



**MEDIA RELEASE
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Argenta collaborates on FDA approval of a novel treatment for river blindness

Auckland, 13 June, 2018 - Argenta Limited, a New Zealand-based global animal health company, has worked with Medicines Development for Global Health (MDGH), a not-for-profit Australian biopharmaceutical company, to gain US Federal Drug Administration (FDA) approval of an innovative treatment for river blindness.

Approved by the FDA today (13 June, EDT), the drug moxidectin (which is widely used to deworm pets and livestock) has been proven to treat river blindness in humans aged 12 years and over with improved efficacy compared with the current standard of care, ivermectin.

River blindness (onchocerciasis) is an eye and skin disease endemic to sub-Saharan Africa, and is caused by a parasitic worm called *Onchocerca volvulus*. The disease causes severe itching, disfiguring skin conditions and visual impairment, including permanent blindness. It is estimated that 16 million people are infected with river blindness, and approximately 200 million were at risk of contracting the disease in Africa.

Moxidectin is the first new FDA-approved treatment for the disease in the last 20 years, and will be manufactured in Argenta's AML Riverside facility in Iowa, USA, and supplied to populations in need by MDGH via various philanthropic agencies.

Dr. Doug Cleverly, Argenta's CEO, says: "Our remoteness in New Zealand from Sub-Saharan Africa makes it hard to fathom the impact of this debilitating disease, which has seen scores of people abandon the fertile land where river blindness is endemic. As a company, we are dedicated to animal health, but this is a special human cause that allows us to use our expertise in the animal field in another area. The skillset Argenta has honed in the area of antiparasitics aligned the business very well to this challenge. And challenges such as these encourage our

inventive nature and if we can succeed in reaching those in need, the improved health potentials are huge.”

The drug approval follows a notification by the FDA to MDGH in December 2017 that the new drug application had qualified for a Priority Review (which expedites the new drug application process from 10 months to six months). Because river blindness is nominated by the FDA as a neglected disease, MDGH will also receive a transferable voucher that can be used or sold for priority review of another drug.

Mark Sullivan, Founder and Managing Director of Medicines Development for Global Health, says: “Achieving FDA approval is a momentous achievement for any biopharmaceutical company, but it is a particularly rare and exciting event in the neglected diseases setting.”

Sullivan continues: “It takes a broad community to develop a new medicine. The FDA approval represents decades of work by thousands of scientists, product developers, disease control specialists, expert advisors, community health workers, funders and study participants. We particularly wanted to acknowledge the fantastic support we’ve received from our manufacturing partners at Argenta.”

MDGH has also received financial support from the Global Health Investment Fund and collaborated closely with the World Health Organisation Special Programme for Research and Training in Tropical Diseases (TDR) on the project.

“The approval is an exemplar of a paradigm-changing approach to funding the development of new drugs for neglected diseases. These diseases are ‘neglected’ primarily due to lack of funding, a direct consequence of the fact that sufferers cannot afford to pay,” says Sullivan. “Consequently, there is a paucity of therapeutic options for onchocerciasis and other neglected diseases. However, the introduction of the FDA neglected diseases priority review voucher program (PRV) has improved this dynamic significantly.”

The Australasian partnership, which will see the drug dispatched in Africa, has been and continues to be a profound experience, Cleverly says: “It has been an unusual collaboration given Argenta focuses on every species apart from humans. However, as the project has progressed it has become very clear there is lot of horsepower and drive behind this development program. MDGH has a depth of understanding, certainly of what was at stake but also of what was required of the team in order for the project to succeed.”

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About Argenta

Argenta provides formulations and clinical research and development, analytical methods development, and small- and commercial scale manufacturing of animal health products. Founded in August 2006, Argenta is the leading provider of new product development and manufacturing services to the international animal health industry. In 2008, Argenta acquired New Jersey based clinical contract research provider, AlcheraBio, and in 2011 it opened a drug product research laboratory in Lawrence, Kansas City in 2011. In the past two years, Argenta has continued its acquisitions with the purchase of a facility in Fort Dodge, Iowa, and another in Dundee, Scotland. Please see www.argentaglobal.com for more information on the company.

About Medicines Development for Global Health

An independent not-for-profit global health company dedicated to the development of affordable medicines and vaccines, Medicines Development for Global Health (MDGH) applies pharmaceutical industry development approaches in the global health setting. The company was founded in 2005 by Mark Sullivan. As a not-for-profit, MDGH uses all funds in excess of running costs for the development of medicines and vaccines that may have limited commercial opportunity, but which address important unmet medical needs.

About river blindness

- River blindness is caused by a parasitic worm and transmitted by the bite of the black fly.
- The black fly breeds near fast-flowing water where many communities gather water for drinking, washing and bathing.
- Symptoms of the disease include severe itching, disfiguring skin conditions, and visual impairment that can lead to permanent blindness, due to chronic inflammation in the cornea.
- More than 99% of people infected with river blindness live in 31 African countries.
- The disease also exists in Latin America and Yemen.