Press release
For media and investors only

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First single-dose medicine for *P. vivax* malaria prequalified by WHO and included in WHO Guidelines

- Important steps to advance access to first single-dose malaria treatment, co-administered with chloroquine for radical cure, in endemic countries
- WHO prequalification and Guidelines for malaria include paediatric *tafenoquine*, responding to the disproportionate burden of relapsing malaria in children

GSK plc (LSE/NYSE: GSK) and Medicines for Malaria Venture (MMV) announced today that the World Health Organization (WHO) has awarded prequalification to *tafenoquine*, the first single-dose medicine for the prevention of relapse of *Plasmodium vivax* (*P. vivax*) malaria. *Tafenoquine*, co-administered with chloroquine, is now also included in WHO's updated Guidelines for malaria, in South America, marking the first time the medicine has been recommended by WHO. This milestone is a significant step toward closing the treatment gap for *P. vivax* malaria.

The WHO prequalification and updated guidelines include both adults and children aged 2 years and older, weighing at least 10 kg. A single-dose medicine provides an opportunity to overcome challenges with adherence to the existing longer, one-two week regimen of the standard of care, which can be a challenge for patients with relapsing malaria whose symptoms improve shortly after treatment initiation[1].

P. vivax is the dominant malaria parasite in most countries outside of sub-Saharan Africa, prevalent in most tropical and sub-tropical areas in the world, with children under five and migrant populations at particular risk. Among these vulnerable groups, infants and children carry a disproportionate burden, being highly vulnerable to severe disease, recurrence and anaemia[2]. The complex lifecycle of the *P. vivax* parasite includes a blood stage and an undetectable dormant liver stage, which can reactivate, causing repeated episodes of malaria following a single infectious bite of a mosquito carrying this parasite.

Thomas Breuer, Chief Global Health Officer, GSK, said: "WHO prequalification of *tafenoquine* opens new possibilities to positively impact and protect more lives; lives of children and vulnerable populations who continue to bear the burden of this devastating disease. Inclusion of *tafenoquine* in the updated Guidelines for malaria is an equally important step forward in efforts to eliminate this preventable and treatable disease. Making treatments simpler for people to take is an ambition of ours across much of our Global Health pipeline and portfolio. Alongside our partners, we remain committed to enabling affordable and equitable access to this new single-dose treatment option for those in need in malaria-endemic countries."

Martin Fitchet, Chief Executive Officer, MMV, said: "Today marks a historic milestone in the fight against malaria. The WHO's prequalification of *tafenoquine* and its inclusion in the updated Guidelines for malaria is a groundbreaking advancement on the road to elimination, which will transform lives by providing a well-tolerated, effective, and single-dose cure to prevent malaria relapses in some of the world's most vulnerable communities. This achievement is a testament to the power of innovation and collaboration in global health, to bring us closer to our vision of a malaria-free world."

Tafenoquine, an 8-aminoquinoline antimalarial drug targeting the liver-stage of *P. vivax* malaria, is recommended as an alternative to primaquine (3.5 mg/kg total dose) for preventing malaria relapses in children over the age of two in South America. A single dose of *tafenoquine* administered to *P. vivax* patients who receive chloroquine treatment provides what is known as radical cure: the treatment of both the blood- and liver-stages of the disease. *Tafenoquine*, like all 8-aminoquinolines, has the potential to cause haemolytic anaemia in people with glucose-6-

phosphate dehydrogenase (G6PD) deficiency, therefore G6PD testing must be performed before prescribing. This is possible with the 'STANDARD' G6PD test, developed in collaboration between SD Biosensor and PATH, which provides a measure of a patient's G6PD enzyme activity levels in two minutes based on a drop of blood from a finger-prick.

WHO prequalification of medicines is crucial as it ensures that the medicine meets standards of quality, safety and efficacy, and is suitable for the target population. The prequalification programme has played a vital role in improving the access to life-saving medications used by millions in low- and middle-income countries.

The WHO Guidelines for malaria are regularly reviewed and updated by the world's leading malaria experts under WHO's convening. This update includes a first recommendation for *tafenoquine* (150mg tablets and 50mg dispersible tablets) with chloroquine in South America.

WHO prequalification and Guideline inclusion follows the launch of *tafenoquine* in Brazil and Thailand in June this year. Approvals for *tafenoquine* have been granted in Australia, Brazil, Colombia, Ethiopia, Guyana, Myanmar, Pakistan, Peru, the Philippines, Thailand, Vietnam and the United States, and the drug is undergoing marketing authorisation evaluation in a number of other countries where *P. vivax* is endemic.

About *tafenoquine*
Tafenoquine is an 8-aminoquinoline with activity against all stages of the *P. vivax* lifecycle, including hypnozoites. It was first synthesised by scientists at the Walter Reed Army Institute of Research in 1978. GSK's legacy in the research and development of *tafenoquine* as a potential medicine for malaria commenced over 20 years ago. In 2008, GSK entered into a collaboration with the not-for-profit drug research partnership, MMV, to develop *tafenoquine* as an anti-relapse medicine for patients infected with *P. vivax*. The *tafenoquine* clinical programme is part of GSK's global health programme aimed at improving healthcare for vulnerable populations.

About Standard G6PD test
The STANDARD G6PD test was developed in collaboration between SD Biosensor and PATH. The handheld device provides a measure of a patient's G6PD enzyme activity levels in two minutes based on a drop of blood from a finger-prick. The Test has been approved by the Australian TGA, and by the Global Fund Expert Review Panel on Diagnostics (ERPD) and is distributed to over 30 countries.

Important safety information
Tafenoquine can cause haemolytic anaemia in patients with G6PD deficiency. The most common side effects are difficulty sleeping, headache, dizziness, nausea and vomiting. Allergic hypersensitivity reactions can occur after taking the drug. Please refer to the Consumer Medicine Information (CMI) summary for important dosage, administration, and safety information available at this link: kozenis-cmi-au.pdf (gsk.com)

About *Plasmodium vivax* malaria
The *Plasmodium* parasite is a complex organism with a lifecycle spanning both humans and mosquitoes. 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 readily treated with most anti-malarial treatments active against the blood-stage parasite. The current treatment (primaquine) for the dormant liver stage must be taken for 7 to 14 days to be effective, a regimen that is associated with poor compliance in unsupervised patients[3,4,5]. The use of a medicine that targets the dormant liver forms of the parasite, co-administered with a medicine to treat the blood stage, is known as radical cure.

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 disease is estimated to cause around 8.5 million clinical infections every year. The clinical features of *P. vivax* malaria include fever, chills, vomiting, malaise, headache and muscle pain, and in some cases, can lead to severe malaria and be fatal.

About GSK
GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

About Medicines for Malaria Venture
MMV is a Swiss-based not-for-profit organization working to deliver a portfolio of accessible medicines with the power to treat, prevent and eliminate malaria. Born in 1999, out of a need for greater health equity, we close critical gaps in research, development and access – working "end-to-end" to expand the use of existing antimalarials and innovate new compounds to protect public health. This starts with women and children.

It's working. As of 2023, MMV-supported products have effectively treated an estimated 680 million people and saved around 15.4 million lives. We cannot stop now.

With a quarter of a billion malaria cases and more than 600,000 deaths reported in 2022, progress towards disease elimination has stalled. MMV is part of an ecosystem of partners determined to change this. Bringing public and private sector partners together, we pioneer new solutions that align with local and global health priorities and promote the equitable development of effective and affordable products that work to help end malaria and advance health for all.

For more information, visit http://www.mmv.org.

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