PRESS RELEASE

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GSK and MMV announce start of phase III programme of tafenoquine for *Plasmodium vivax* malaria

GlaxoSmithKline (GSK) and Medicines for Malaria Venture (MMV) today announced the start of a phase III global programme to evaluate the efficacy and safety of tafenoquine, an investigational medicine which is being developed for the treatment and relapse prevention (radical cure) of *Plasmodium vivax* (*P. vivax*) malaria.

P. vivax malaria, a form of the disease caused by one of several species of *Plasmodium* parasites known to infect humans, occurs primarily in South and South East Asia, Latin America and the horn of Africa. Severe anaemia, malnutrition and respiratory distress are among the most serious consequences described to be caused by the infection.

The phase III programme includes two randomised, double-blind treatment studies to investigate tafenoquine in adult patients with *P. vivax* malaria. The "DETECTIVE" study (TAF112582) aims to evaluate the efficacy, safety and tolerability of tafenoquine as a radical cure for *P. vivax* malaria, co-administered with chloroquine, a blood stage anti-malarial treatment. The "GATHER" study (TAF116564) aims to assess the incidence of hemolysis and safety and efficacy of tafenoquine compared to primaquine, the only approved treatment currently available for the radical cure of *P. vivax* malaria.

Tafenoquine is not yet approved or licensed for use anywhere in the world.

"*P. vivax* malaria can affect people of all ages and is particularly insidious because it has the potential to remain dormant within the body in excess of a year, and causes some patients to experience repeated episodes of illness after the first mosquito bite," said Nicholas Cammack, Head, Tres Cantos Medicines Development Centre for Diseases of the Developing World. "Our investigation of tafenoquine for the treatment of *P. vivax* malaria is part of GSK's efforts to tackle the global burden of malaria. Working with our partners, including MMV, we are determined to stop malaria in all its forms."

"One of the big challenges we face in tackling malaria is to have new medicines to prevent relapse, caused by dormant forms of *P. vivax*, said Dr Timothy Wells, MMV's Chief Scientific Officer. "The phase III programme is designed to build upon the promising results of the phase IIb study which showed that treatment with tafenoquine prevented relapses. If successful, tafenoquine has the potential to become a major contributor to malaria elimination.[1] It's a great privilege to be working with GSK on this project; they have a clear commitment to changing the face of public health in the countries in which we are working."

About *P. vivax* malaria

P. vivax malaria is a neglected tropical disease and a major cause of uncomplicated acute malaria. It has a significant public health and economic impact primarily in South and South East Asia, Latin America and the horn of Africa, where the majority of the estimated 70-390 million annual clinical cases occur. The *P. vivax* parasite causes relapses from a dormant liver form established immediately after an infected mosquito bite. This dormant form leads to the reappearance of clinical malaria anywhere between a few weeks to several months, and sometimes in excess of a year, after the initial infection.

About Tafenoquine

Tafenoquine is an investigational 8-aminoquinoline derivative with activity against the *P. vivax* lifecycle, including the form that lies dormant in the liver. Tafenoquine was first discovered by scientists at the Walter Reed Army Institute of Research in 1978 and is being developed in collaboration with GSK and MMV. The clinical programme investigates a single dose of tafenoquine, as part of a 3-day treatment course with chloroquine, in patients with *P. vivax* malaria.

Tafenoquine was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) in December 2013. Breakthrough Therapy designation is the newest of the FDA's programmes aimed at accelerating the development and review times of drugs for serious or life-threatening conditions.

GSK – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

Medicines for Malaria Venture (MMV) is a leading product development partnership (PDP) in the field of antimalarial drug research and development working towards the vision of a malaria-free world. 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 has developed and brought to registration four new medicines with partners from over 300 pharmaceutical, academic and endemic-country partners in more than 50 countries. With its partners MMV manages the largest portfolio of antimalarial R&D projects ever assembled, encompassing over 65 projects.

MMV is grateful to its donors, including the Bill and Melinda Gates Foundation, the governments of Australia, Ireland, Switzerland, the United Kingdom, the United States of America, Norway and Japan, as well as the Wellcome Trust, the ExxonMobil Foundation and Newcrest Mining Ltd, whose support make this vital work possible.

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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 'Risk factors' in the company's Annual Report on Form 20-F for 2013.

References

1. Ric N Price, François Nosten. Single-dose radical cure of Plasmodium vivax: a step closer. *The Lancet* 2014; Volume 383, Issue 9922: 1020 - 1021. doi:10.1016/S0140-6736(13)62672-0.

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