

FOR IMMEDIATE RELEASE

Brazil becomes the first malaria-endemic country to register single-dose tafenoquine for children with relapsing malaria

Geneva, 21 August 2023. Medicines for Malaria Venture (MMV) is pleased to announce that Anvisa, the National Regulatory Agency for Brazil, has approved the use of single-dose tafenoquine (Kozenis¹) in children aged 2 years and above in combination with chloroquine for the radical cure of *Plasmodium vivax* (*P. vivax*) malaria. Brazil is the first malaria endemic country to approve the use of tafenoquine for children. This represents a significant step forward in the fight against malaria: a single-dose treatment option could lead to more children being effectively protected against debilitating *P. vivax* malaria relapses.

The approval includes a novel, 50 mg tablet, co-developed by MMV and GSK, that allows for accurate, weight-based dosing and can be dispersed in water to facilitate use for children. The current standard of care for treating children with *P. vivax* malaria in Brazil requires a 7-day course of treatment with a drug called primaquine and at present, there are no quality-assured, age-specific paediatric formulations available. Ensuring that children complete the full 7-day course of treatment and receive the correct dose are difficult challenges for parents, caregivers and health workers. If the correct course of treatment is not completed it is less effective, and the child will remain vulnerable to repeated relapses.

In Brazil over 40% of *P. vivax* and mixed infections last year were in children and young people below the age of 20². Children are especially vulnerable to severe disease, recurrence, and anaemia which affects their growth and development. With today's approval, the door is open to extend this new treatment option to children from 2 years of age.

"MMV is proud to have co-developed single-dose tafenoquine with GSK, and we are thrilled to see the first malaria endemic country, Brazil, approve the use of this life-changing drug for children," said Dr. David Reddy, CEO of MMV. "This child-friendly treatment can help put a stop to relentless *P. vivax* malaria relapses which are particularly dangerous for children."

Brazil accounts for 27% of all malaria cases in the WHO Region of the Americas³. *P. vivax* is the dominant parasite species in the country, responsible for 83% of reported malaria case in 2021⁴. In June Brazil became the first malaria-endemic country to adopt tafenoquine into their National Health System for people aged 16 years and above. Tafenoquine represents a major breakthrough in the treatment of *P. vivax* malaria, as it is given in a single, convenient dose, making it easier for healthcare workers to administer and for patients to complete their treatment.

¹ Trademark owned or licensed by GSK.

² Cases reported through the National Surveillance System for Malaria (SIVEP-MALARIA) in 2022: 110,580 autochthonous cases of *P. vivax* and mixed infections; of which 44,838 (40,5%) in people under 20 years of age.

³ WHO, World Malaria Report (2022), 'three countries accounted for almost 80% of all estimated cases in the WHO Region of the Americas: Venezuela (Bolivarian Republic of) (34%), Brazil (27%) and Colombia (17%).'

<https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2022>

⁴ Annex 4 – I. 'Reported malaria cases by species, 2010-2021', WHO, World Malaria Report (2022), *ibid*.

MMV and GSK are committed to ensuring that tafenoquine is made available to the millions of children affected by *P. vivax* malaria worldwide and have filed regulatory submissions in several endemic countries, with further submissions planned.

About *P. vivax* malaria

P. vivax malaria has a significant public health and economic impact, primarily in South-Asia, South-East Asia, Latin America and the Horn of Africa. The *Plasmodium* parasite is a complex organism with a lifecycle spanning both humans and mosquitoes.⁵ 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 dormant liver forms of the parasite cannot be treated with most antimalarial treatments active against the blood-stage parasite. The co-administration of a blood-stage antimalarial such as chloroquine and a medicine that targets the dormant liver forms of the *P. vivax* parasite is known as radical cure.

About tafenoquine

Tafenoquine, co-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 ≥ 16 years old. It was subsequently approved for this same population by regulators in Australia, Brazil, Colombia, Ethiopia, Peru, the Philippines and Thailand. 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. The submission to TGA was supported by a Phase 2b clinical study (TEACH)⁶ that evaluated dosages of tafenoquine based on weight for children between the age of 2 years, and weighing at least 10 kg, and up to 15 years.

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 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 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 haemolytic anaemia, during treatment with the 8-aminoquinoline class of drugs (such as tafenoquine and

⁵ Lima Jr JC, Pratt -Riccio LR. Major Histocompatibility Complex and Malaria: Focus on Plasmodium vivax Infection. *Frontiers in Immunology* 2016; 7(13): 1 -14

⁶ Vélez ID, Hien TT, Green JA, et al. Tafenoquine exposure assessment, safety, and relapse prevention efficacy in children with Plasmodium vivax malaria: open-label, single-arm, non-comparative, multicentre, pharmacokinetic bridging, phase 2 trial. *The Lancet Child & Adolescent Health*, 2022. [https://doi.org/10.1016/S2352-4642\(21\)00328-X](https://doi.org/10.1016/S2352-4642(21)00328-X).

primaquine) and only patients with G6PD enzyme activity >70% of normal should receive tafenoquine.

About 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.

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.

MMV manages a portfolio of over 65 antimalarial medicines, the largest ever assembled. With partners, they have brought forward 15 medicines that are treating patients. These medicines have saved 13.6 million lives in absolute terms. For more information, visit <http://www.mmv.org>

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