

**PRESS RELEASE**

**WHO provides first-ever approval for rectal artesunate product for severe malaria**

**MMV collaboration helps make life-saving intervention more widely available**

**Geneva, 27 February 2018.** On 22 February 2018, Indian pharmaceutical company Cipla Ltd. received confirmation of approval from the World Health Organization (WHO) Prequalification Programme for their 100mg rectal artesunate suppositories (RAS) for the pre-referral management of severe malaria. The much-awaited approval, achieved with support from MMV and funding from Unitaid, makes the Cipla product the first to receive prequalification for this indication. Importantly, prequalification will enable countries to procure life-saving RAS, thus ensuring the product's greater uptake and distribution.

"This is an important milestone," said Dr David Reddy, CEO of MMV. "This approval from the WHO prequalification programme will expand access to RAS and help save more young lives from malaria during that critical journey between a rural community setting and an appropriately equipped treatment centre. We are proud to have worked closely with WHO TDR, Unitaid, WHO's Global Malaria Programme and Cipla to reach this important moment. It's a true testament to the power of partnerships. Now that we have this international quality approval in place for RAS, we will continue the work with all stakeholders to support its introduction and availability into remote health settings to help save the lives of young children suffering from severe malaria."

Severe malaria can kill within 24 hours if left untreated, and travel times to hospital can be long, particularly for children from remote rural communities. WHO TDR's 2009 study demonstrated that a single dose of RAS 100mg, given as soon as a presumptive diagnosis of severe malaria has been made<sup>1</sup>, can halve the likelihood of disability and death for young patients unable to access WHO-preferred first-line treatment for severe malaria, injectable artesunate (Inj AS), within 6 hours.<sup>2</sup> After receiving RAS, patients should be referred to a facility where they can receive Inj AS to treat their malaria infection.

In 2005, WHO first recommended the use of RAS for pre-referral management of young children with severe malaria. Until now, no RAS product has met international quality standards, leaving countries with limited options to cope with children in need of pre-referral care.

---

<sup>1</sup> ["Rectal artesunate for pre-referral treatment of severe malaria"](#) WHO-GMP Information Note, October 2017

<sup>2</sup> Gomes MF *et al.* ["Pre-referral rectal artesunate to prevent death and disability in severe malaria: a placebo-controlled trial."](#) *Lancet*. 14;373(9663):557-66 (2009).

To bridge this gap, MMV worked with Cipla to obtain WHO prequalification for their RAS 100mg products. Cipla received a temporary authorization for one year from the Global Fund Expert Review Panel in 2016, allowing its product to be procured with donor funds.

“We have together achieved a major breakthrough by bringing together partners to secure WHO prequalification for a game-changing rectal artesunate product,” said Unitaid’s Executive Director, Lelio Marmora. “We now have a formidable weapon in our armoury that has the potential, once fully deployed, to sharply reduce the number of children under five succumbing to severe malaria.”

To date, Cipla has registered RAS 100 mg in two high-burden countries and the dossier is under review in a further 14 countries. Close to 150,000 treatments have been distributed to countries by the company. For 2018, orders for RAS 100 mg have been placed to supply close to a dozen high-burden malaria countries.

## Notes for editors

### About malaria and children

Malaria places a heavy burden on the health of children. With intensive global effort, it is estimated that 6.2 million deaths due to malaria were prevented between 2001 and 2015; 5.9 million (95%) of which were those of young children. However, malaria continues to take its toll. In 2016, the disease took the lives of over 300,000 children under the age of 5 years. The launch of WHO pre-qualified RAS 100mg will make available a critical, quality pre-referral intervention that will help save many more young lives.

Buying time to save a life – [read one-year-old Inness’ story](#) of survival from malaria thanks to the availability of severe malaria medicines, including RAS



### About WHO prequalification

Prequalification is a service provided by WHO to assess the quality, safety and efficacy of medicines. Every year, billions of US dollars' worth of medicines are purchased by international procurement agencies for distribution in resource-limited countries. Prequalification gives these agencies the choice of a wide range of quality-assured medicines for bulk purchase.

