Bayer and DNDi sign agreement to develop an oral treatment for river blindness

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The doctor points to skin nodule containing many adult filarial worms on a patient with onchocerciasis. Credit: DNDi

Bayer HealthCare and the Drugs for Neglected Diseases initiative (DNDi) have signed an agreement under which Bayer will provide the active ingredient emodepside to support DNDi in its effort to develop a new oral drug to treat river blindness (or onchocerciasis). The world's second leading infectious cause of blindness, river blindness is a

neglected tropical disease caused by a filarial worm.

Emodepside originates from the Japanese pharmaceutical company Astellas and has been developed by Bayer HealthCare's Animal Health division for veterinary use. The compound has been found to be effective in killing adult worms in pre-clinical studies, thus showing potential as a new 'macrofilaricidal' drug for the treatment of patients with river blindness. Astellas has granted Bayer the rights to develop emodepside along these lines.

Large-scale programmes for the treatment and control of filarial diseases, such as river blindness, have been in place for over twenty years, based on administering drugs to entire populations. While these mass drug administration (MDA) programmes have seen considerable successes, treatments must be repeated at regular intervals of every 6 or 12 months for up to 17 years to cover the life span of adult worms. This is primarily due to the fact that currently used treatments are 'microfilaricidal', which means that they kill only the young worms. A macrofilaricide such as emodepside, by killing adult worms, could dramatically reduce treatment time of MDAs and could be used in areas and circumstances where the use of microfilaricidal drugs is limited.

'We need to build on the experience and progress of the past twenty years and give new impetus to research and development for new health tools to accelerate the elimination of river blindness in targeted countries of Africa', explains Dr Bernard Pécoul, Executive Director of DNDi. 'Through our collaboration with Bayer on the development of emodepside, we hope to bring a new, safe, short-course, field-adapted treatment to patients and offer a new public health approach for countries long affected by this disease.'

'The provision of drugs for treating neglected tropical diseases like Chagas disease and African sleeping sickness has been an essential

component of our social engagement for many years now', says Dr Olivier Brandicourt, Chairman of the Board of Management of Bayer HealthCare. 'We are looking forward to joining DNDi in its mission to develop better and adapted treatments for patients with neglected diseases.'

Within the framework of the agreement, DNDi will be responsible for the preclinical and clinical development of emodepside and Bayer for the pharmaceutical development, manufacturing, registration and supply of the drug. The agreement ensures that emodepside, if successful in subsequent phases of drug development, would be available at the lowest sustainable price to ensure affordability and access in the current 31 African disease-endemic countries.

The rights to use technology or data generated within the collaboration allow each party to pursue the project with third partners in case of withdrawal of the other party, thus securing the development and accessibility of emodepside for the benefit of patients.

About river blindness (onchocerciasis)

Onchocerciasis, also known as river blindness, is endemic in 36 countries in Africa, the Arabian Peninsula and the Americas. It affects over 25 million worldwide, over 6 million of which suffer debilitating symptoms and some 270,000 afflicted with blindness. The disease hinders economic development in areas where it occurs. Fear of infection through the bite of the blackfly vector leads to abandonment of fertile riverside areas where it abounds. The adult parasitic worm can live for up to 15 years in the human body. The female adults produce millions of microfilariae that trigger serious visual impairment (including blindness), lesions, and intense itching and depigmentation of the skin. Female blackflies ingest microfilariae if they bite an infected person. Some of the microfilariae may transform into infective larvae

and may be injected into another person through the same blackfly, where the parasites complete their life cycle.

Potential advantages of a macrofilaricidal drug for river blindness

- Could reduce duration of treatment which, with current treatments, is based on mass drug administration (MDA) rounds that can last up to 17 years.

- Could be used in areas where the use of microfilaricidal drugs is limited due to safety concerns in areas where patients with river blindness are co-infected with Loa loa (African eye worm) and have very high levels of microfilariae in the blood. Treatment of these patients with current drugs can cause serious adverse reactions - possibly due to the sudden, massive death of the juvenile Loa worms - including brain damage (encephalopathy), which can be fatal.

- Could be used in individual patient treatment (case management).

About emodepside

Originating from the Japanese pharmaceutical company Astellas, the compound has been developed by Bayer Animal Health for animal health uses and commercialized as an anthelmintic veterinary drug for cats and dogs in combination with praziquantel (Profender™) and in combination with toltrazuril (Procox™). Following its successful animal use, the compound has been found in relevant animal models of the human diseases to be effective in killing the adult worm in pre-clinical studies, a unique feature permitting to envisage a shorter therapeutic intervention to treat infected patients.

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