

Open Access Initiative Reveals Drug Hits for Deadly Neglected Tropical Diseases

DNDi screens MMV's open access Malaria Box, leading to three potential drug classes to treat sleeping sickness and leishmaniasis, which threaten the lives of millions throughout sub-Saharan Africa and pockets around the world.

[Geneva, Switzerland – 13 November 2012] - The Drugs for Neglected Diseases *initiative* (DNDi) and Medicines for Malaria Venture (MMV) announce today the identification of three chemical series targeting the treatment of deadly neglected tropical diseases (NTDs), through DNDi's screening of MMV's open access Malaria Box. The resulting DNDi screening data are among the first data generated on the Malaria Box to be released into the public domain, exemplifying the potential of openly sharing drug development data for neglected patients.

The open access Malaria Box (mmv.org/malariabox) is an MMV initiative launched in December 2011 to catalyse drug discovery for malaria and neglected diseases. It contains 400 molecules, selected by experienced medicinal chemists to offer the broadest chemical diversity possible and is available free of charge. In return, MMV requests that any data gleaned from research on the Malaria Box are shared in the public domain within two years. To date, more than 100 Malaria Boxes have been delivered to over 20 countries for research on diseases including malaria, neglected diseases, HIV and cancer.

DNDi, in partnership with the Laboratory for Microbiology, Parasitology and Hygiene (LMPH), University of Antwerp, screened all the compounds in the Malaria Box against the parasites responsible for the three NTDs on which DNDi mainly focuses: sleeping sickness (human African trypanosomiasis), leishmaniasis (including visceral leishmaniasis, or kala azar, also known as black fever), and Chagas disease. This initial screen identified two potential drug series for the treatment of sleeping sickness and one for leishmaniasis. The DNDi screens have yielded valuable information that will strengthen DNDi's research pipeline. All the biological data from DNDi's screen, together with the existing preliminary data from MMV, are now publicly available on the open-source ChEMBL database (www.ebi.ac.uk/chembl/malaria).

"This is a really great example of partnership in action," said Dr David Reddy, MMV's CEO. "MMV and DNDi already work synergistically to tackle tropical diseases. Now, through the Malaria Box we can freely explore molecules that could potentially work against several debilitating tropical diseases, for the benefit of vulnerable populations the world over. It's hugely gratifying to see the idea of the Malaria Box starting to pay off."

Today, DNDi and MMV also announce an agreement to collaborate on drug discovery research by sharing compounds from their respective preclinical pipelines. Compounds provided by DNDi will be screened by MMV for antimalarial activity, and early stage compounds provided by MMV will be assessed by DNDi for their activity against the parasites causing sleeping sickness, leishmaniasis, Chagas disease, and filarial parasitic-worm diseases. This agreement highlights the potential for increased collaboration among Product Development Partnerships (PDPs) like MMV and DNDi to accelerate the development of treatments for some of the world's most neglected diseases and patients.

"Open access initiatives, such as the Malaria Box, are part of an encouraging new paradigm," says Dr Bernard Pécoul, Executive Director of DNDi. "We have to maintain a sharp focus on neglected patient needs and increase our efforts to open up research knowledge, reduce duplication in research efforts, and work together to fill the R&D gaps for diseases that afflict the poorest populations of the world."

About DNDi

The Drugs for Neglected Diseases initiative (DNDi) is a not-for-profit research and development organization working to deliver new treatments for neglected diseases, in particular sleeping sickness (human African trypanosomiasis), Chagas disease, leishmaniasis, filarial parasitic-worm infections, malaria, and paediatric HIV. DNDi was established in 2003 by Médecins Sans Frontières/Doctors Without Borders (MSF), the Oswaldo Cruz Foundation (FIOCRUZ) of Brazil, the Indian Council of Medical Research (ICMR), the Kenya Medical Research Institute (KEMRI), the Ministry of Health of Malaysia, and the Institut Pasteur of France. The Special Programme for Tropical Disease Research (WHO/TDR) serves as permanent observer.

Since its inception in 2003, DNDi has delivered six new treatments for neglected patients: two fixed-dose antimalarials (ASAQ and ASMQ), nifurtimox-eflornithine combination therapy (NECT) for late-stage sleeping sickness, sodium stibogluconate and paromomycin (SSG&PM) combination therapy for visceral leishmaniasis in Africa, a set of combination therapies for visceral leishmaniasis in Asia, and a paediatric dosage form of benznidazole for Chagas disease.

DNDi has helped establish three clinical research platforms: Leishmaniasis East Africa Platform (LEAP) in Kenya, Ethiopia, Sudan, and Uganda; the HAT Platform based in the Democratic Republic of Congo (DRC) for sleeping sickness; and the Chagas Clinical Research Platform in Latin America. Strong regional networks such as these help strengthen research and treatment-implementation capacity in neglected disease-endemic countries. www.dndi.org

About MMV

MMV is recognized as the leading product development partnership (PDP) in the field of antimalarial drug research and development. It was established as a foundation in 1999, and registered in Switzerland.

MMV's mission is to reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs.

MMV's vision is a world in which these innovative medicines will cure and protect the vulnerable and under-served populations at risk of malaria, and help to ultimately eradicate this terrible disease.

MMV's strength comes from its product development partnership (PDP) model reflected in its current network of more than 170 pharmaceutical, academic and endemic-country partners in over 40 countries. With more than 65 promising projects, MMV is currently managing the largest portfolio of antimalarial R&D projects ever assembled.

In February 2012, one MMV-supported artemisinin combination therapy (ACT), Pyramax[®], (pyronaridine-artesunate) co-developed with Shin Poong, received a positive scientific opinion under Article 58 from the European Medicines Agency (EMA) for the treatment of *P. falciparum* and *P. vivax* in areas of low transmission with evidence of artemisinin resistance. In October 2011, Eurartesim[®] (dihydroartemisinin-piperaquine), an ACT developed in partnership with Sigma Tau, was granted regulatory approval by the EMA and in November 2010, Guilin's artesunate injection for the treatment of severe malaria, Artesun[®], was approved by the WHO's Prequalification programme with assistance from MMV. In addition, Coartem[®] Dispersible (artemether-lumefantrine), a child-friendly version of the ACT Coartem[®], was developed by Novartis in partnership with MMV and launched in 2009. Since June 2012, 137 million courses of Coartem Dispersible treatment have been supplied to 35 malaria-endemic countries. www.mmv.org

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