

PRESS RELEASE

**Medicines for Malaria Venture announces collaborations
with Cipla and Strides**

Collaborations set to advance life-saving pre-referral treatment for severe malaria

Switzerland and India, 27 November 2014: Medicines for Malaria Venture (MMV) signs collaboration agreements with two Indian pharmaceutical companies, Cipla Limited and Strides Arcolab Limited for the development of rectal artesunate for pre-referral treatment of children with severe malaria.

The collaborations, established under the MMV-led "Improving Severe Malaria Outcomes" project funded by [UNITAID](#)¹, aim to develop a rectal artesunate product for submission to WHO prequalification. Cipla and Strides will each develop a product building on the clinical studies led by TDR, the Special Programme for Research and Training in Tropical Diseases led by the World Health Organization.

The goal is to achieve WHO-prequalification of a rectal artesunate product by 2016.

"This is a significant milestone in our project to improve severe malaria outcomes," said Dr David Reddy, MMV's CEO. "We have agreed a clear pathway with these two manufacturers to bring this product to an internationally acceptable quality standard. This will help make the product available to more patients, buying more time and saving more lives. We look forward to working closely with Cipla and Strides and thank UNITAID for supporting these efforts."

Mr. Subhanu Saxena, MD & Global CEO, Cipla Limited said: "We are happy to join hands with Medicines for Malaria Venture, that shares our ongoing commitment to fight against Malaria. Cipla is one of the major suppliers of antimalarial products worldwide and we have designed many innovative medicines for children in developing countries. Through this collaboration, we will endeavour to make rectal artesunate accessible to each and every child with severe malaria in a pre-referral setting in malaria-endemic countries.

"We are excited to be part of this initiative, as it will expand access to quality, affordable medicines for a wider population and save more lives," said Mohan Kumar CEO, Strides Arcolab Limited.

¹ UNITAID invests to increase availability to better and more affordable products to prevent, test and treat HIV/AIDS, tuberculosis and malaria in developing countries. It was launched in 2006 by Brazil, Chile, France, Norway and the United Kingdom. UNITAID is hosted by the World Health Organization and is currently supported by 17 contributing members.

Notes for editors

About the topic

An estimated 5.6 million cases of severe malaria each year result in around 627,000 deaths, mostly of children under 5.² Severe malaria is the result of inadequately treated uncomplicated malaria and can quickly lead to death.

A WHO-TDR trial conducted in 17,000 patients in Bangladesh, Ghana and Tanzania demonstrated that "if patients with severe malaria cannot be treated orally and access to injections will take several hours, a single inexpensive artesunate suppository at the time of referral substantially reduces the risk of death or permanent disability."³

Although the WHO guidelines for the treatment of malaria recommend use of rectal artesunate,⁴ there is currently no product with WHO prequalification or marketing authorisation by a stringent regulatory authority. This prevents international donors from funding the procurement of this potentially life-saving treatment.

About Cipla Limited

Cipla is a global pharmaceutical company which uses cutting edge technology and innovation to meet the everyday needs of all patients. For more than 70 years, Cipla has emerged as one of the most respected pharmaceutical names in India as well as across more than 150 countries. Cipla's portfolio includes over 1500 products in various therapeutic categories with one quality standard globally. Cipla's turnover in 2013/14 was 1.7 billion USD.

Whilst delivering a long-term sustainable business, Cipla recognises its duty to provide affordable medicines. Cipla's emphasis on access for patients was recognized globally for the pioneering role played in HIV/AIDS treatment as the first pharmaceutical company to provide a triple combination anti-retroviral (ARV) in Africa at less than one dollar a day and thereby treating many millions of patients since 2001.

Cipla's research and development focuses on developing innovative products and drug delivery systems and has given India and the world many 'firsts' for instance Triomune. In a tightly regulated environment, the company's manufacturing facilities have approvals from all the main regulators including US FDA, UKMHRA, WHO, MCC, ANVISA, and PMDA which means the company provides one universal standard both domestically and internationally.

² World Health Organization. World Malaria Report 2013:
www.who.int/malaria/publications/world_malaria_report_2013/en/

³ Gomes MF *et al.* Pre-referral rectal artesunate to prevent death and disability in severe malaria: a placebo-controlled trial. *Lancet*. 373(9663):557-66 (2009).

⁴ World Health Organization. Guidelines for the treatment of malaria. Second edition
March 2010: <http://www.who.int/malaria/publications/atoz/9789241547925/en/>

About Medicines for Malaria Venture (MMV)

MMV is a leading product development partnership (PDP) in the field of antimalarial drug research and development. Its 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.

Since its foundation in 1999, MMV has developed and brought to registration four new medicines with its partners: Pyramax®, (pyronaridine-artesunate) co-developed with Shin Poong; Eurartesim® (dihydroartemisinin-piperaquine) with Sigma-Tau; Guilin's artesunate injection for the treatment of severe malaria, Artesun®; and Coartem® Dispersible (artemether-lumefantrine), a child-friendly formulation developed with Novartis. Since 2009, over 250 million courses of Coartem Dispersible treatment have been supplied to 50 malaria-endemic countries; and since prequalification in 2010, an estimated 25 million vials of artesunate injection have been delivered, saving 165,000 additional lives.

Managing the largest portfolio of antimalarial R&D projects ever assembled, of over 65 projects, MMV has seven new drugs in clinical development addressing unmet medical needs in malaria, including medicines for children, pregnant women and relapsing malaria, and drugs that could support the elimination/eradication agenda. MMV's success in research and access & product management comes from its extensive partnership network of over 300 pharmaceutical, academic and endemic-country partners in 50 countries.

MMV's vision is a world in which innovative medicines will cure and protect the vulnerable and under-served populations at risk of malaria, and ultimately help to eradicate this terrible disease. For more information, please visit <http://www.mmv.org>

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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.

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