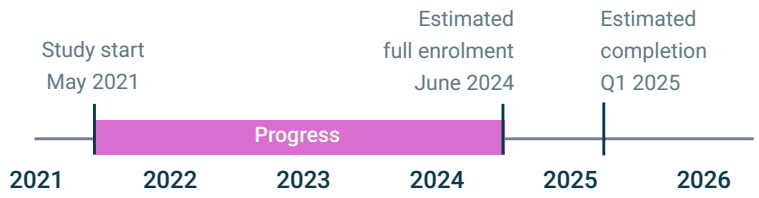


Why is this study important?

The question of whether to use ivermectin once per year or twice per year has been debated for decades. This study will provide important data on the optimal ivermectin and moxidectin regimens to inform the onchocerciasis community in their decision-making on treatment frequency during onchocerciasis elimination campaigns. The data will facilitate disease and cost-effectiveness modelling of each strategy in various field settings, including estimated times to disease transmission elimination. This information will enable both national programs and funders to select what product and dosing strategy to use in different circumstances to achieve disease elimination targets.

A single-dose endemic-community safety study, MDGH-MOX-3002 (NCT04311671):

This 12,500 participant study comparing safety of a single dose of moxidectin with ivermectin had recruited around 10,000 participants by year end 2023. To accelerate recruitment into the study, a second clinical trial site in Côte d'Ivoire was opened mid-2023. This site recruited people living in areas endemic for both river blindness and lymphatic filariasis. Both sites have now recruited children aged 4 to 11 years old.



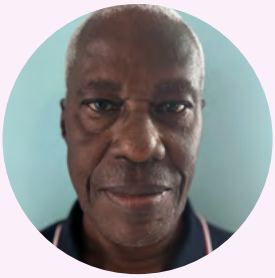
Why is this trial important?

This large study is evaluating the 'real world' use of moxidectin in typical river blindness and lymphatic filariasis-endemic community settings – where some participants will have neither disease, some will have one disease and others may have both diseases. The resulting data will be used to support the World Health Organization's decision making regarding the inclusion of moxidectin in treatment guidelines for these diseases.

PILOT FIELD PROJECTS TO DEMONSTRATE ACCEPTABILITY AND FEASIBILITY OF MOXIDECTIN

During 2022 and 2023 discussions continued with the World Health Organization and with potential stakeholder countries on the implementation of pilot field projects. Pilot field projects are large community directed treatment programs used to assess the acceptability and feasibility of moxidectin in real-world use settings. With the receipt of World Health Organization Onchocerciasis Technical Advisory Subgroup endorsement, these projects are expected to begin in 2024. The first pilot community treatment program for river blindness with moxidectin is planned for the Twifo Atti-Morkwa district of Ghana in partnership with the Ghana Health Service, the University of Health and Allied Sciences in Ghana, the Bruyère Research Institute in Canada, and The Leona M. and Harry B. Helmsley Charitable Trust.

Photos (next page): Top: *Children participating in the study are having lunch together with the parent who stays with them in the UHAS Research Center. Here they can also watch TV and play.* ***Second:*** *Study nurse administering moxidectin to study participant.* ***Third:*** *A study nurse is obtaining a blood sample for pharmacokinetic and safety analysis from a child whose mother is assisting.* ***Bottom:*** *Dr Opoku, the PI, and a study nurse, are examinig a child in the presence of an interpreter and the mother. [Photo credit: Mr Edem Agbogah, Study Co-ordinator]. [Headshot photo credit: Dr Nicholas Opoku].*



Nicholas Opoku, MBCHB, MSC

Senior Lecturer, Department of Epidemiology & Biostatistics, FN Binka School of Public Health, University of Health and Allied Sciences, Ghana

Dr Nick Opoku was one of the original Investigators for the Phase 3 study which demonstrated the superiority of moxidectin over ivermectin at decreasing skin microfilarial burden, and which was the basis for the 2018 United States Food and Drug Administration approval of moxidectin. More recently he was Principal Investigator for the moxidectin paediatric study (protocol number MDGH-MOX-1006; NCT03962062), which was an open label study to identify the optimal moxidectin dose for children aged 4-11.

Conducting this study involved twin challenges: the navigation of three different institutional ethics committees and the Ghana Food and Drugs Authority to obtain approval to proceed with the study; and maintaining Covid-19 transmission prevention protocols while the study was ongoing. Thankfully, both were negotiated successfully and data from this study, which is now complete, will be submitted to the United States Food and Drug Administration to support expansion of the moxidectin approved label to include children aged 4-11.

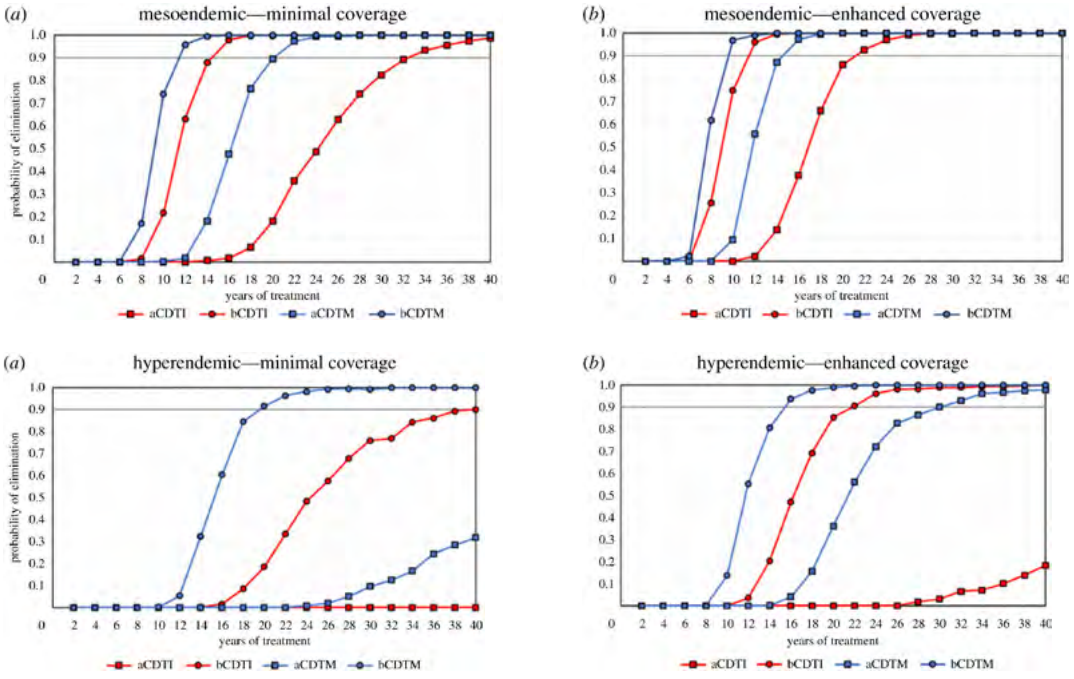
Dr Opoku is excited about the potential for moxidectin:

