

## Brazil becomes the first malaria-endemic country to adopt single-dose tafenoquine and STANDARD G6PD Test for the treatment of relapsing *Plasmodium vivax* malaria

- Over 80% of the 139,021 malaria cases reported in Brazil in 2021 were caused by *P. vivax*.
- Handheld test and single-dose medicine will support Brazil's malaria elimination goal by improving patient adherence and ensuring patient safety.

**Brasília/Geneva/Seattle 07 June 2023.** Medicines for Malaria Venture (MMV) and PATH are excited to announce that Brazil has become the first malaria-endemic country to incorporate the STANDARD™ G6PD Test and single-dose tafenoquine<sup>a</sup> in the public health system for the treatment of *Plasmodium vivax* (*P. vivax*) malaria. These innovative new health technologies provide simple effective radical cure thereby preventing the debilitating relapse of *P. vivax* malaria.

"The Brazilian National Malaria Program is currently focused on malaria elimination, an ambitious goal for which innovation is key. The incorporation of this new treatment into the public health system will enable vivax malaria patients to access a safer and shorter treatment, that especially benefits the population living in remote areas of the Amazon region", Ethel Maciel, Ministry of Health's Secretary for Health Surveillance and Environment.

"We are thrilled by the Brazilian government's decision," said Dr. David Reddy, CEO of MMV. "Brazil played a key role in the efficacy and safety studies that led to the approval of single-dose tafenoquine for *P. vivax* relapse prevention, and the first real-world implementation of G6PD testing and tafenoquine. It is great to see the country leading the way with the assessment and adoption of these new health technologies."

"We are excited that this national adoption policy opens a new horizon to eliminate malaria in Brazil. National rollout of tafenoquine and the G6PD diagnostic test and their integration into patient treatment regimen can lead to healthier lives. We're grateful for all the contributions of the Ministry of Health, researchers, and the malaria workers in Amazonas and Rondônia that made this moment possible," said Kammerle Schneider, Chief Programs & Innovation Officer at PATH.

The decision to adopt the tools was based on a review of evidence by CONITEC, the Brazilian Commission of Technology Incorporation in the Public Health System, at the request of the Ministry of Health. This review included evidence on the safety and efficacy; results from the first and second interim analyses of TRuST—the largest real-world study on the use of single-dose tafenoquine and G6PD testing conducted in Brazil in 2021–2022; a qualitative study on patient and health worker perceptions of G6PD

---

<sup>a</sup> Brand name Kozenis. Trademark owned or licensed by GSK.

testing and single-dose tafenoquine linked to TRuST; a cost-effectiveness analysis and a budget impact analysis. TRuST was co-sponsored by the Brazilian Ministry of Health and MMV and led by Dr. Marcus Lacerda from Dr. Heitor Vieira Dourado Tropical Medicine Foundation (FMT-HVD) and Dr. Dhelio Pereira, Tropical Medicine Research Centre of Rondônia (CEPEM) in the municipalities of Manaus and Porto Velho.

*P. vivax* malaria is estimated to cause between 4.5 and 5.5 million clinical infections every year.<sup>1</sup> The clinical features of *P. vivax* malaria include fever, chills, vomiting, malaise, headache, muscle pain, and in some cases, can lead to severe malaria and death.<sup>2</sup> The disease has considerable economic and social impact, perpetuating cycles of poverty. One of the main challenges to malaria control in Brazil is poor treatment adherence, leading to relapses and continued transmission. Accessing remote populations, notably indigenous communities is another major challenge. The simplicity of these new tools will support Brazil's malaria elimination goal by improving treatment adherence.

## **About *P. vivax* malaria**

*P. vivax* malaria has a significant public health and economic impact, primarily in South Asia, Southeast Asia, Latin America, and the Horn of Africa. The *Plasmodium* parasite is a complex organism with a lifecycle spanning both humans and mosquitoes.<sup>3</sup> After an infected mosquito bite, the *P. vivax* parasite infects the blood and causes an acute malaria episode. It also has the ability to lie dormant in the liver (in a form known as hypnozoite), from where it periodically reactivates to cause relapses of *P. vivax* malaria. Hence, a single *P. vivax* infection can give rise to multiple episodes of malaria in the absence of a new mosquito bite. These relapses can occur weeks, months, or even years after the initial infection.

The complete treatment of *P. vivax* malaria (known as radical cure) requires the co-administration of a blood-stage antimalarial such as chloroquine and a medicine that targets the dormant liver form of the parasite.

## **About tafenoquine**

Tafenoquine, developed by GSK and MMV, was first approved by the US Food and Drug Administration for the radical cure (prevention of relapse) of *P. vivax* malaria in July 2018 for use in combination with chloroquine for adults and adolescents  $\geq 16$  years old. It was subsequently approved for this same population by regulators in Australia, Brazil, Thailand, Peru, Colombia, and the Philippines. It has been approved for children from 2 years and weighing at least 10 kg by the Australian Therapeutic Goods Administration (TGA), with additional approvals pending review in endemic countries.

Regulatory applications are being progressed in other malaria-endemic countries. All approvals are based on efficacy and safety data from a comprehensive global clinical development program for *P. vivax* radical cure, conducted in nine malaria-endemic countries, which supported an overall positive benefit-risk profile for the use of the product.

