BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Moxidectin gets USFDA nod to treat River Blindness

14 June 2018 | News

Not-for-profit Biopharmaceutical Company receives FDA approval for a new river blindness treatment.

Medicines Development for Global Health (MDGH) and the World Health Organisation Special Programme for Research and Training in Tropical Diseases (TDR) have announced that the United States (U.S.) Food and Drug Administration (FDA) approved moxidectin 8 mg oral for the treatment of river blindness (onchocerciasis) in patients aged 12 years and older. The FDA has also awarded MDGH a priority review voucher (PRV).

River blindness is caused by a parasitic worm, Onchocerca volvulus. The disease manifests as severe itching, disfiguring skin conditions and visual impairment, including permanent blindness, caused by the worm's larvae (microfilariae).

The approval of moxidectin was based on data from two randomized, double blind, active controlled clinical studies. Each study met its respective primary endpoints, showing a statistically significant superiority of moxidectin over the current standard of care, ivermectin, in suppressing the presence of the microfilariae in skin.

"FDA approval is a momentous achievement for any biopharmaceutical company, but it is a particularly rare and exciting event in the neglected diseases setting," said Mark Sullivan, Founder and Managing Director of MDGH. "It takes a broad community to develop a new medicine. FDA approval represents decades of work by thousands of scientists, disease control specialists, expert advisors, community health workers, funders and study participants. We particularly acknowledge the US$13 million investment from the Global Health Investment Fund (GHIF) as well as the extraordinary persistence and dedication of the team at TDR, without whom this would not have happened."

TDR (the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases) was instrumental in the development of moxidectin. "We are delighted about the FDA's decision," says TDR Director John Reeder. "It is a milestone toward the river blindness endgame and our objective to enable African countries to integrate

moxidectin into their elimination strategies."

MDGH is the first not?for?profit company to register a medicine through the tropical disease PRV program. "This is exactly what we had in mind when we proposed the PRV program," said Duke University's Professor David Ridley, an author of the 2006 paper on which the voucher scheme is based.

"The voucher incentive helped Medicines Development for Global Health attract funding to complete testing and registration for a drug that had been on the shelf. I'm delighted that the voucher program is playing a role in treating patients with river blindness, and one day eliminating the disease."