> **"A single dose of moxidectin suppresses skin microfilariae for a longer period of time than ivermectin which is particularly useful in reducing the frequency of dosing, which could improve compliance and accelerate elimination of onchocerciasis transmission."**

MODELLING THE ACCELERATION OF RIVER BLINDNESS ELIMINATION WITH MOXIDECTIN

Figures below: *Modelling of elimination probabilities in scenarios where the infection is either moderately common (mesoendemic) or very common (hyperendemic), after years of annual (squares) or biannual (circles) community-directed treatment with ivermectin (CDTI) or moxidectin (CDTM) (see endnotes for details)[1].*

For many years, experts studying river blindness have understood that annual treatment with ivermectin might not be adequate to achieve elimination of disease transmission in some settings. Building upon the data from Phase 2 and Phase 3 clinical trials with single-dose moxidectin, the EPIONCHO-IBM team at Imperial College London modelled possible scenarios for achieving elimination of transmission by comparing ivermectin and moxidectin strategies in a range of endemicity settings, factoring in annual vs biannual treatment frequencies, and accounting for different rates of therapeutic coverage and adherence[1]. Projections from this modelling indicate that 6-monthly administration of moxidectin could reduce by half the number of years needed to achieve elimination of transmission in areas with moderate endemicity (mesoendemic) of river blindness and may be the *only* strategy that can achieve elimination of transmission in hyperendemic regions. We expect this modelling to be enriched with the availability of additional data, including that generated from the studies described earlier.



ADDITIONAL CLINICAL STUDIES

A Phase 2 clinical study, IIS-MOX-2006 [NCT04049851], assessing the safety of moxidectin in comparison to ivermectin in *Loa loa*-infected individuals and led by the Institut de Recherche pour le Développement (IRD) and the CRFilMT in Cameroon completed in August 2023.

At present, river blindness elimination programs are complicated for individuals living in areas that are also endemic for loiasis, due to the risk of serious adverse reactions in individuals with high *loa loa* microfilaria. It is hoped that the data generated in this study will pave the way for the use of moxidectin in the treatment of river blindness in *loa loa* endemic areas without the risk of serious adverse reactions.

Tony Oka Ukety, MD, DO, MPH

Medical Director, Centre de Recherche en Maladies Tropicales (CRMT), Rethy, Ituri Province, The Democratic Republic of Congo

Since 2020, Dr Tony Ukety has been serving as Principal Investigator for the two Phase 3b/4 studies investigating the use of moxidectin in river blindness: the repeat dose study (MDGH-MOX-3001; NCT03876262) and the large safety study (MDGH-MOX-3002; NCT04311671).

Dr Ukety's work focuses on Health Zones located in Ituri Province in northeastern Democratic Republic of Congo, which have been suffering from regular and severe political unrest due to the presence of multiple rebel groups. As he describes it:

> **"The biggest challenge was to implement simultaneously two clinical trials with many tasks within a very politically unstable environment in a war-torn country. It is really a miracle that the implementation has reached so far, approaching the end of recruitment of participants for both studies."**

Dr Ukety remains optimistic about conducting clinical trials in the Democratic Republic of Congo: "With a strong commitment and very careful human resource management coupled with some flexibility in decision making, it is possible to conduct clinical trials in the Democratic Republic of Congo. The country is potentially rich in many respects, including a variety of scientific information as well as capable human resources who only need to be reinforced and mentored accordingly."

He is optimistic that the results of these moxidectin studies will be promising and looks forward to their publication. In the meantime, he remains passionate about the fertile and beautiful area that he works in, with the maize crop flourishing in the clinic's garden.

Photo: *Dr Ukety next to maize plants in the clinic garden. [Photo credit and headshot photo credit: Dr Tony Ukety].*

Moxidectin in additional indications

In addition to moxidectin in river blindness, we have initiated clinical evaluations of moxidectin in treating lymphatic filariasis, scabies, soil transmitted helminths, and strongyloidiasis – all of which are considered neglected tropical diseases by the World Health Organization.

Lymphatic filariasis

ABOUT LYMPHATIC FILARIASIS

Lymphatic filariasis (also known as elephantiasis) is a painful and debilitating disease caused by a parasitic roundworm (of the family Filariodidea) transmitted through the bite of infected mosquitos. Inside the human body, the worms travel through the lymph system, often undetected, and mature into adult worms that produce millions of microfilariae (baby worms). Eventually this causes abnormal enlargement of the arms, legs, and (in males) genitalia.

51.4
million
global infections

According to the World Health Organization, in 2021, 51.4 million people globally were infected with the filarial parasites that cause lymphatic filariasis and 884.9 million people were at risk of infection. The World Health Organization aims to eliminate lymphatic filariasis as a public health problem in 58 of 72 countries by 2030. Lymphatic filariasis is currently targeted by treating whole communities in endemic regions with albendazole, either alone or in combination with ivermectin and/or diethylcarbamazine (DEC). The triple therapy option, involving a combination of ivermectin, DEC and albendazole (IDA), is most effective however is only used in areas where onchocerciasis is not prevalent – i.e. outside of Africa – due to the risk of serious adverse ocular events in people with onchocerciasis. Despite the World Health Organization's ambitions, many countries still endure a high burden of disease and there remains a need for alternative treatments that can be used in lymphatic filariasis elimination programs in onchocerciasis co-endemic regions.

