

Medicines Development for Global Health Announces Submission of the Moxidectin for River Blindness NDA to the FDA and Priority Review Designation

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Medicines Development for Global Health (MDGH), a not-for-profit global health company, today announced that it has submitted a New Drug Application to the US Food and Drug Administration (FDA) for moxidectin as an oral treatment for river blindness (onchocerciasis). The FDA have confirmed that moxidectin has qualified for priority review. The FDA designates drugs for priority review that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. With the designation, the FDA now aims to review the moxidectin registration application within six months (compared with a standard review period of 10 months). If the application is approved, MDGH will receive a transferable Priority Review Voucher that entitles the holder to priority review of another drug or therapy by the FDA.

From the late 1990s, the Special Programme for Research and Training in Tropical Diseases (TDR), hosted at the World Health Organization (WHO), has worked extensively with researchers, the Onchocerciasis Control Programme in West Africa, the African Programme for Onchocerciasis Control (APOC) and country onchocerciasis control programmes, affected communities to evaluate the use of moxidectin for the treatment of river blindness.

In 2014, MDGH secured the rights to develop moxidectin for human use from the WHO.

A US\$10 million investment from the Global Health Investment Fund (GHIF) enabled MDGH to manufacture moxidectin to support registration, conduct an additional human study to complete the clinical data package, and prepare the comprehensive registration application to the FDA for moxidectin for river blindness.

“Moxidectin has the potential to be an important medicine in the treatment of river blindness and contribute to the elimination of this disease. We are delighted to submit the moxidectin dossier to the FDA, the product of 18 years of research by thousands of scientists and study participants”, said Mark Sullivan, Managing Director of MDGH.

“We are delighted to see this milestone toward our vision of moxidectin being registered and made available to the countries and communities to accelerate progress towards elimination of onchocerciasis” said John Reeder, Director of TDR.

“It remains a privilege to work with Medicines Development to bring moxidectin through its final stages of registration for use in humans. There has been no drug registered to fight river blindness since 1987 so moxidectin will be instrumental in the effort towards elimination of onchocerciasis,” said Curt LaBelle, Managing Partner of GHIF.

About River Blindness (onchocerciasis): Onchocerciasis is a disease caused by the parasitic worm *Onchocerca volvulus* which is transmitted through the bites of infected black flies. Each adult female

worm, which can live for up to 15 years in the human body, produces millions of microfilariae that migrate through the skin and can invade the eyes. The disease symptoms include severe skin inflammation, intense itching, enlarged lymph nodes and visual impairment that can ultimately lead to blindness. Onchocerciasis is the second leading cause of infectious blindness and the fourth leading cause of preventable blindness worldwide. Onchocerciasis is endemic in some of the world's poorest and most disadvantaged communities with around 197 million people, >99% of those at risk of infection, living in sub-Saharan Africa. Large scale control programmes were initially based on vector control, later complemented and then replaced by mass drug administration (MDA) of ivermectin in areas where at least around 40% of adults were infected. These have significantly reduced prevalence of infection and symptoms. Elimination of onchocerciasis from Africa is now targeted. The global community recognises that this will require alternative treatment strategies and that build on the foundation of ivermectin donation.

About Medicines Development for Global Health: MDGH is a not for profit biopharmaceutical company headquartered in Melbourne, Australia. Established in 2005, this unique organization is dedicated to the development of affordable medicines and vaccines for neglected diseases prevalent in low and middle income countries. The company works on the development of a portfolio of products, including vaccines, small molecules and biological therapies targeting predominantly infectious, immunologic and oncologic diseases.

For additional information about MDGH, please visit www.medicinesdevelopment.com

About TDR: TDR, the Special Programme for Research and Training in Tropical Diseases is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty. It is hosted at the WHO and is sponsored by the United Nations Children's Fund, the United Nations Development Programme, the World Bank and WHO.

For additional information about TDR, please visit www.who.int/tdr

About the Global Health Investment Fund: The GHIF is a \$108 million social impact investment fund designed to provide financing to advance the development of drugs, vaccines, diagnostics and other interventions against diseases that disproportionately burden low- and middle-income countries. The GHIF seeks opportunities that have a clear impact on public health in developing countries but also have value in high-income countries.

For additional information about GHIF, please visit www.ghif.com