PRESS RELEASE TAFENOQUINE APPROVED IN PERU

Perú becomes second malaria-endemic country in Latin America to approve single-dose tafenoquine for radical cure of *P. vivax* malaria

• Tafenoquine is the first drug approved for the radical cure (relapse prevention) of *P. vivax* malaria in more than 60 years.
• As a single dose, tafenoquine offers a much shorter treatment regimen compared to current standard of care, with the benefit of increasing patient compliance and helping to advance malaria elimination efforts.

Lima, January 2021. GSK and Medicines for Malaria Venture (MMV) announced that the General Directorate of Medicines, Supplies and Drugs (DIGEMID) has issued marketing authorization for single-dose tafenoquine for radical cure (prevention relapse) of *Plasmodium vivax (P. vivax)* malaria in patients 16 years of age or older receiving chloroquine for acute *P. vivax* infection (blood-stage). Peru becomes the second malaria endemic country in Latin America after Brazil to approve single dose tafenoquine for the prevention of relapse of *P. vivax* malaria.

As a single-dose treatment, tafenoquine facilitates compliance and thus overcomes one of the major limitations of the only other drug approved for the prevention of relapse of *P. vivax* malaria, primaquine, which needs to be taken for 7 days.

“The history of Peru and malaria are deeply entwined. In the nineteenth century, the famous writer Ricardo Palma, made malaria part of his narratives in the book Tradiciones Peruanas. In the same way, the cinchona tree, formerly known to be effective against malaria and from which quinine is derived, is part of the National Emblem”, said Dr José Sandoval, GSK Peru’s Medical Director.

Dr Sandoval also notes that "This treatment represents a great step in the fight against this disease and we are confident to have a new tool suitable for use in the population vulnerable to malaria in the Amazon region."

Dr David Reddy, CEO of MMV said, “Each episode of malaria prevents a child or an adult from functioning normally, and in susceptible individuals, the disease can potentially be fatal…. As a single-dose medicine, tafenoquine can increase patient adherence and help accelerate the journey towards malaria elimination in Peru."

Notes to editors

About tafenoquine

Tafenoquine medicine developed by GSK and MMV was first approved by the US Food and Drug Administration for the relapsing form of *P. vivax* malaria for use in adults and adolescents ≥16 years old who are receiving chloroquine therapy for acute *P. vivax* infection in July 2018. It was subsequently approved by regulators in Australia, Brazil and Thailand.

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, which supported an overall positive benefit–risk profile for the use of the product.

Tafenoquine should be co-administered with chloroquine to treat the blood and liver stages of acute P. vivax malaria infections. Before taking tafenoquine or primaquine, patients should be tested for deficiency of a specific enzyme known as glucose-6-phosphate dehydrogenase (G6PD), which helps protect red blood cells. Patients with a deficiency of the G6PD enzyme could have serious adverse reactions, such as haemolytic anaemia, during treatment with radical cure drugs.

PATH, a non-profit global health organization led a collaboration with diagnostics manufacturer SD Biosensor, with input from MMV and GSK, which resulted in provisional approval by the Expert Review Panel for Diagnostics (ERPD) of the first quantitative G6PD test at the point of care in July 2019.

About *P. vivax* malaria

P. vivax malaria accounts for around ~ 6.4 million clinical infections per year worldwide and has a significant impact on public health and the economy, mainly in South Asia, Southeast Asia, Horn of Africa and Latin America[1]. *P. vivax* is the predominant malaria parasite in Latin America, accounting for two-thirds of all cases. Peru is one of the Latin American countries with the highest burden of *P. vivax*[2] malaria.

In 2019, 19,227 confirmed cases of *P. vivax* were reported in Peru and, in 2020, 10,670 were registered (by the first week of November)[3]. In 2019, *P. vivax* was reported to be the cause of 79.3% of malaria cases in Peru[4]. *P. vivax* malaria is debilitating, particularly due to recurrent infections due to relapses, and has a 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 it can be fatal.

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1 World Health Organization. World malaria report 2020: https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2020. Accessed: Jan 21, 2021.
2 The origins of malaria in South America. Pesquisa Fapesp. Sao Paulo, no. 265, mar. 2018. Available in: https://revistapesquisa.fapesp.br/en/the-origins-of-malaria-in-south-america/. Accessed: Jan 21, 2021.
3 Centro Nacional de Epidemiología, Prevención y Control de Enfermedades: https://www.dge.gob.pe/epipublic/uploads/boletin/boletin_202045.pdf Accessed: Dic 04 2020.
4 MINSA. Análisis de Situación de Salud del Perú 2019: https://www.dge.gob.pe/portal/docs/asis/Asis_peru19.pdf Accessed: Jan 21, 2021.

The Plasmodium parasite is a complex organism with a lifecycle spanning both humans and mosquitoes. After an infected mosquito bite, the P. vivax parasite enters the blood and travels to the liver. It may emerge from the liver to cause an acute malaria episode or may lie dormant in the liver (in a form known as hypnozoite) from where it periodically reactivates to cause relapses of *P. vivax* malaria weeks, months or even years after the initial infection. 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 dormant liver forms of the parasite cannot be treated with most antimalarial treatments active against the blood-stage parasite.

The use of a medicine that targets the dormant liver forms of the *P. vivax* parasite, co-administered with currently available blood stage antimalarials such as chloroquine is known as radical cure. Up to recently, the 8-aminoquinoline primaquine, was the only medicine approved to target the dormant liver stage to prevent relapse [5]. However, primaquine's 7-14-day treatment regimen is often associated with poor compliance, resulting in reduced effectiveness [6].

About partners

Medicines for Malaria Venture (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.

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 2.2 million lives have been saved by these medicines.

MMV's success is based on its extensive network of around 150 active partners from the pharmaceutical industry, academia, and research and malaria programmes in malaria-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 ultimately help to eradicate this terrible disease. www.mmv.org

GSK is a global, science-led health care company with a special purpose: helping people do more, feel better, live longer. www.gsk.com.

5 Wells TNC et al. Targeting the hypnozoite reservoir of Plasmodium vivax: the hidden obstacle to malaria elimination. Trends Parasitol 2010; 26:145-151. Accessed: Jan 21, 2021.
6 Takeuchi R et al. Directly-observed therapy (DOT) for the radical 14-day primaquine treatment of malaria on the Thai-Myanmar border. Malar J 2010;9:308. Accessed: Jan 21, 2021.
Abreha A et al. Comparison of artemether-lumefantrine and chloroquine with and without primaquine for the treatment of Plasmodium vivax infection in Ethiopia: A randomized controlled trial. PLoS Med 2017;14:e1002299. Accessed: Jan 21, 2021
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This is a  contribution. For further information, consult your health specialist.

NP-PE-NA-PRSR-210001
January 2021