We are working with partners to evaluate the therapeutic efficacy of moxidectin combination regimens for the treatment of lymphatic filariasis to potentially accelerate its elimination as a public health problem.

Photos: Left page: *Native black African woman carries a load on her head in the hills of South Africa. [Photo credit: AdobeStock stock photo ID: 209092779].* ***Right:*** *A man suffering lymphatic filariasis in Amethi, Uttar Pradesh, India. [Photo credit: Shutterstock stock photo ID: 1965836653].*

CLINICAL STUDIES

Phase 2/3 study (IIS-MOX-2005; NCT04410406):

In Cote d'Ivoire, a Phase 2/3 study sponsored by the Death to Onchocerciasis and Lymphatic Filariasis (DOLF) project group at Washington University is evaluating four different moxidectin or ivermectin combination regimens (protocol number IIS-MOX-2005; NCT04410406).

The primary endpoint for this study is maintenance of complete clearance of microfilariae. Preliminary data, presented at the 2023 Annual Meeting of the American Society of Tropical Medicine and Hygiene, show that a single dose of moxidectin in combination with albendazole (MoxA) is superior to an annual dose of ivermectin in combination with albendazole (IA) for microfilariae clearance at 12- and 24-months post-treatment. MoxA results in a similar clearance to the gold standard triple drug combination IDA. Additionally, the moxidectin-containing regimens were found to be more effective than IA and at least as effective as IDA at clearing circulating filarial antigen and adult worm nests. These findings suggest that moxidectin and albendazole could replace ivermectin and albendazole to accelerate lymphatic filariasis elimination in endemic countries. We are optimistic about the role moxidectin could play in eliminating lymphatic filariasis in large areas of Africa where many areas are co-endemic for onchocerciasis and IDA cannot be used for safety reasons[4].

We are currently planning Phase 3 confirmatory studies to determine the relative safety and efficacy of moxidectin-containing regimens compared to ivermectin-containing regimens. The aim is to confirm the results of the Phase 2/3 proof-of-concept trial and generate additional data to support inclusion of moxidectin in the World Health Organization lymphatic filariasis treatment guidelines and elimination programs in Africa and Asia.

"These data are particularly exciting, because they suggest that moxidectin plus albendazole works as well as the triple drug treatment with ivermectin, DEC, and albendazole, the best available therapy for lymphatic filariasis elimination, but which can't be used in most of Africa. Moxidectin-albendazole may help level the playing field between Africa and the rest of the world by providing an IDA-equivalent option for lymphatic filariasis elimination in Africa."

Dr Philip Budge, Principal Investigator, DOLF

Sally Kinrade, B. Pharm, MPH

Vice President, Project Leader for Onchocerciasis and Lymphatic Filariasis, Medicines Development for Global Health

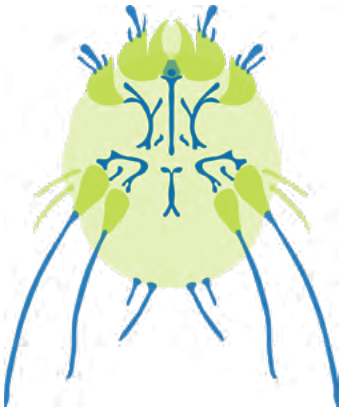
Sally Kinrade has been closely supervising moxidectin's progress since before its original New Drug Application to the US FDA, but that was only the start. Since then she has provided leadership to all of the activities necessary to support its transition to field use – work that is continuing into 2024.

To do so has required navigating the complexities of this work and maintaining optimal quality with highly constrained resources. There are a myriad of activities that go into bridging the original [2018] US FDA approval all the way to WHO guideline recommendations and access in onchocerciasis-endemic countries.

To Sally, one aspect of her work stands out: "it has been a privilege to be able to work with a fabulous small team of dedicated scientists, and generous, knowledgeable advisors in support of making available the first new drug for treatment of onchocerciasis in 30 years".

Photo: *Sally with Dr Nicholas Opoku at the University of Health and Allied Sciences (UHAS) campus where several studies of moxidectin in onchocerciasis have been conducted. [Photo credit and headshot photo credit: Sally Kinrade].*

"What most excited me about moxidectin is its potential to accelerate efforts towards elimination of onchocerciasis, and to be able to impact many other parasitic diseases that affect millions across the globe".



200
million
global infections

Scabies

ABOUT SCABIES

Scabies is another neglected tropical disease for which moxidectin is being evaluated as a potential new treatment option. Scabies is one of the most common skin diseases in the world, with more than 200 million people affected at any given time. While the disease disproportionately impacts people in low- and middle-income countries, it is also prevalent in high-income countries. Scabies is caused by a tiny mite that burrows into the skin where it lays its eggs. Intense itching results, which can cause serious discomfort and significantly impair quality of life. In cases where the skin is broken by repeated scratching, more serious consequences are possible, including bacterial infections which may ultimately contribute to kidney disease and heart valve damage. Scabies spreads easily in settings where people live in close contact.

Moxidectin is an investigational medicine designed to be a single dose oral treatment for scabies, potentially simplifying the current treatment options. If successful, moxidectin could dramatically improve the scabies treatment paradigm. Existing topical treatments are cumbersome and messy, requiring application over the entire body for at least eight hours and typically requiring repeat application several days later, whilst oral treatments are not approved or accessible in all regions and typically also require two doses separated by at least a week.

Photo: *Microscopic image of a scabies mite. [Photo credit: Shutterstock stock photo ID: 1350477944].*

Alessandra Handisurya, MD

Associate Professor, Department of Dermatology, Medical University of Vienna, Austria

Dr Alessandra Handisurya had been noticing the increased incidence of scabies in Austria since 2016, and more importantly "I saw how these infestations affected and, unfortunately stigmatized my patients". While seeking out improved treatment options for her patients, she contacted Medicines Development for Global Health in relation to moxidectin.

Fast forward several years, Dr Handisurya served as Investigator at the Viennese site for the Phase 2 dose-finding study of single dose moxidectin in scabies (MDGH-MOX-2001; NCT03905265). It was her first industry-driven clinical trial, and she appreciated working closely with the Medicines Development for Global Health team who guided her through study initiation at her clinic.

