

PRESS RELEASE

Delivery of child-friendly antimalarial hits the 100 million mark

Geneva, 22 February 2012. One hundred million treatments of Coartem® *Dispersible* (artemether-lumefantrine), an antimalarial developed especially for children with *Plasmodium falciparum* malaria, have been delivered by Novartis to 39 malaria-endemic countries, Medicines for Malaria Venture (MMV) announced today.

Coartem® *Dispersible* is the product of the partnership between MMV and Novartis. It is the first WHO prequalified child-friendly artemisinin-combination therapy (ACT) and addresses an unmet need for paediatric medicines. Young children in Africa are disproportionately affected by malaria, with 86% of malaria deaths occurring in children under the age of 5 years.

Ahead of the international community's call for better child-friendly medicines, MMV and Novartis signed an agreement in 2003 to develop the first paediatric ACT. The child-friendly formulation was launched in 2009.

"This is indeed a landmark achievement for both Novartis and MMV," said MMV's CEO, David Reddy. "Never before have 100 million paediatric treatments been distributed in such a short time frame to assist children suffering from malaria. Today, we have proved that partnerships can succeed in not only developing new, high-quality medicines for malaria but also delivering these to vulnerable populations. This success only increases our determination to address remaining unmet medical needs by bringing forward new antimalarial medicines as our part in defeating this disease. We are indebted to our partners like Novartis and to our donors*, who are crucial to the success of MMV."

"Reaching the 100 million milestone in less than 3 years is the culmination of a successful collaboration between Novartis and MMV," said Linus Igwemezie, Head of the Novartis Malaria Initiative. "Partnerships are at the core of the Novartis Malaria Initiative and we are delighted at the success these collaborations have had in providing effective malaria treatments to millions of patients who are most in need. There is still much to be done and we are committed to continue applying our innovation power to help improve access to affordable and quality antimalarials."

"The success of Coartem® *Dispersible* shows why research and development is at the heart of the British Government's fight against malaria," said Stephen O'Brien, Under-Secretary of State for International Development, UK. "Product Development Partnerships, such as Medicines for Malaria Venture, bring together the public and private sectors to use their combined expertise to develop new drugs. Children are the most vulnerable to this deadly disease. By developing this paediatric treatment, Medicines for Malaria Venture and Novartis have given the hope of a healthier life to millions of the world's poorest children."

Focused measures have been taken to facilitate the uptake of this medicine, including registration in 39 malaria-endemic countries, a without-profit pricing model and special packaging designed to improve compliance. These measures have not only led to increased demand but also to an accelerated uptake, underlining the advantage of the paediatric formulation. By reaching this milestone the Novartis Malaria Initiative and MMV have proven that drug development partnerships can truly advance the fight against malaria.

** See 'About MMV' on page 4*

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We ask you not rely unduly on these statements. Such forward-looking statements reflect the current views of Medicines for Malaria Venture (MMV) and its partner(s) regarding future events, and involve known and unknown risks and uncertainties.

MMV accepts no liability for the information presented here, nor for the consequences of any actions taken on the basis of this information. Furthermore, MMV accepts no liability for the decisions made by its pharmaceutical partner(s), the impact of any of their decisions, their earnings and their financial status.

Notes for Editors

Young children in Africa are disproportionately affected by malaria with 86% of malaria deaths occurring in children under the age of five. However, malaria does not only kill, it also debilitates. It is the cause of nearly 20% of low-birth weight babies in malaria-endemic regions and 6% of these end in fatality (Guyatt & Snow, 2004). Severe malaria often leads to cerebral damage, hindering a child's mental development (Roll Back Malaria, 2002). Malaria also contributes heavily to malnutrition, an underlying cause of death in more than half of all fatalities in children under five (The Lancet, 2008).

A randomized, multicentre study in approx. 900 children weighing 5-35kg with uncomplicated *P. falciparum* malaria in 5 African countries demonstrated that this innovative, child-friendly ACT has a comparable safety and efficacy profile to crushed tablets of its parent drug Coartem®. The sweet-tasting formulation disperses in small amounts of liquid, is easy to administer to young children, ensures effective dosing, and has a proven high cure rate of 97.8% (Abdulla S *et al*, 2008).

References

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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 network of more than 170 pharmaceutical, academic and endemic-country partners in 45 countries. MMV also works in close partnership with a number of WHO programmes that include the Special Programme for Research and Training in Tropical Diseases (TDR), the Global Malaria Programme (GMP) and Roll Back Malaria (RBM).

MMV is currently managing the largest portfolio of antimalarial R&D projects ever assembled. Of over 50 promising projects, one MMV-supported artemisinin combination therapy (ACT), Pyramax[®] (pyronaridine-artesunate), is undergoing regulatory review by the European Medicines Agency (EMA) in 2012. In October 2011, dihydroartemisinin-piperaquine (Eurartesim[®]), 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 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.

The key to MMV's success lies in the focus of its mission, and the diversity of its team of almost 50 personnel from more than 20 countries, handpicked for their expertise and commitment to global health.

Since foundation, MMV has received financial support from the following donors: Bill and Melinda Gates Foundation; UK DFID; Rockefeller Foundation; Netherlands Minister Devt. Co-operation; WHO/RBM; Swiss Government (DEZA/SDC); World Bank; Wellcome Trust; ExxonMobil Foundation; BHP Billiton; USAID; EU CRIMALDDI; Irish Aid; National Institutes of Health (NIH); Spanish Agency for International Development; Newcrest.

www.mmv.org

About the Novartis Malaria Initiative

Focused on access, treatment, R&D and capacity-building, the Novartis Malaria Initiative is one of the healthcare industry's largest access-to-medicine programs measured by the number of patients reached annually. Since 2001, the initiative has delivered over 400 million malaria treatments without profit to the public sector in more than 60 countries, contributing to saving an estimated 1 million lives. Over the last two years, Novartis and partners have discovered two new classes of compounds with great antimalarial potential. And just recently, the access project "SMS for Life" was honored by the UN's Innovation Working Group and mHealth Alliance for helping advance the goals of the UN Secretary-General's Every Woman Every Child Initiative. Together with our partners, we are committed to the common goal of malaria elimination.

www.malaria.novartis.com