

## PRESS RELEASE

### **Thailand becomes first malaria-endemic country in Asia-Pacific to approve tafenoquine for radical cure of *P. vivax* malaria**

GSK Thailand and Medicines for Malaria Venture (MMV) today announce that the Thai Food and Drug Administration (Thai FDA) has granted Marketing Authorization Approval for single-dose tafenoquine, 150 mg tablets for the radical cure (prevention of relapse) of *Plasmodium vivax* (*P. vivax*) malaria in patients aged 16 years and older.

“Thailand has been able to make significant progress against malaria over the past decades. Just over 5,000 cases were reported in 2019, which is an overall drop by half compared to 2017,” said Dr. Cheewanan Lertpiriyasuwat, Director, Division of Vector Borne Diseases, Department of Diseases Control, Thailand’s Ministry of Public Health. “However, *P. vivax* has replaced *P. falciparum* as the dominant species, accounting for 85% of total cases. *P. vivax* is now the thorn in the side of Thailand’s malaria elimination efforts. We will need new tools to tackle this parasite if we are to eliminate malaria completely from our country. It is hoped that tafenoquine together with a glucose-6-phosphate dehydrogenase (G6PD) enzyme test could be the new tools needed to help us reach our goals.”

As a single dose cure, tafenoquine facilitates compliance and therefore aims to overcome one of the major limitations of the only other approved medicine for a radical cure of *P. vivax* malaria, primaquine, which in Thailand is recommended to be taken daily over 14 days. Approval is an important first step to open-up access to tafenoquine more broadly across Asia-Pacific where the *P. vivax* species of the malaria parasite is becoming the most dominant.

A study to determine the feasibility of implementing quantitative point-of-care G6PD testing with tafenoquine through the health system is set to begin in the coming months sponsored by the Thai Ministry of Public Health with support from MMV. Study findings will be used to guide the roll-out of the new tools across malaria-endemic areas of Thailand.

“Globally, the human and economic cost of relapsing malaria is high,” said Dr. David Reddy, MMV’s CEO. “Moreover, as gains are made against *P. falciparum* in Asia-Pacific, we’re seeing the proportion of cases of *P. vivax* increase. That’s why the approval of tafenoquine to prevent the debilitating relapse of *P. vivax* in Thailand is so important. As a single dose medicine, we hope that tafenoquine will increase patient adherence and help Thailand and other countries in the Asia-Pacific move closer to malaria elimination.”

“GSK has been committed to the fight against malaria from researching new medicines and vaccines in our laboratories to supporting global public health goals. With the strength of the partnership involving Thailand’s Ministry of Public Health, MMV and GSK, the approval of tafenoquine in Thailand marks another important step in the fight against infectious diseases in the developing world. We will help determine how best to direct patient access to this medicine in Thailand as part of the global efforts to eradicate malaria,” concluded Mr. Viriya Chongphaisal, General Manager, GlaxoSmithKline (Thailand) Limited.

## About tafenoquine

Tafenoquine, developed by GSK and MMV, was first approved by the US Food and Drug Administration in July 2018, by the Australian Therapeutic Goods Administration in September 2018 and by the Brazilian Health Regulatory Agency (ANVISA) in October 2019.

Tafenoquine needs to be co-administered with chloroquine to treat both the blood and liver stages of acute *P. vivax* malaria infections. Before taking the medicine, patients must be tested for deficiency of a specific enzyme known as glucose-6-phosphate dehydrogenase (G6PD), which helps protect red blood cells. Patients with a G6PD enzyme deficiency could have severe adverse reactions, like hemolytic anemia, during treatment with radical cure drugs.

## About *P. vivax* malaria

*P. vivax* malaria globally accounts for about ~7.5 million clinical infections per year and has a significant public health and economic impact, primarily in South Asia, South-East Asia, the horn of Africa and Latin America. The clinical features of *P. vivax* malaria include fever, chills, vomiting, malaise, headache and muscle pain and, in some cases, can be fatal.

## About the partners

**Medicines for Malaria Venture (MMV)** is a leading product development partnership (PDP) in antimalarial drug research in its 20th year. 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. Since its foundation, MMV and partners have developed and brought forward eleven new medicines estimated to have saved around 2.2 million lives.

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.

[www.mmv.org](http://www.mmv.org)

**GSK** is a science-led global healthcare company with a special purpose: to help people do more, feel better, and live longer. [www.gsk.com](http://www.gsk.com).

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