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

hemolytic anemia, during treatment with the 8-aminoquinoline class of drugs (such as tafenoquine and primaquine) and only patients with G6PD enzyme activity >70% of normal should receive tafenoquine.

## About the STANDARD G6PD Test

The STANDARD G6PD Test, manufactured by SD Biosensor, is a novel quantitative test for G6PD deficiency intended for use at the point of care. The test uses a handheld battery-operated analyzer that measures both G6PD activity and hemoglobin levels and provides a numeric measurement of G6PD activity normalized by hemoglobin (U/g Hb). This value can then be used in a semi-quantitative manner to classify individuals as G6PD deficient, intermediate, or normal according to thresholds provided by the manufacturer.

It is currently the only quantitative point-of-care G6PD test commercially available to support the introduction and use of tafenoquine and is distributed to over 30 countries.

The World Health Organization (WHO) recommends conducting a G6PD test prior to treatment with primaquine. Until recently the only reliable tests for G6PD deficiency have been limited to laboratory-based diagnostics that require significant expertise, time, and resources to run. The STANDARD G6PD test provides a health worker with a result in under 2 minutes, informing them as to whether a patient presenting with a *P. vivax* infection has sufficient G6PD activity in their red blood cells to be treated with an 8-aminoquinoline drug. The introduction of this test enables the use of tafenoquine, which is only indicated for use in patients with G6PD enzyme activity >70% of normal, in locations where people seek health care, including at primary health care facilities in remote locations such as the Brazilian Amazon.

## About TRuST

The Tafenoquine Roll-out Study (TRuST) was the first real-world, observational study to assess the feasibility of providing appropriate relapse-prevention treatment with tafenoquine or primaquine based on G6PD test results. It was launched in Brazil in September 2021. The study, co-sponsored by the Brazilian Ministry of Health and MMV, was led by Dr. Marcus Lacerda and Dr. Dhelio Pereira. Global Health Strategies (GHS) Brazil has played a pivotal role in supporting the TRuST team.

TRuST was rolled out in a phased manner. The first phase started in September 2021 and was conducted in nine higher- and medium-level health facilities in Manaus and Porto Velho, in the Amazon region.<sup>b,4</sup> In February 2022, the study expanded to 40 lower-level facilities in the same municipalities. Enrollment finished in August 2022, and in December 2022 a comprehensive dossier was submitted to CONITEC requesting the incorporation of single-dose tafenoquine and the STANDARD G6PD Test into the national health system (SUS).

## About PATH

PATH is a global organization that works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world's most pressing health challenges. Our team of innovators comprises more than 1,600 employees in offices in 21 countries. With expertise in science, health, economics, technology, advocacy, and dozens of other specialties, PATH

---

<sup>b</sup> An estimated 5% of the population in this region is G6PD-deficient.

# PRESS RELEASE



develops and scales solutions—including vaccines, drugs, devices, diagnostics, and innovative approaches to strengthening health systems worldwide. We work in more than 70 countries to transform bold ideas into sustainable solutions that improve health and wellbeing for all, reaching over 150 million people, on average, each year. For more information visit: <http://www.path.org>

## About Medicines for Malaria Venture (MMV)

MMV is a leading product development partnership 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 the 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 and product management interventions that aim to facilitate increased access to malaria medicines by vulnerable populations in disease-endemic countries and support their appropriate use.

MMV manages a portfolio of more than 65 antimalarial medicines, the largest ever assembled. With partners, they have brought forward 15 medicines that are treating patients. These medicines have saved more than 3 million lives. For more information, visit <http://www.mmv.org>

## About PAVE

PAVE is the Partnership for Vivax Elimination led by MMV and PATH bringing together national malaria programs, researchers, funders, and other organizations to eliminate *P. vivax* malaria.

PAVE supports countries in achieving their elimination goals through:

- working with national malaria programs to identify optimal radical cure tool options and strategies for their given contexts to achieve higher patient coverage.
- generating and making available high-quality evidence on *P. vivax* case management that can be considered by national governments in making policy decisions and guiding implementation.
- advancing the development of quality-assured medicines and diagnostics for *P. vivax*.

### Enquiries:

Elizabeth Poll	+41 79 907 59 92	(Geneva)
Katy Athersuch	+33 61 999 56 21	(Geneva)
Mariana Becerra	+1 2027660197	(Washington D.C)

# PRESS RELEASE



## References

1. World Health Organization (WHO). *World Malaria Report 2022*. Geneva; WHO; 2022.
2. Price RN et al. Vivax malaria: neglected and not benign. *Am J Trop Med Hyg*. 2007;77:79–87.
3. Lima Jr JC, Pratt -Riccio LR. Major Histocompatibility Complex and Malaria: Focus on Plasmodium vivax Infection. *Frontiers in Immunology*. 2016;7(13):1 -14.
4. Dombrowski JG et al. G6PD deficiency alleles in a malaria-endemic region in the Western Brazilian Amazon. *Malaria Journal* 16. 2017;253. <http://doi.org/10.1186/s12936-017-1889-6>.