#### **About Cipla Ltd.**

Cipla is a global pharmaceutical company which uses cutting edge technology and innovation to meet the everyday needs of all patients. In the last 80+ years, Cipla has emerged as one of the most respected pharmaceutical names in India as well as across more than 80 countries. Our portfolio includes over 1500 products across wide range of therapeutic categories with one quality standard globally.

Whilst delivering a long-term sustainable business, Cipla recognises its duty to provide affordable medicines. Cipla's emphasis on access for patients was recognised 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 a 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.

#### **About Unitaid**

Unitaid is an international organisation that invests in new ways to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, more cheaply and more effectively. We also work to improve access to diagnostics and treatment for HIV co-infection including hepatitis C. Unitaid researches and identifies new health solutions with potential to alleviate the burden of HIV/AIDS, tuberculosis and malaria, as well as HIV co-infections including hepatitis C. Through calls for proposals, Unitaid finds partners best qualified to put key innovations into practice who then receive grants from Unitaid to fast-track access and reduce costs of more effective medicines, technologies and systems.

#### **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 delivering new, effective and affordable antimalarial drugs.

Since its foundation in 1999, MMV and partners have developed and brought forward seven new medicines: *Coartem*<sup>®</sup> *Dispersible* (artemether-lumefantrine), a child-friendly formulation developed with Novartis; Guilin's artesunate injection *Artesun*<sup>®</sup> for the treatment of severe malaria; *Eurartesim*<sup>®</sup> (dihydroartemisinin-piperaquine) with Sigma-Tau; *Pyramax*<sup>®</sup> and *Pyramax*<sup>®</sup> Granules for children (pyronaridine-artesunate) co-developed with Shin Poong; and Guilin's sulphadoxine-pyrimethamine + artesunate amodiaquine (SP+AQ) for seasonal malaria chemoprevention, which received WHO prequalification with MMV's support. Furthermore, with MMV support, both Cipla and Strides Shasun's rectal artesunate (RAS) products have been issued 12-month authorizations for procurement by the Global Fund Expert Review Panel (ERP), while regulatory/WHO prequalification review is ongoing. In addition, MMV has taken over the stewardship of two approved artemisinin combination therapies (ACTs) developed by Drugs for Neglected Diseases initiative (DNDi) and partners – artesunate-amodiaquine (ASAQ) and artesunate-mefloquine (ASMQ).

Since 2009, over 350 million courses of *Coartem Dispersible* treatment have been supplied to 50 malaria-endemic countries; and since prequalification in 2010, an estimated 100 million vials of artesunate injection have been delivered, saving 650,000 additional lives. In total, over one and a half million lives are estimated to have been saved by MMV co-developed drugs.

MMV and partners manage a portfolio of 65 projects, the largest portfolio of antimalarial R&D and access projects ever assembled. The portfolio includes nine 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 160 active global partnerships. Since its inception in 1999, MMV has built an extensive network of over 400 pharmaceutical, academic and endemic-country partners in more than 55 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.

MMV's work is only possible due to the support of our partners and committed donors.

[www.mmv.org](http://www.mmv.org)

#### **For more information:**

Senior Director Communications, MMV

Jaya Banerji

Phone +41 79 707 71 81

e-mail: [banerji@mmv.org](mailto:banerji@mmv.org)

#### **MMV Disclaimer**

This document contains certain forward-looking statements that may be identified by words such as ‘believes’, ‘expects’, ‘anticipates’, ‘projects’, ‘intends’, ‘should’, ‘seeks’, ‘estimates’, ‘future’ or similar expressions, or by discussion of, among other things, vision, strategy, goals, plans, or intentions. It contains hypothetical future product target profiles, development timelines and approval/launch dates, positioning statements, claims and actions for which the relevant data may still have to be established. Stated or implied strategies and action items may be implemented only upon receipt of approvals including, but not limited to, local institutional review board approvals, local regulatory approvals, and following local laws and regulations. Thus, actual results, performances or events may differ from those expressed or implied by such statements.

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.