> **"What excited me most about moxidectin is its ease of use, especially its one-time application, and the not-for-profit approach of the Sponsoring company".**

Photos: Top left: *Dr Handisurya's team looking for scabies mites on the hand of a patient by reflectance confocal microscopy.* ***Top right:*** *Dr Handisurya and colleague working in the outpatient ward of the department trying to explain scabies to patients.* ***Bottom left:*** *Dr Handisurya and co-worker Dr Marcus Lisy, MD, (right) in front of the department during the Covid-19 pandemic.* ***Bottom right:*** *Dr Handisurya's co-workers Dr Marcus Lisy, MD, (left) and Simone Dworzak, MSc, from ad-hoc clinical (right) after one of their site-visits. [Photo credit: Headshot: © feelimage.at. All others provided by Dr Handisurya].*

CLINICAL STUDIES

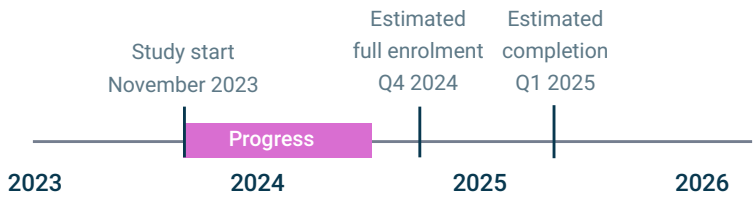
Phase 2a study (MDGH-MOX-2001; NCT03905265):

We have long aspired to see moxidectin developed into an effective, single dose scabicide and in 2022, we completed a **Phase 2a study (MDGH-MOX-2001; NCT03905265)** in 22 patients with scabies and achieved proof of concept, showing moxidectin kills the mites responsible for the disease (manuscript in preparation for publication).

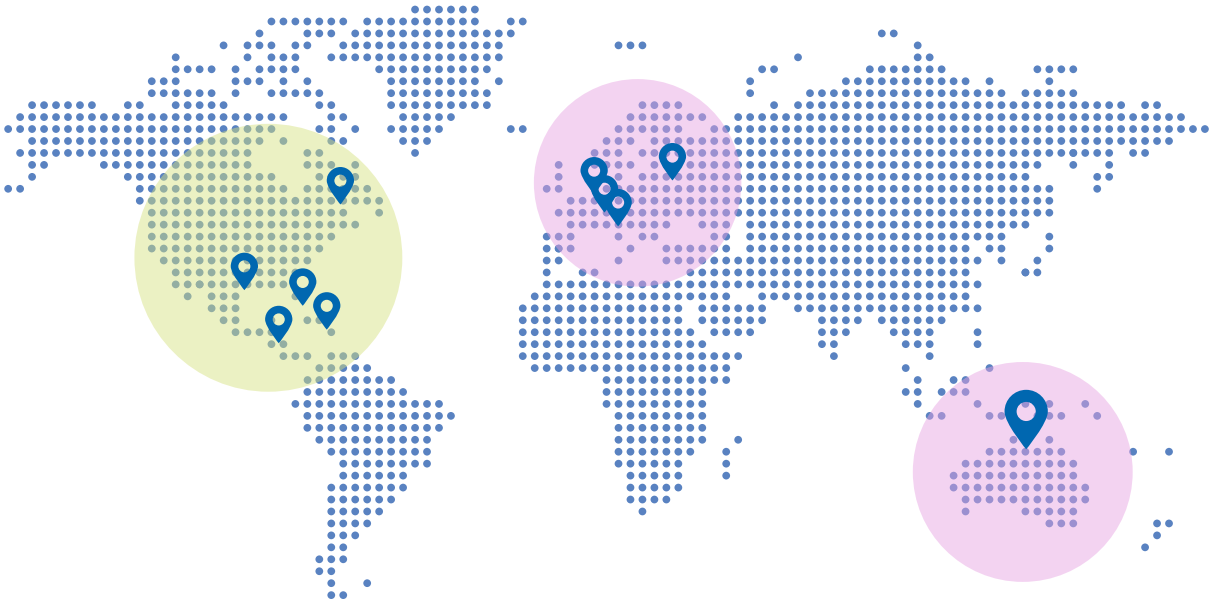
Phase 2b study (MDGH-MOX- 2002; NCT0587544):

We subsequently received clearance from the United States Food and Drug Administration for the Investigational New Drug (IND) application for moxidectin for scabies and have commenced a **Phase 2b study (protocol number MDGH-MOX- 2002; NCT05875441)** designed to evaluate the efficacy and safety of single doses of 8, 16 or 32 mg moxidectin compared to placebo in adults with scabies. This study enrolled its first patient in November 2023.

This study will confirm the dose ahead of pivotal Phase 3 studies to support submission for marketing authorisation to the United States Food and Drug Administration and the European Medicines Agency.



We have licensed the rights to moxidectin in high-income countries to our strategic partner Atticus Medical Pty Ltd, which is funding the scabies development program (along with some aspects of the onchocerciasis development program). To ensure development and access to moxidectin for the most underserved communities globally, Medicines Development for Global Health retains the rights to moxidectin in low- and middle-income countries.



Phase 2a study:

Vienna, Austria
Créteil, France
Nice, France
Saint-Etienne, France
Darwin, Australia

Phase 2b study:

Miami, USA
Philadelphia, USA
Houston, USA
San Pedro Sula, Honduras
Ponce, Puerto Rico

Primary outcome measures:

Mortality Rate for Adult Scabies Mites (Efficacy)

Incidence and severity of Treatment Emergent Adverse Event (Safety)

Primary outcome measures:

Proportion of index subjects achieving complete cure (Efficacy)

Incidence and severity of Treatment Emergent Adverse Event (Safety)

Photo: *Scabies causes intense itching, which can cause serious discomfort. [Photo credit: iStock stock photo ID: 1338374037].*

Soil-transmitted helminthiasis and Strongyloidiasis

1.5
billion
global infections

ABOUT SOIL-TRANSMITTED HELMINTHS

The soil-transmitted helminths include roundworm (Ascaris lumbricoides), whipworm (Trichuris trichiura) and hookworm nematodes (Ancylostoma duodenale and Necator americanus) and are among the most common of all neglected tropical disease infections with an estimated 1.5 billion people affected worldwide. These parasitic worms are transmitted through contaminated soil where sanitation is poor. Soil-transmitted helminth infections cause a range of health problems, including abdominal pain, diarrhea, blood and protein loss, rectal prolapse, and physical and cognitive impairment. Current treatments recommended by the World Health Organization are albendazole and mebendazole. New treatments with superior efficacy are required against whipworm and hookworm, and to mitigate the risk of drug resistance. Both ivermectin and moxidectin have shown some promise for treatment of soil-transmitted helminths, although studies have found a wide variation in ivermectin efficacy in studies conducted in different countries.

