

PRESS RELEASE

Pyramax[®] Granules becomes first paediatric antimalarial to receive EMA article 58 positive scientific opinion

- **Around half a million children under 5 years old die every year from lack of adequate treatment for malaria**
- **Child-friendly Pyramax[®] Granules (pyronaridine-artesunate), developed by Medicines for Malaria Venture and Shin Poong Pharmaceutical, will offer a new choice in the treatment of these children**
- **The European Medicines Agency's positive scientific opinion under article 58 will facilitate the new medicine's use in malaria-endemic countries**

Geneva, 20 November 2015: Pyramax[®] Granules, the child-friendly fixed-dose artemisinin combination therapy (ACT) of pyronaridine and artesunate, becomes the first paediatric antimalarial to be granted a positive scientific opinion from the European Medicines Agency (EMA) under Article 58. Article 58 was established to enable the EMA to undertake a scientific assessment and provide guidance, in cooperation with the World Health Organization (WHO), on products that are not intended for use in Europe, thereby providing a valuable service for the wider global health community. The *Pyramax Granules* opinion will support the registration and use of this new medicine for young children in malaria-endemic countries.

Adapted to the needs of children, *Pyramax Granules* is taste-masked, suspends in approximately two teaspoons of liquid, and is taken once-daily for 3 days with or without food. This formulation is well suited to sick children, who need to take the full dose in order to achieve complete cure. *Pyramax Granules* is also the first paediatric medicine to be indicated for the treatment of acute, uncomplicated blood-stage malaria caused by either of the two main species of parasite, *P. falciparum* and *P. vivax*.

“Around 78% of people dying from malaria are children less than 5 years of age,” said David Reddy, MMV's CEO. “The timely development of age-appropriate formulations to address the needs of this particularly vulnerable population is essential. Following this positive scientific opinion from EMA, MMV, Shin Poong and other partners can work with endemic countries to pursue national approvals for *Pyramax Granules* and make the medicine available to children in need.”

Pyramax Granules and the tablet formulation [Pyramax[®]](#) (for adults and children weighing >20kg) were developed by the product development partnership Medicines for Malaria Venture (MMV) and Shin Poong Pharmaceutical Co. Ltd., Republic of Korea. The partnership has taken the drug combination through pre-clinical studies and 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 and a large Phase IIIb/IV safety and efficacy study with patients from Mali, Burkina Faso and Guinea. The Phase IIIb/IV study was led by the West African Network for Clinical Trials of Antimalarial Drugs (WANECAM) with funding from the European & Developing Countries Clinical Trials Partnership (EDCTP) and MMV.

In parallel with the introduction of *Pyramax Granules* in endemic countries, MMV and Shin Poong will work with partners to conduct a Phase IV pharmacovigilance study to generate further data about *Pyramax* tablets and *Pyramax Granules* in real-life settings.

“We are proud to have reached this landmark achievement with our long-standing partner Medicines for Malaria Venture,” said Jei Man Ryu, CEO of Shin Poong Pharmaceutical. “We have worked with dedication to achieve this goal and will continue to collaborate with MMV to ensure that this important life-saving medicine reaches the children for whom we developed it. Unacceptable numbers of children continue to die of malaria and this medicine will be of enormous benefit to those children suffering from either *P. vivax* or *P. falciparum* blood-stage malaria.”

Notes for editors

About *Pyramax*[®] – see [Pyramax Facts](#)

About WANECAM

The WANECAM network, includes four West African countries, (three of which participated in the study: Burkina Faso, Guinea and Mali) and four European countries (England, France, Germany and Sweden) that work in partnership as a cross-border research team to contribute to the evaluation of new antimalarial drugs.

The network is funded primarily by MMV and the European and Developing Countries Clinical Trials Partnership (EDCTP). Other funders are the UK Medical Research Council, Swedish International Development Cooperation Agency, German Ministry for Education and Research, University Claude Bernard (Lyon, France), Malaria Research and Training Centre (Bamako, Mali), Centre National de Recherche et de Formation sur le Paludisme (Burkina Faso), Institut de Recherche en Sciences de la Santé (Bobo-Dioulasso, Burkina Faso), and Centre National de Formation et de Recherche en Santé Rurale (Republic of Guinea).

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 five new medicines: Coartem[®] *Dispersible* (artemether-lumefantrine), a child-friendly formulation developed with Novartis; Guilin’s artesunate injection Artesun[®] for the treatment of severe malaria; Eurartesim[®] (dihydroartemisinin-piperaquine) with Sigma-Tau; *Pyramax*[®] (pyronaridine-artesunate), co-developed with Shin Poong; and Guilin’s sulfadoxine-pyrimethamine + artesunate amodiaquine (SP+AQ) for seasonal malaria chemoprevention, which received WHO prequalification with MMV’s support.

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 36 million vials of artesunate injection have been delivered, with the potential to save an additional 200,000–240,000 lives compared to treatment with quinine.

Managing the largest portfolio of antimalarial R&D projects ever assembled, of over 65 projects, MMV has 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 375 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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About Shin Poong Pharm.Co.,Ltd

Under the management philosophy of 'for the health of the people', Shin Poong Pharm.Co.,Ltd specializes in manufacturing remedy drugs with sincere efforts put into producing every single tablet of life-saving drugs ranging from ingredients to finished products based on our state-of-the-art manufacturing facilities and quality assurance system. We are committed to realizing the spirit of Shin Poong 3V (Vision, Venture and Victory) with top-notch competitiveness based on in-house ingredient synthesizing technologies obtained through rigorous R&D efforts and to further developing the company into the one that receives confidence from our customers and that contributes to promoting the wellbeing of human beings.

For more information, please visit: www.shinpoong.co.kr/

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