GSK submits regulatory application for single-dose tafenoquine for the treatment of *Plasmodium vivax* malaria to Australia’s Therapeutic Goods Administration

- GSK’s innovative science drives progress in developing medicines for infectious diseases

GSK and Medicines for Malaria Venture (MMV) today announced the submission of a regulatory application by GSK to the Australian Therapeutics Good Administration (TGA) seeking approval of single-dose tafenoquine treatment for the radical cure (prevention of relapse) of *Plasmodium vivax* (*P. vivax*) malaria.

Approval of tafenoquine by the TGA, who will act as the reference regulatory authority, will help facilitate registrations in countries where malaria is endemic. 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 TGA submission includes phase III data from the previously reported GATHER and DETECTIVE studies conducted by GSK in partnership with MMV. It follows the announcement of a submission to the US Food and Drug Administration in November 2017.

Pauline Williams, Head of Global Health R&D, GSK said: “*Plasmodium vivax* malaria has a significant impact on global public health and we want to help these vulnerable patient populations. This regulatory submission shows our continued commitment to lead the fight against malaria and our collaborative efforts with MMV to support the World Health Organization’s goal to end malaria for good. If tafenoquine is approved by Australia's Therapeutic Goods Administration, it will help pave the way for potential approvals in countries where malaria is endemic. The availability of this single-dose medicine could potentially revolutionise the treatment of this terrible disease and become an important tool in malaria eradication efforts.”

David Reddy, CEO of Medicines for Malaria Venture said: “MMV and GSK are committed to the development of single-dose tafenoquine for relapsing malaria. After many years of working in partnership we are delighted to now reach the exciting milestone of regulatory filing with the Australian Therapeutic Goods Administration (TGA). The world has been waiting over 60 years for a new medicine for this indication and a single dose medicine would be unprecedented. Submission to the TGA is particularly important given Australia’s recently announced Indo-Pacific Health Security Agenda that promotes malaria elimination, and improved regulatory processes in the region toward that goal. The burden of relapsing malaria falls heavily in the region, and Australia is taking leadership to end this scourge.”

Should it be approved for use, GSK and MMV are committed to making tafenoquine available at a not-for-profit price in malaria-endemic countries to enable wide patient access to those who need it most. Tafenoquine is not approved for use anywhere in the world. GSK plans to progress regulatory filings in other countries in 2018.

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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 can lie dormant in the liver (known as a hypnozoite) and periodically reactivate causing malaria relapses. 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 do more, feel better, live longer. For further information please visit 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 under-served populations at risk of malaria, and help to ultimately eradicate this terrible disease.

For more information visit www.mmv.org
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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.