

**PRESS RELEASE**

# **Strong Recommendation for Pyronaridine-Artesunate in Revised WHO Malaria Treatment Guidelines**

*Inclusion in the latest version of the WHO Guidelines for malaria is a key step towards broader use of the medicine*

**Geneva, Switzerland and Seoul, South Korea 25 November 2022.** MMV and Shin Poong Pharm. Co., Ltd. welcome the formal inclusion of Pyramax® (pyronaridine-artesunate) in the [World Health Organization's \(WHO\) Guidelines for Malaria](#) following an extensive review process.

The WHO's Guidelines for the Treatment of Malaria are the standard reference which guide country-level policies for managing malaria. New medicines are only recommended for inclusion following a robust and in-depth evaluation of evidence using the [GRADE](#) framework, which provides a systematic approach for making clinical practice recommendations. Following this review – which included one of the largest clinical studies to evaluate real-world efficacy and safety of any antimalarial – the Guideline Development Committee recommended the formal inclusion of *Pyramax* in the guidelines with a “STRONG” recommendation – the highest level of confidence.

*Pyramax* is a fixed dose artemisinin-based combination therapy (ACT) and the only one to be specifically indicated for the blood-stage treatment of the two dominant species of malaria parasite: *P. falciparum* and *P. vivax*. The medicine is also available in a child-friendly granule formulation to ensure palatability and therefore correct dosage in this vulnerable population.

Both *Pyramax* tablets and *Pyramax* granules received European Medicines Agency (EMA) positive scientific opinions from the Committee for Medicinal Products for Human Use (CHMP) through Article 58, based on a robust development programme. To date, over 2.9 million malaria patients have been treated with the medicine, including children under the age of 1.

Both formulations are currently registered for the treatment of uncomplicated malaria in 29 countries in Africa and Asia.

Following the positive scientific opinions for use, a large Cohort Event Monitoring study was implemented in 5 African countries<sup>1</sup> under the supervision of the CANTAM Network<sup>2</sup> to evaluate the safety and effectiveness of *Pyramax* under conditions similar to everyday clinical practice. This study, which reported high effectiveness (D28 PCR-adjusted cure rate of 98.6%), included over 8,500 acute malaria episodes in 7,154 patients, and has recently been published in *PLoS Medicine*<sup>3</sup>.

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<sup>1</sup> Gabon: Albert Schweitzer Hospital (CERMEL), Lambaréné, Côte d'Ivoire: Health Center of Azaguié & Health Center of Agboville, Cameroon: Biotechnology Center, University of Yaoundé & Mfou District Hospital, Congo: Congo foundation for the Medical Research, Brazzaville, Makélélé Hospital, Health Center of Madibou, DR of Congo: Faculty of Medicine, University of Kinshasa, Mont-Amba Hospital, Kinshasa, Evangelic Medical Institute of Kimpesé

<sup>2</sup> For more information about CANTAM, please visit: <https://www.cantam.org/index.php/cantam-about-us>

<sup>3</sup> To read the CANTAM study, please visit: <https://journals.plos.org/plosmedicine/article/authors?id=10.1371/journal.pmed.1003669>

*Pyramax* was included in the WHO's list of pre-qualified medicines in 2012, and in the WHO's Essential Medicines Lists for both adults and children in 2017. *Pyramax* has subsequently undergone a positive review by the WHO's Advisory Committee on the Safety of Medicinal Products in 2019, which included a review of interim data from the CANTAM study.

Following this review in October 2019 and pending the next revision of their Guidelines for Malaria, the WHO published an Information Note supporting the use of *Pyramax* at country level, stating that "*artesunate-pyronaridine can be considered a safe and efficacious ACT for the treatment of uncomplicated malaria in adults and children weighing 5 kg and over in all malaria-endemic areas....countries can consider including this medicine in their national treatment guidelines for the treatment of malaria*".

"The addition of *Pyramax* to the *WHO Guidelines for malaria* is an achievement that we are proud to have reached with our long-standing partner Shin Poong Pharm. Co., Ltd.," said Dr David Reddy, MMV's CEO. "We ventured into the *Pyramax* project to help save the lives of adults and children with malaria. Therefore, we will continue to work with Shin Poong to register both the tablets and granules of *Pyramax* in more malaria-endemic countries, facilitating equitable access to this important new addition to the malaria treatment toolkit."