100
million
global infections

ABOUT STRONGYLOIDIASIS

Strongyloidiasis is caused by *Strongyloides stercoralis*. Unlike other soil-transmitted helminths, S. stercoralis has a different lifecycle and the infection it causes can be fatal. The World Health Organization estimates that up to 100 million people, particularly children, are infected with this parasitic worm. Treatment options are limited, with ivermectin being the medicine of choice, while other anthelmintic medicines, such as albendazole and mebendazole, lack sufficient efficacy as a single agent.

We continue to collaborate with the Swiss Tropical and Public Health Institute, Switzerland, who are sponsoring several trials to determine the safety and efficacy of moxidectin in different common intestinal parasitic worm diseases.

CLINICAL STUDIES

SOIL-TRANSMITTED HELMINTHS

In Tanzania (IIS-MOX-2002: NCT04700423):

This open label study included 5 different regimens: moxidectin plus albendazole, ivermectin plus albendazole, albendazole monotherapy, ivermectin monotherapy, or moxidectin monotherapy in adolescents aged 12–19 with whipworm. The primary outcome was egg reduction rate (ERR) after treatment.

In Cote d'Ivoire (IIS-MOX-2004: NCT04726969):

This randomised controlled study compared moxidectin plus albendazole, albendazole, and ivermectin plus albendazole in adolescents or adults (ages 12–60) with whipworm[5]. The primary outcome was cure rate after treatment.

These recently completed studies concluded all treatments had high rates of egg reduction, with combination treatments being superior to monotherapy, and moxidectin plus albendazole inferior to ivermectin plus albendazole with an ERR geometric mean of 96.8% compared to 99.0%. The studies observed variable rates for cure[6]. Understanding the variability in cure rate responses between different settings is important for future work. The single-dose, weight-independent administration makes moxidectin well suited for large scale soil-transmitted helminth mass drug administration programs, warranting further research on the moxidectin and albendazole combination. The next planned study is a double blind randomised controlled study in school aged children in Tanzania, which is expected to start in the first quarter of 2024 **(protocol number IIS-MOX-3006: NCT06188715).**

CLINICAL STUDIES

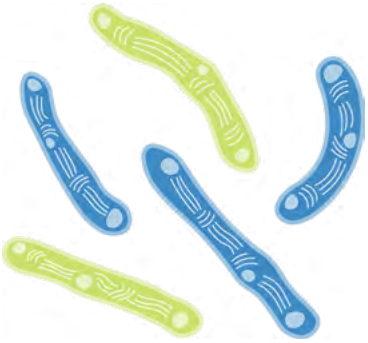
STRONGYLOIDIASIS

Phase 2/3 study (IIS-MOX-2001:NCT04056325 & IIS-MOX-2002:NCT04848688):

A Phase 2/3 study was recently completed in Cambodia and Laos and was published in The Lancet Infectious Diseases. This study confirmed the non-inferiority in terms of cure rate of moxidectin compared to ivermectin in treating strongyloidiasis[7].

Dovramilast

Since we licensed-in dovramilast (formerly CC-11050, AMG-634), an investigational phosphodiesterase type 4-inhbitor (PDE4) from Amgen at the end of 2020, we have continued its development for leprosy type 2 reaction, and for tuberculosis. Both indications are undergoing Phase 2 clinical trials with proof of concept achieved in humans.



200
thousand
new cases each year

Leprosy

ABOUT LEPROSY

Leprosy is one of the oldest-recorded diseases in history, first reported in 1400 BC. Yet, according to the World Health Organization, it still occurs in over 120 countries, with 200,000 new cases each year including 15,000 children. More than 3 million people are estimated to live with visible impairments or disfigurement due to leprosy, with many experiencing stigma and social exclusion.

We are developing dovramilast for the treatment of leprosy type 2 reaction. Leprosy type 2 reaction is a lifelong risk for people who have had leprosy that can occur long after the infection is cured. This painful complication of leprosy manifests in up to 50% of people who contract the disease and silently compounds disability in some of the world's most disadvantaged communities. Commonly characterised by the presence of inflamed and painful skin nodules, leprosy type 2 reaction is actually a multisystem disorder and it can be sufficiently serious to require prolonged hospitalisation. Patients with leprosy type 2 reaction are, in general, chronically ill and fatigued, feverish, in pain and suffering from insomnia, and can also experience painful inflammation in multiple systems or organs. Consequences of recurrent leprosy type 2 reaction may be serious and long lasting, in the worst cases leading to permanent nerve damage and deformities The only effective treatments are thalidomide, which is teratogenic (interferes with foetal development) in humans, and steroid therapy, which cause severe side effects with chronic use. In 2022, the World Health Organization reported over 6,200 new leprosy type 2 reaction cases globally[8], but as a neglected tropical disease with poor data, this figure is likely to be grossly underestimated.

Dovramilast, a host-directed therapy (acts on human biology rather than the causative bacteria), is intended to replace both prednisolone and thalidomide, providing a well-tolerated, non-teratogenic treatment to women of childbearing potential, children, and the broader community for the first time.

Photo: Left page: *A farmer carrying dry wheat after harvesting. [Photo credit: AdobeStock stock photo ID: 600818295.]*

CLINICAL STUDIES

Our collaboration with The Leprosy Mission Nepal continues in a Phase 2 trial (NCT03807362):

This study is divided into two parts. Part 1 – which is now complete – evaluated the safety and efficacy of dovramilast in 10 male patients with newly-diagnosed leprosy type 2 reaction. The first study demonstrated a consistent effect of dovramilast treatment within 28 days. The study results were presented at the 2022 International Leprosy Congress in Hyderabad, India. Part 2 of this study will commence in Q1 2024 and will recruit 40 additional patients for up to 52-weeks of treatment.

