Press Release

Cipla launches quality-assured Rectal Artesunate Suppositories for severe malaria in young children

Mumbai, India & Geneva, Switzerland, 25 July 2017: Cipla Ltd, a global pharmaceutical company, and the product development partnership Medicines for Malaria Venture (MMV) today announced the launch of 100 mg Artesunate Rectocaps/Rectal Artesunate Suppositories (RAS), a life-saving, pre-referral intervention for the management of severe malaria in young children.

Initially developed by the World Health Organization's (WHO) Tropical Diseases Research programme, RAS 100 mg manufactured by Cipla was recently added to the Global Fund Expert Review Panel's list of quality-assured medicines, while the process of WHO prequalification of this medicine moves through its final stages. This authorization makes it the first quality-assured RAS product.

Umang Vohra, MD and Global CEO Cipla Ltd. said, "Cipla is committed to providing access to affordable medicines. Our endeavour is to make RAS 100 mg available in rural areas in Africa and to national community health programmes, notably with the support of international donors that have already pledged to procure Rectal Artesunate."

"MMV welcomes this excellent news," said Dr David Reddy, MMV's CEO. "RAS is a life-saving intervention. With the launch of Cipla's product, the first to be quality-assured, more malaria-endemic countries will now be able to provide it to more of their children. We are proud to have worked with Cipla in its quest to ensure universal access to high quality and affordable treatments, especially for vulnerable young populations suffering from severe malaria."

Cipla's RAS product contains 100 mg of Artesunate and is indicated in children from 6 months to 6 years. It was developed with the support of MMV (with UNITAID financing) and will now soon be available in four sub-Saharan countries.

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About Rectal Artesunate Suppositories

Rectal artesunate suppositories (RAS) for the pre-referral management of severe malaria is a critical intervention intended for infants and children who are critically ill and unable to take oral medicines. Untreated severe malaria can be fatal, especially in the first 24 hours; but this risk can fall to 10-20% with prompt treatment and care. In many malaria-endemic countries, treatment delays due to distance from health facilities can result in fatal outcomes. The WHO recommends pre-referral administration of RAS, in treating cases of suspected severe malaria where intramuscular injection of artesunate is not available, to treat children < 6 years with a single rectal dose (10mg/kg bw) of artesunate and refer immediately to an appropriate facility for further care.[1] This approach helps buy time until parenteral treatment can be administered and thereby reduces the risk of death or permanent disability.[2,3,4] Sixteen countries have already included RAS in their treatment guidelines.

RAS 50 mg and 200 mg have been on WHO's Essential Medicines List since 2007, and the 100 mg dose was recently added in June 2017. MMV and its partner Cipla have developed the only RAS presentation (100 mg suppository) that has been approved for purchase with donor funds (via Global Fund's ERP product list, while WHO prequalification review is ongoing).

As a pre-referral intervention, RAS is not intended to substitute for parenteral artesunate, which must be administered to patients with severe malaria whenever possible. In addition, RAS is not intended as a substitute for the treatment of uncomplicated malaria, for which WHO recommends the use of artemisinin-combination therapies (ACTs).

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 lives were saved from malaria between 2001 and 2015; 5.9 million (95%) of whom 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. The launch of RAS will make available a critical pre-referral intervention that will help save many more young lives.

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[1] Guidelines for the treatment of malaria - 3rd edition. Geneva: World Health Organization; 2015: http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf?ua=1&ua=1.
[2] Rectal Artesunate Stakeholders' Meeting Report Nairobi, 19 February 2016 *https://www.mmv.org/sites/default/files/uploads/.../MMV_RASreport_20160513.pdf*
[3] Gomes MF *et al.* Pre-referral rectal artesunate to prevent death and disability in severe malaria: a placebo-controlled trial. *The Lancet.* 373(9663):557-66 (2009).
[4] WHO-TDR website. Rectal artesunate testing and delivery (2016): http://www.who.int/tdr/research/malaria/rectal_artesunate/en

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.
www.cipla.com

About Medicines for Malaria Venture

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 that are estimated to have saved over a million lives. In addition, MMV has taken over the stewardship of two approved artemisinin combination therapies (ACTs) developed by Drugs for Neglected Diseases *initiative* (DND*i*) and partners.

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 extensive partnership 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.
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