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Ghana Approves Medicines Development for Global Health Moxidectin For River Blindness

Medicines Development for Global Health says it has Ghana Food and Drugs Authority approval for its moxidectin 2mg oral tablet for river blindness.

The Melbourne-based not-for-profit Medicines Development for Global Health (MDGH) said Ghana was the “first river blindness-endemic country to approve moxidectin”.

In 2018, the company said it had US Food and Drug Administration approval for oral moxidectin 8mg for river blindness or onchocerciasis in patients aged 12 years and older (BD: Jun 14, 2018).

In 2019, MDGH said the Copenhagen-based Novo Nordisk bought its priority review voucher, but did not disclose the price (BD: Aug 13, 2019).

MDGH media spokesman Dr George Rugarabamu told Biotech Daily that the Ghana approval was for adults and children over the age of four years.

Dr Rugarabamu said that moxidectin came in a 2mg tablet and people aged eight years and over would be given four of the 2mg tablets, with younger children given two tablets.

The company said river blindness was caused by the parasitic worm, Onchocerca volvulus and was spread through the worm’s larvae, microfilariae, which caused severe itching, skin changes and could lead to visual impairment, including permanent blindness.

MDGH said the World Health Organization and endemic countries currently targeted the elimination of parasite transmission through mass administration of ivermectin.

The company said moxidectin reduced “skin microfilariae levels more profoundly and for longer than ivermectin” was expected to accelerate elimination of parasite transmission.

MDGH said it would provide moxidectin at cost-plus pricing, without profit, to low-and-middle income countries.

The company said that more than 200 million people were at risk of river blindness infection in 29 African countries.

MDGH said it would conduct a community treatment program in the Twifo Atti-Morkwa district, 150km west of the Ghanan capital Accra, in January 2025; with the district identified by the Ghana Health Service a priority for moxidectin after higher-than-expected disease prevalence was found following multiple rounds of ivermectin administration.

The company said the approval was “an important step forward in efforts towards elimination goals”.

MDGH said the development and delivery of moxidectin was supported by the UNICEF (United Nations Children’s Fund), UNDP (United Nations Development Programme), the World Bank and the World Health Organization Special Programme for Research and Training in Tropical Disease.

MDGH managing-director Mark Sullivan said the Ghana FDA approval was the “first registration of moxidectin in a country disproportionately affected by neglected tropical diseases”.

“This is a new model, it is the first time a not-for-profit company has achieved regulatory approval and will deliver a completely novel medicine into an endemic country without the involvement of a multi-national pharmaceutical company or generic company partner,” Mr Sullivan said.

“Ghana has shown leadership in the evaluation of moxidectin and we have been delighted to support them,” Mr Sullivan said.

MDGH vice president and project leader Sally Kinrade said the approval was “the culmination of more than 25 years in the development of moxidectin for the treatment of river blindness and other human diseases”.

“It is fitting that Ghanaian communities will be the first to benefit from the implementation of moxidectin to help progress their disease elimination goals given that the first study of moxidectin in infected people was conducted in Ghana,” Ms Kinrade said.

Medicines Development for Global Health is a not-for-profit organization.