Concurrently, we have been planning one of the two pivotal studies required for regulatory approval of dovramilast in leprosy type 2 reaction. The study in acute or recurrent leprosy type 2 reaction patients is designed to confirm the optimal dose of the improved formulation of dovramilast and compare efficacy and safety to the current standard of care (steroid therapy). We participated in a pre-Investigational New Drug meeting with the United States Food and Drug Administration in 2023 and expect to commence the clinical trial in 2024 with study sites in West Africa, North America and the Indo-Pacific region.

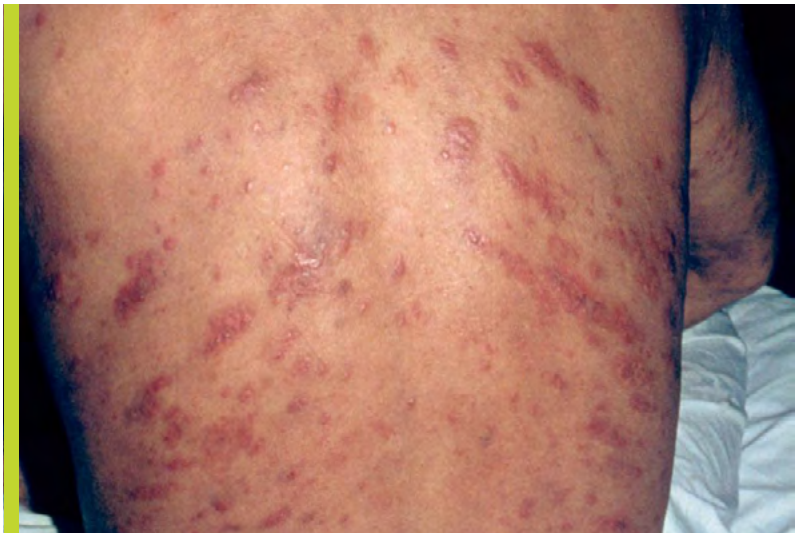
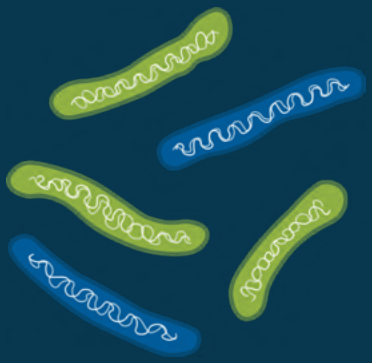


Photo: *Raised, red lesions are seen on the back of this patient, suggestive of leprosy type 2 reaction. [Photo credit: Wellcome Collection. Attribution 4.0 International (CC BY 4.0)].*

After the development and submission of a comprehensive data package, the United States Food and Drug Administration awarded Orphan Drug Designation to dovramilast for leprosy type 2 reaction in November 2023.

Orphan Drug Designation is granted by the United States Food and Drug Administration to medicines that demonstrate promise for the treatment of rare diseases affecting fewer than 200,000 people in the United States. Dovramilast's designation provides several benefits to Medicines Development for Global Health, including seven years of market exclusivity upon FDA approval, tax credits for clinical development expenses, and assistance with clinical trial design. Most importantly, it underscores the FDA's recognition of dovramilast's potential to address the significant unmet medical need in leprosy type 2 reaction.



Tuberculosis

ABOUT TUBERCULOSIS

Tuberculosis is a disease caused by the bacteria *Mycobacterium tuberculosis*. The infection primarily affects the lungs, but can disseminate to any part of the body, such as the kidney, spine, and brain. Despite being both a preventable and curable disease, it is the infectious disease causing the second largest number of deaths, after Covid-19, with 10 million new cases and 1.6 million deaths reported in 2021.

Current treatments for tuberculosis involve long duration antibiotic regimens and often leave patients with clinically significant lung injury and increased mortality post-cure. Concurrent administration of host-directed (directed at human biology rather than the biology of the causative bacteria) therapy can potentially shorten the duration of tuberculosis treatment and minimize lung injury. Dovramilast has shown promising preliminary results in the clinic for host-directed therapy of tuberculosis, suggesting it might preserve and enhance lung function as measured by FEV1[9].

1.6
million
deaths from TB in 2021

Photo: *A scan of a patient's lungs to check for Tuberculosis infection. [Photo credit: AdobeStock stock photo ID: 562210067.]*

CLINICAL STUDIES

Phase 2 host-directed therapy clinical study:

Following on from these promising results, a Phase 2 host-directed therapy clinical study in rifampicin-resistant tuberculosis patients in Africa and Europe conducted by the Aurum Institute (www.auruminstitute.org) was initiated in 2022.

Financials

FUNDING THE FUTURE

Our purpose is to improve the lives of people suffering from neglected tropical diseases. As a not-for-profit organisation[10], we can devote all of our resources into developing and delivering medicines for those who need them most. We have developed a resource-efficient model to conduct rigorous clinical trials and the associated development activities in a cost-effective manner. However, running clinical trials to exacting standards is still an expensive business that requires novel and diverse funding arrangements.

The use of proceeds received from the sale of the United States Food and Drug Administration priority review voucher[11], along with social impact investment and grant funding has enabled us to contribute to addressing health equity in low- and middle-income countries. When taking on the sponsorship of moxidectin in 2014, we were fortunate to be able to leverage the potential value of the priority review voucher to attract funding from the social impact fund, the Global Health Investment Fund. As part of the Global Health Investment Fund's social impact investment, we signed legally binding supply, pricing, and quality obligations so that when moxidectin was approved by the Food and Drug Administration on 13 June 2018, and a priority review voucher was awarded, the proceeds (after repaying the impact investors) were committed to global health research and development. In 2019, part of these funds were used to establish and co-fund a company jointly owned with the Global Health Investment Fund, called Atticus Medical Pty Ltd.

