WHO Prequalifies A New Artemisinin-Based Combination Treatment (ACT) for Malaria

Artesunate-Mefloquine Fixed-Dose Combination (ASMQ FDC) to be rolled out throughout Asia

[Kuala Lumpur, Malaysia, Mumbai, India, and Geneva, Switzerland – 3 October 2012] – **Cipla, one of the leading generic pharmaceutical companies, along with the non-profit research and development organization Drugs for Neglected Diseases *initiative* (DND*i*) today announced the prequalification of the fixed dose combination (FDC) of Artesunate (AS) and Mefloquine (MQ) – ASMQ FDC – by the World Health Organization (WHO). This Cipla-manufactured ASMQ FDC is the first artesunate-mefloquine FDC to be prequalified by WHO and is recommended for the treatment of malaria.**

'The prequalification announcement is recognition that ASMQ FDC meets WHO's high quality standards and we aim to make this treatment widely available throughout Asia', commented Dr Jaideep Gogtay, Medical Director, Cipla.

'The availability of ASMQ FDC will have a direct impact on patients, especially in Asia', said Bernard Pécoul, Executive Director, DND*i*. '*It addresses an important public health need in the region as it forms part of the malaria treatment arsenal necessary to control the disease.'*

This combination of AS and MQ is one of five Artemisinin Combination Therapies (ACTs) currently recommended by WHO for the treatment of uncomplicated *P. falciparum* malaria, and is the first-line treatment in a number of South East Asian countries. ASMQ FDC was registered in India in 2011 and in Malaysia in early 2012. In India, about 18,000 adult patients have already been treated with this combination.

ASMQ FDC was originally developed by DND*i* and the Brazilian government-owned pharmaceutical company Farmanguinhos/Fiocruz and was registered in Brazil in 2008. A South-South technology transfer between Farmanguinhos and Cipla was achieved in 2010 to facilitate the implementation of ASMQ FDC in Asia. Prequalification is a major milestone, as it indicates that ASMQ FDC meets WHO standards of quality, safety, and efficacy.

In addition to being easy to use (a single daily dose of 1 or 2 tablets over three days), ASMQ FDC will increase patient compliance and contribute to reducing the risk of resistance development, as it ensures both drugs are taken together and in correct proportions (4 dosage forms based on age/weight dosing).

Scientific evidence supporting the development of ASMQ FDC derives from the well-established use of their combined administration, as demonstrated by clinical data including more than 11,000 patients. In 2009, a study in Myanmar comparing the effectiveness of the four fixed-dose ACTs, then recommended by WHO, showed that ASMQ FDC had the highest cure rate and the lowest rate of gametocyte carriage, providing the greatest post-treatment suppression of recurrent *P. falciparum* malaria and the most effective suppression of blood-stage *P. vivax* malaria.

The ASMQ FDC is manufactured in Cipla's world class manufacturing facility in Patalganga, India, which is approved by WHO-Geneva, US FDA, MHRA-UK and various other regulatory bodies.

A prequalified status makes ASMQ FDC eligible to tenders that receive funding from international procurement agencies, such as UNICEF and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

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About the WHO PQP
WHO PQP is the only global medicines quality assurance programme. Originally created with a focus on medicines for the treatment of HIV/AIDS, tuberculosis, and malaria, the WHO PQP now also provides prequalification services for medicines and products for reproductive health and for zinc. Since 2001, over 240 medicines have been prequalified. WHO staff, together with experts from national regulatory authorities around the world, carefully review submitted dossiers. Inspectors are sent to the sites where the finished pharmaceutical product and its active pharmaceutical ingredient(s) are manufactured to verify they comply with WHO good manufacturing practice. The list of prequalified medicines has become a vital tool for all the international procurement agencies who, each year, bulk-purchase billions of US dollars' worth of medicines for distribution in resource-limited countries.

About ASMQ FDC
The combination of AS and MQ, two well-established drugs for the treatment of uncomplicated *P. falciparum* malaria, has proven its efficacy after 20 years of clinical use. However, the non-fixed dose combination posed problems of patient compliance and potential development of drug resistance. In order to address this, ASMQ FDC was developed by the Fixed-Dose Artesunate-Based Combination Therapies (FACT) Consortium, created by DND*i* and the Special Programme for Research and Training in Tropical Diseases (WHO-TDR) in 2002. Through an innovative partnership supported and facilitated by DND*i* in 2008, Cipla entered into an agreement with Farmanguinhos/Fiocruz and will manufacture ASMQ FDC and ensure it is available at pre-agreed, affordable prices. ASMQ FDC was registered in Brazil in 2008, in India in 2011, and in Malaysia in early 2012. It is easy to use, with once daily administration of one or two tablets over three days for patients of all ages (from children aged 6 months through to adults) and has a two-year shelf-life in tropical conditions.

About DND*i*
The Drugs for Neglected Diseases *initiative* (DND*i*) 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, specific helminth (filarial) infections, malaria, and paediatric HIV. Since its inception in 2003, DND*i* has delivered six treatments: 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. DND*i* has helped establish three clinical research platforms: Leishmaniasis East Africa Platform (LEAP) in Kenya, Ethiopia, Sudan, and Uganda; the HAT Platform based in Africa for sleeping sickness; and the Chagas Clinical Research Platform in Latin America.
www.dndi.org

About Cipla
Cipla laid foundations for the Indian pharmaceutical industry back in 1935 with the vision to make India self-reliant in healthcare. Over the years Cipla has emerged as one of the most respected names not just

in India but worldwide. Its state of the art R&D centre has given the country and the world many firsts. This includes the revolutionary AIDS cocktail for less than a dollar a day. With over 34 manufacturing units across the country, Cipla manufactures over 2000 products in 65 therapies.

With a turnover of over US $ 1.4 billion, Cipla serves doctors and patients in over 170 countries. It has earned a name for maintaining one global standard across all its products and services. Cipla continues to support, improve and save millions of lives with its high-quality drugs and innovative devices.
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