"The official inclusion of *Pyramax* into WHO's Guidelines for malaria is a crucial step allowing malaria endemic countries to choose *Pyramax* as a first line ACT with confidence. The managerial decision to commence the *Pyramax* project was based on Shin Poong's core values and company policies, which have guided us for over half a century. We will continue to produce qualified products to supply potent, reliable, simple treatment to patients", said Shin Poong Pharm. Co., Ltd.

## **Notes for editors**

### **Background on the malaria burden**

According to the latest [World Malaria Report](#), released on 6 December 2021, there were an estimated 241 million cases of malaria and 627,000 resulting deaths worldwide in 2020. This represents about 14 million more cases in 2020 compared to 2019, and 69,000 more deaths. Approximately two-thirds of these additional deaths (47,000) were linked to disruptions in the provision of malaria prevention, diagnosis and treatment caused by the COVID-19 pandemic. Moreover, in the past 2 years, the emergence of parasite mutations associated with drug resistance in Africa has been confirmed, with delayed parasite clearance (and therefore delayed cure) already seen in Rwanda, Uganda and the Horn of Africa.

The WHO African Region continues to carry a disproportionately high share of the global malaria burden. In 2020, the region was home to 95% of all malaria cases and 96% of all deaths. About 80% of all malaria deaths in the region are among children under five years of age.

In 2020, six countries accounted for just over half of all malaria deaths worldwide: Nigeria (27%), the Democratic Republic of the Congo (12%), Uganda (5%), Mozambique (4%), Angola (3%) and Burkina Faso (3%).

### **About *Pyramax*<sup>®</sup>**

*Pyramax*, a fixed-dose combination of pyronaridine and artesunate and the newest ACT combination to be approved by a Stringent Regulatory Authority. Development began in 2000 as a joint venture between Shin Poong Pharm. Co., Ltd. and WHO TDR. Subsequently, development was continued by Shin Poong Pharm. Co., Ltd., the University of Iowa, and Medicines for Malaria Venture (MMV).

This once-daily, 3-day therapy is indicated for the treatment of acute uncomplicated malaria in adults and children over 20 kg (*Pyramax*<sup>®</sup> tablets) and in children and infants between 5 and 20 kg (*Pyramax*<sup>®</sup> granules).

### **About Article 58**

Article 58 of Regulation (EC) No 726/2004 establishes a mechanism whereby the European Medicines Agency (EMA) may give a scientific opinion, in the context of cooperation with the World Health Organization (WHO), for the evaluation of certain medicinal products for human use intended exclusively for markets outside the European Union.

Article 58 of the Regulation responds to the need to protect and promote public health and to give scientific assistance to non-EU countries in the context of cooperation with WHO whilst at the same time facilitating rapid access by those countries to important new medicinal products.

### **About Shin Poong Pharm. Co., Ltd.**

Shin Poong was founded in 1962 with headquarters based in Seoul, Korea. Shin Poong is one of the largest pharmaceutical companies in Korea that produces both active pharmaceutical ingredient and finished pharmaceutical product in facilities, to which European Union Good Manufacturing Practices (EU GMP) certification was granted in 2012 for its flagship antimalarial product *Pyramax*<sup>®</sup> (pyronaridine tetraphosphate and artesunate).

'For the health of the people' is the driven corporate philosophy of the Company. Shin Poong contributed largely to eradicate parasitic diseases from Korea during 1970s and 80s and from other countries in Africa, China, and Southeast Asian countries through strong collaboration with the World Health Organization (WHO).

Shin Poong with its partners were pioneers in Public Development Partnership' access providing a healthcare model to end global epidemics of infectious diseases and to work for end-to-end execution from early discovery to field implementation for endemic infections.

For more information, please visit <https://shinpoong.co.kr/en/main/main.php>

### **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 facilitating delivery of new, effective and affordable antimalarial drugs.

MMV receives funding and support from government agencies, private foundations, international organizations, corporations, corporate foundations and private individuals. These funds are used to finance MMV's portfolio of R&D projects, as well as specific, targeted access & product management (APM) interventions that aim to facilitate increased access to malaria medicines by vulnerable populations in disease-endemic countries and support their appropriate use.

Since its foundation in 1999, MMV and partners have built the largest portfolio of antimalarial R&D and access projects ever assembled and have brought forward 15 new medicines. Almost 3 million lives have been saved by these MMV co-developed medicines. MMV's success is based on its extensive partnership network of around 150 active partners including from the pharmaceutical industry, academia and endemic 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 help to ultimately eradicate this terrible disease.

For more information, visit <http://www.mmv.org>

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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.