ATTICUS MEDICAL STRATEGIC RELATIONSHIP

Atticus Medical is a for purpose, for profit clinical-stage biotechnology company developing moxidectin for the potential treatment of scabies and headlice. Atticus Medical owns the rights to moxidectin in high-income countries, with Medicines Development for Global Health retaining all the rights to moxidectin in low- and middle-income countries.

Medicines Development for Global Health's strategic relationship with Atticus Medical represents an innovative new model for the development of global health medicines. Atticus Medical funds the development of new medicines that have both a global health impact *and* the potential to achieve financial returns – for example through the commercialisation of those medicines in high-income countries or through the receipt and sale of priority review vouchers. Medicines Development for Global Health, with its extensive development capability, provides Atticus Medical with the research and development services. As most of the requirements necessary to develop and market a medicine in high-income countries and low- and middle-income countries are the same, Atticus Medical's program funding delivers outcomes for both parties. Medicines Development for Global Health seeks grant and philanthropic funding to address any low- and middle-income country specific needs such as supply of quality medicines and World Health Organization guideline inclusion.

OTHER FUNDING

April 2022

In April 2022 we closed a social impact investment with 14 Australian family offices. The funds raised were deployed on dovramilast to appoint a project leader and to define the development and regulatory pathway for the medicine thereby making it an attractive proposition for other funding groups.

$4.9 million (USD)

October 2022

In October 2022 we received a US$4.9M grant from the Bill & Melinda Gates Foundation to generate additional clinical and field implementation data on moxidectin for the treatment of onchocerciasis and lymphatic filariasis. The 4-year funding will help us to conclude two key studies: a repeat-dose trial comparing annual or biannual doses of either moxidectin or ivermectin and a single-dose endemic community safety study of moxidectin and implement pilot field projects.

$16 million (AUD)

September 2023

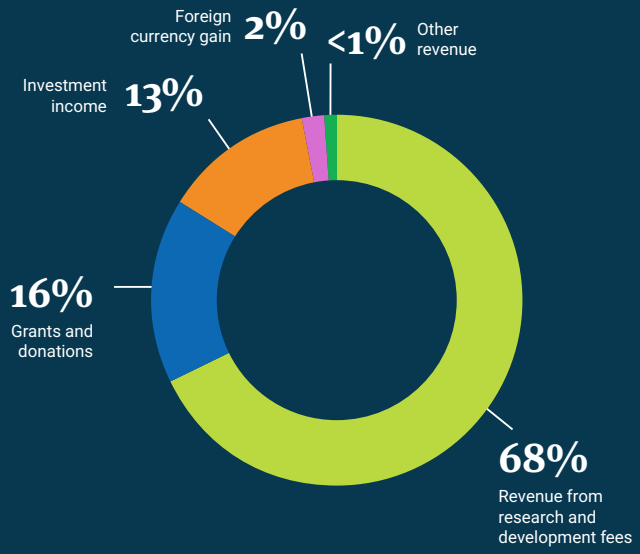
Our work continues to benefit from public sector funding received in 2019 and 2021 from the European and Developing Countries Clinical Trials Partnership and the Luxembourg National Research Fund for the ongoing clinical trial programs for moxidectin.

As the scope of our work and the potential for impact increases, so does the need for additional funding. A new philanthropic team has recently been established, under the leadership of Dr Emily McCaffrey (Head of Philanthropy). Emily brings extensive fundraising experience to the organisation. We want to grow awareness of Medicines Development for Global Health as a leader in developing new medicines for neglected diseases and make sure that our work is a destination point for global health philanthropy.

If you would like to talk to us about how you can support our work you can reach out directly to Emily at philanthropy@MDGH.com or donate to us via the 'Support Us' page on our website:

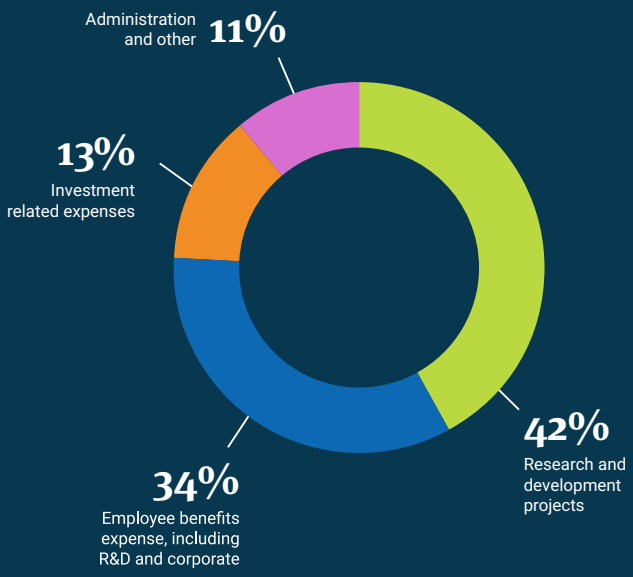
www.medicinesdevelopment.com/support-us

FY2023 FINANCIAL SUMMARY



Revenue by type

Revenue from research and development fees	6,359,413
Grants and donations	1,547,092
Other revenue	20,018
Investment income	1,266,016
Foreign currency gain	213,042
TOTAL REVENUE	**9,405,581**



Use of funds

Research and development project costs	5,085,293
Employee benefits expense, including R&D and corporate	4,173,432
Administration and other	1,396,887
Investment related expenses	1,568,717
TOTAL EXPENSES	**12,224,329**

Notes: The above financial summary is based on Medicines Development for Global Health's audited financial statements, which are audited by the firm Kidmans Partners. Detailed financial reports are available on the Australian Charities and Not-for-profits Commission website (click here). Medicines Development for Global Health is a not-for-profit organisation. Our mission is to address health inequity by researching, developing and delivering new and improved medicines for neglected diseases that disproportionately affect those in low- and middle-income countries. Medicines Development for Global Health is incorporated in Australia (Australian Company Number 116 977 523) and registered as a charity with the Australian Charities and Not-for-profits Commission making it a Deductible Gift Recipient (DGR, type 1). Our affiliate offices are also registered charities in the United Kingdom (Medicines Development for Global Health Limited, a UK Charitable Incorporated Organisation (CIO) with registered charity number #1200620) and United States (Medicines Development for Global Health, Inc., a 501(c)(3) tax-exempt charity).

