



## **PRESS RELEASE**

### **Brazil becomes first malaria-endemic country to approve single-dose tafenoquine (Kozenis) for radical cure of *P. vivax* malaria**

- *Tafenoquine (Kozenis) is the first new medicine to be approved for the radical cure of relapsing P. vivax malaria in more than 60 years.*
- *As a single dose, tafenoquine offers potential to improve patient compliance and effective radical cure, heralding an important step forward in malaria elimination efforts.*
- *A feasibility study is planned to assess the use of quantitative G6PD point-of-care testing together with tafenoquine in routine clinical practice in Brazil.*

**Geneva and Rio de Janeiro, 30 October 2019.** GSK Brazil and Medicines for Malaria Venture (MMV) today announced that the Brazilian Health Regulatory Agency (ANVISA) has granted Marketing Authorization Approval, under Priority Review, for single-dose tafenoquine (brand name Kozenis) for the radical cure (prevention of relapse) of *Plasmodium vivax* (*P. vivax*) malaria in patients aged 16 years and older who are receiving chloroquine for acute *P. vivax* (blood-stage) infection.

The Ministry of Health, in partnership with MMV, will conduct a study to understand the feasibility of implementing quantitative point-of-care G6PD testing with tafenoquine in real-world settings before treatment is made available in Brazil. This study, known as TRuST is being conducted in the municipalities of Manaus and Porto Velho. The study outcomes, expected in the first quarter of 2021, will assist the Ministry of Health to determine how to best deploy tafenoquine in *P. vivax* endemic areas.

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 radical cure of *P. vivax* malaria, primaquine, which needs to be taken over 7 or 14 days.

According to Dr. Marcus Lacerda, Director of Research at the Tropical Medicine Foundation Doctor Heitor Vieira Dourado (FMT-HVD) of Manaus: "This approval is an important step forward for malaria control and elimination in Brazil and in the Amazon region. After years of



research, and following completion of the feasibility study, we hope to finally have a new tool that is appropriate for use in the population that is vulnerable to malaria – enabling patients to complete the treatment course.”

“Globally, the human and economic cost of relapsing malaria is high” said Dr David Reddy, MMV’s CEO. “Each malaria episode keeps a child from school or an adult from work and in susceptible individuals the disease can potentially be fatal. Moreover, as gains are made against the other key malaria parasite, *P. falciparum*, we’re seeing the proportion of cases of *P. vivax* increase. That’s why the approval of this new tool, tafenoquine, in the first malaria-endemic country is so important. As a single dose medicine, we hope that tafenoquine will increase patient adherence and help countries, like Brazil, move closer to malaria elimination.”

The President of GSK’s pharmaceutical division in Brazil, José Carlos Felner said: “The approval of tafenoquine in Brazil marks another important step in the fight against neglected diseases. In 2018 alone, the Ministry of Health recorded over 194,000 cases of malaria.<sup>1</sup> We are now awaiting the completion of feasibility studies that will help determine next steps on how best to direct patient access to tafenoquine in Brazil as part of global efforts to eradicate malaria.”

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## Notes for editors

### About tafenoquine

Tafenoquine, developed by GSK and MMV, was first approved in July 2018 by the US Food and Drug Administration (brand name Krintafel) and in September 2018 by the Australian Therapeutic Goods Administration (brand name Kozenis). Regulatory applications are being progressed in other malaria-endemic countries.

All approvals were based on efficacy and safety data from a comprehensive global clinical development programme for *P. vivax* radical cure, conducted in nine malaria-endemic countries including Brazil, which supported an overall positive benefit–risk profile for the use of the product.

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<sup>1</sup> BRAZIL. Ministry of Health. Brazil reduces malaria cases by 38% compared to 2018. Available at: <[http://saude.gov.br/noticias/agencia-saude/45391-brasil-reduz-em-38-casos-de -malaria-in-relation-to-2018](http://saude.gov.br/noticias/agencia-saude/45391-brasil-reduz-em-38-casos-de-malaria-in-relation-to-2018)>. Accessed on: Oct 25 2019.



Tafenoquine needs to be co-administered with an appropriate blood-stage antimalarial therapy to treat both the blood and liver stages of acute *P. vivax* malaria infections. Before taking tafenoquine or primaquine, 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. PATH, a non-profit global health organization, led a collaboration with the diagnostics manufacturer SD Biosensor, with input from MMV and GSK, that resulted in the provisional approval by the Expert Review Panel for Diagnostics (ERPD) of the first quantitative point-of-care G6PD test in July 2019.

### **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.<sup>2</sup> *P. vivax* is the predominant malaria parasite in Latin America, accounting for two-thirds of all cases. Brazil is one of the Latin American countries with the heaviest burden of *P. vivax* malaria.<sup>3</sup>

Over the last 20-30 years in Brazil, there has been a steady decline in the proportion of cases due to *Plasmodium falciparum*. As a result, in 2017, *P. vivax* was reported to be the cause of almost 90% of Brazil's malaria cases.<sup>2</sup> *P. vivax* malaria is debilitating in particular because of its recurrent infections due to relapses and has substantial economic impact on families and nations. 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 the field of antimalarial drug research and development 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 in 1999, MMV and partners have built the largest portfolio of antimalarial R&D and access projects ever assembled, have brought forward eleven new medicines and have assumed the access stewardship of a further two. An estimated 1.9 million lives have

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<sup>2</sup> World Health Organization. World malaria report 2018: <https://www.who.int/malaria/publications/world-malaria-report-2018/en/>

<sup>3</sup> The origins of malaria in South America. Pesquisa Pesquisa Fapesp. Sao Paulo, no. 265, mar. 2018. Available at: <https://revistapPesquisa.fapesp.br/2018/03/20/as-origens-da-malaria-na-america-do-sul>. Accessed on: Oct 25 2019.



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

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