GSK submits US regulatory application for single-dose tafenoquine for *Plasmodium vivax* malaria

- Regulatory milestone affirms GSK’s strong commitment and scientific capabilities to fighting infectious diseases

GSK and Medicines for Malaria Venture (MMV) today announced the submission of a new drug application (NDA) by GSK to the United States Food and Drug Administration (FDA), seeking approval of single-dose tafenoquine for the radical cure (prevention of relapse) of *Plasmodium vivax* (*P. vivax*) malaria in patients 16 years of age and older. If approved, tafenoquine would be the first new medicine for the prevention of relapse of *P. vivax* malaria in more than 60 years, potentially addressing the need for a single-dose and effective medicine for this debilitating disease.

The submission follows the decision made by FDA in December 2013 to grant tafenoquine Breakthrough Therapy Designation, an initiative aimed at expediting the development and review times of drugs for serious or life-threatening conditions. The NDA submission includes Phase III data from the previously reported GATHER and DETECTIVE studies conducted by GSK in partnership with MMV.¹

Pauline Williams, Head of Global Health R&D, GSK said: “This regulatory filing marks a significant and historical milestone in our global health efforts. Treating *Plasmodium vivax* malaria is particularly challenging because the parasite can lie dormant in the liver resulting in relapses. Poor compliance to primaquine in real-world settings can lead to higher relapse rates than those seen in the controlled setting of clinical trials, so a single dose treatment is an attractive proposition. GSK and MMV have been working together since 2008 to develop single-dose tafenoquine as an alternative to primaquine. If approved, tafenoquine will potentially become an important tool to help eliminate *P. vivax* malaria for good. We look forward to the outcome of the filing.”

David Reddy, CEO of Medicines for Malaria Venture said, “MMV and GSK are committed to the development of single-dose tafenoquine for relapsing malaria. Following a long-standing partnership, we have now reached the exciting milestone of regulatory filing. This is significant because without treatment to stop the relapses, infected patients live with the constant threat of malarial symptoms returning without warning. Relapsing malaria thereby contributes significantly to the burden of disease in affected countries. The world has been waiting over 60 years for a new medicine for this indication and a single dose medicine would be unprecedented.”

Tafenoquine is not approved for use anywhere in the world. GSK plans to progress regulatory filings in other countries in 2017 and 2018.

**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 has the ability to lie dormant in the
liver (known as a hypnozoite) and periodically reactivate causing 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 or even years after the initial infection.

*P. vivax* malaria has a significant public health and economic impact, primarily in South and South East Asia, Latin America and the horn of Africa. The disease is estimated to cause around 8.5 million clinical infections every year. Each of these infections keeps a child or adult from school or work for at least 3 days. Studies have shown that beyond lost time, malaria can also have adverse effects on cognitive ability.

**About tafenoquine**

Tafenoquine was first synthesised by scientists at the Walter Reed Army Institute of Research in 1978. GSK entered into a collaboration with MMV in 2008 to develop tafenoquine as an anti-relapse medicine for patients infected with *P. vivax*. It is an investigational 8-aminoquinoline derivative with activity against the *P. vivax* lifecycle, including hypnozoites.

**GSK’s commitment to malaria**

Malaria is one of the greatest global healthcare challenges of today. Whilst progress has been made in the fight against malaria this progress is fragile. At GSK, we want to help change this and maintain momentum. That’s why we will continue to make our expertise available and continue to collaborate with many different types of organisations across the world in a number of key areas including investing in research to help discover new medicines and vaccines for malaria, making treatments available to as many people who need them as possible, working in collaboration with communities to help build core skills through education helping improve local healthcare services and advocating in support of the global malaria community to ensure that there are sufficient resources to combat malaria.

GSK – a science-led global healthcare company with a special purpose: to help people to do more, feel better, live longer. For further information please visit [www.gsk.com](http://www.gsk.com).

**Medicines for Malaria Venture (MMV)** - 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, and brought forward seven new medicines that are already saving lives. MMV’s success is based on its extensive partnership network of over 400 pharmaceutical, academic and endemic-country partners in more than 55 countries.

MMV’s vision is a world in which innovative medicines will cure and protect the vulnerable and underserved populations at risk of malaria, and help to ultimately eradicate this terrible disease.

For more information visit [www.mmv.org](http://www.mmv.org)

**GSK enquiries:**

UK Media enquiries: Simon Steel +44 (0) 20 8047 5502 (London)

David Daley +44 (0) 20 8047 5502 (London)

US Media enquiries: Sarah Spencer +1 215 751 3335 (Philadelphia)

Evan Berland +1 215 751 5497 (Philadelphia)

Analyst/Investor enquiries: Sarah Elton-Farr +44 (0) 20 8047 5194 (London)

Tom Curry +1 215 751 5419 (Philadelphia)
PRESS RELEASE

Gary Davies +44 (0) 20 8047 5503 (London)
James Dodwell +44 (0) 20 8047 2406 (London)
Jeff McLaughlin +1 215 751 7002 (Philadelphia)

MMV enquiries:
Jaya Banerji +41 79 707 7181 (Geneva)
Elizabeth Poll +41 79 907 5992 (Geneva)

References

Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D ‘Principal risks and uncertainties’ in the company’s Annual Report on Form 20-F for 2016.