OUR FUNDERS

Our advancements in neglected disease research and product development in 2022 and 2023 were made possible thanks to various public and private sector grants, impact investment, program development management fees and in-kind contributions. We are grateful for these contributions to our programs:

Interested in joining our efforts? Become a supporter today.

- The European and Developing Countries Clinical Trials Partnership
- The Luxembourg National Research Fund
- The Bill & Melinda Gates Foundation
- Atticus Medical Pty Ltd
- Murdoch Children's Research Institute
- Amgen Inc
- Lonza Group AG
- Lyrebird Charitable Fund
- Wolf Capital Pty Ltd
- The Tegmen Fund Pty Ltd
- Salt Catalyst Pty Ltd
- Roberts Family Foundation Pty Ltd
- Alyse Pty Ltd and Este Louise Darin Cooper Pty Ltd
- Isaacson Davis Foundation
- Michael & Janet Buxton Foundation
- Australian Philanthropic Services Foundation Pty Ltd
- Spinifex Pty Ltd
- Gaudry Foundation Pty Ltd
- Height Morris Foundation
- I and D Gust Family Trust
- Phastar
- The Pecan Fund

Detailed financial reports, including audited financial statements, are available on the ACNC website.

7

Leadership and governance

BOARD OF DIRECTORS

Dr Lorna Meldrum
Chair of the Board

Professor Andrew Wilks
Director

David McGregor
Director

Mark Sullivan, AO
Managing Director

Daren Armstrong
Company Secretary

LEADERSHIP TEAM

Mark Sullivan, AO
Managing Director

Brett Carter
Chief Operating Officer

Amanda Handley
Vice President, Head of Development

Sally Kinrade
Vice President, Project Leader Onchocerciasis & Lymphatic Filariasis

Dr Danielle Smith
Global Head of Regulatory Affairs

Photo: Left page: *Woman carrying a basket on her head in Sierra Leone, West Africa. [Photo credit: AdobeStock stock photo ID: 119061265.]*

DEVELOPMENT COMMITTEE

- Joe Camardo MD (Chair)
- George Morstyn MD
- Jerry Fisher PhD
- Fran Brown PhD
- Ralph Smalling MS
- Brian Kearney PharmD
- Craig Rayner PharmD

COLLABORATOR PROFILE

Craig Rayner, PharmD, MBA, FRCP Edin

Director of Regional Research Centre for Respiratory Medicines and Tropical Diseases, Moderna

Dr Craig Rayner has been a long-standing collaborator and friend of Medicines Development for Global Health, and his work has impacted multiple facets of moxidectin's story. He provided essential and insightful expertise into clinical pharmacology, translational medicine, regulatory science and pharmacometrics, across most of the indications that moxidectin is being investigated for and he is now a member of Medicine Development for Global Health's independent Development Committee which provides guidance and advice on program development.

His initial work on the moxidectin program was developing an efficient and regulatory acceptable multi-objective clinical pharmacology trial to address program questions on cardiac safety (QT), formulation bridging and characterising moxidectin's absorption, distribution, metabolism and excretion (ADME) parameters.

His enthusiasm for moxidectin lies in the potential for mass drug administration programs to substantially reduce the burden of river blindness globally, and to one day help lead to elimination of the disease transmission. In addition, he sees the positive impact of moxidectin on the burden many millions of people live with because of its potential to treat other important worm and ectoparasite diseases.

> **"Medicines Development for Global Health constructs "world best" virtual product development teams to work on their development programs. They assemble highly innovative experts from across the globe to come up with scientifically robust and highly efficient programs, to accelerate medicines to patients we all serve".**

[Headshot photo credit: Dr Craig Rayner].

ENDNOTES

[1] *Kura et al., 2023. Can mass drug administration of moxidectin accelerate onchocerciasis elimination in Africa?. Philosophical Transactions of the Royal Society B.* https://doi.org/10.1098/rstb.2022.0277

[2] *Opoku et al, 2018. Single dose moxidectin versus ivermectin for Onchocerca volvulus infection in Ghana, Liberia, and the Democratic Republic of the Congo: a randomised, controlled, double-blind phase 3 trial. The Lancet* https://doi.org/10.1016/S0140-6736(17)32844-1

[3] *Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.* https://www.who.int/publications/i/item/9789240010352

[4] *This study is funded by the Bill and Melinda Gates Foundation and sponsored by Washington University in St. Louis with support from Medicines Development for Global Health.*

[5] *Sprecher et al., 2023. Efficacy and Safety of Moxidectin-Albendazole and Ivermectin-Albendazole Combination Therapy Compared to Albendazole Monotherapy in Adolescents and Adults Infected with Trichuris trichiura: A Randomized, Controlled Superiority Trial. Clin Infect Dis doi: 10.1093/cid/ciad387. PMID: 37357904.*

[6] *Welsche et al., 2023. The Lancet Infectious Diseases* https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(22)00589-8.pdf

[7] *Sprecher et al., 2023. The Lancet* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4496130

[8] *Weekly epidemiological record - Global leprosy (Hansen disease) update, 2022: new paradigm – control to elimination World Health Organization . Weekly epidemiological record. 2023; 37 (98) : 409–430.* https://cdn.who.int/media/docs/default-source/weekly-epidemiological-record/wer9837-eng-fre.pdf

[9] *Wallis et al., 2021. The Lancet Respiratory Medicine* https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30448-3/fulltext

[10] *Registered with the Australian Charities and Not-for-profits Commission, a 501(c)3 entity in the United States, and a registered charity with the Charity Commission for England and Wales*

[11] *Priority Review Vouchers are awarded by the United States Food and Drug Administration for the approval of a new medicine to treat a neglected tropical disease. The voucher is transferrable and has a market value around US$100M*

Cover photo: *Woman and children from Dassanech tribe carrying water to their village, Ethiopia. [Photo credit: AdobeStock stock photo ID: 305502494].*

Medicines Development for Global Health Limited is a not-for-profit company
—an Australian Public Company registered as a health promotion charity.
ABN: 79 116 977 523

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