Pyramax receives positive opinion from the EMA

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Pyramax, a fixed-dose combination of pyronaridine and artesunate, becomes the first antimalarial to be granted a positive scientific opinion from the European Medicines Agency (EMA) under Article 58. This once daily, 3-day treatment is indicated for acute, uncomplicated *Plasmodium falciparum* and blood-stage *Plasmodium vivax* malaria in adults and children over 20 kg.

Pyramax tablets are the result of collaboration between the product development partnership Medicines for Malaria Venture, and Shin Poong Pharmaceutical Co. Ltd., Republic of Korea. The approval is based upon clinical trials comparing the safety and efficacy of Pyramax to that of artemether-lumefantrine and a loose combination of artesunate and mefloquine for *P. falciparum* malaria, and versus chloroquine for *P. vivax* malaria.

It is the first artemisinin combination therapy (ACT) to be approved by a stringent regulatory authority for the treatment of both *P. falciparum* and *P. vivax* malaria, and the only ACT with trials in *P. vivax* malaria conducted to stringent regulatory standards.

"EMA's positive scientific opinion of Pyramax comes at a critical time," said David Reddy, CEO of MMV. "Parasite resistance to artemisinin, as well as to the partner drugs in some ACTs, is on the rise and a new alternative is urgently needed. Pyramax can help fill that urgent need and the positive opinion will help ensure its availability in areas where other ACTS are failing. Our next step is to ensure that healthcare workers

understand how to appropriately use the drug. We will also work to complete development of paediatric formulations of this new combination."

Initially, Pyramax will be registered in countries with areas of low malaria transmission where there is reported artemisinin resistance and diminished efficacy of other ACTs. It will be an important additional tool for WHO's artemisinin resistance containment strategy in these countries, where its use will also facilitate the collection of more information on this combination. As liver enzyme elevations were noted in some subjects, until further data after retreatment is obtained, it is recommended that Pyramax be administered not more than once.

Taking over the project from WHO/TDR in 2002, when Pyramax was entering preclinical trials, MMV embarked on a partnership with Shin Poong. Since then, the partnership has taken the drug through early clinical studies leading to four successful, pivotal Phase III clinical trials with over 3,500 patients in 18 countries in sub-Saharan Africa, Southeast Asia and India. In addition, safety and efficacy has been confirmed for the Pyramax paediatric granules formulation in children as young as 6 months and work is on-going to submit the dossier in the near future.

"The managerial decision to commence the Pyramax project was based on Shin Poong's core values and company policies, which have guided us for nearly half a century," said Mr. Chang Kyun Kim, President of Shin Poong. "It represents an effort to fulfil our corporate social responsibilities and to realize universal values. To advance these values, Shin Poong will extensively collaborate with the WHO to register Pyramax in malaria-endemic countries and supply Pyramax at an affordable price so that many lives, especially those of children, can be saved and the general public's health can be maintained."