

## PRESS RELEASE

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# GSK and MMV announce FDA Breakthrough Therapy designation for tafenoquine for *Plasmodium vivax* malaria

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GlaxoSmithKline (GSK) and Medicines for Malaria Venture (MMV) announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for tafenoquine, an investigational medicine for the treatment and relapse prevention of *Plasmodium vivax* malaria. Tafenoquine is not yet approved or licensed for use anywhere in the world. 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.

*P. vivax* malaria is a neglected tropical disease and a major cause of uncomplicated 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 and several months after the initial infection. There is a need to provide alternative treatments to manage *P. vivax* relapse with shorter treatment regimens.

The Breakthrough Therapy designation was granted based on the results from an international, multicentre, randomised Phase II clinical trial in more than 300 patients with uncomplicated *P. vivax* malaria. Headline results from this trial were presented at the American Society of Tropical Medicine and Hygiene Meeting in November 2013, and detailed results published in *The Lancet* in December 2013. Plans are underway to start a Phase III study in 2014.

### About Breakthrough Therapy Designation<sup>1</sup>

The Breakthrough Therapy designation was enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA). The goal is to expedite the development and regulatory review of designated drugs to treat serious or life-threatening medical conditions when the drug may have substantial improvement over available therapies. Breakthrough Therapy designation includes all the features of the Fast Track designation, as well as more intensive guidance from the FDA on a drug's clinical development programme.

### 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 causing relapse of infection weeks to months following the initial mosquito bite. Tafenoquine was first discovered by scientists at the Walter Reed Army Institute of Research in 1978 and is being developed in collaboration between GSK and MMV. Tafenoquine is being administered as a single dose during clinical trials in patients with *P. vivax* malaria.

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<sup>1</sup>U.S. FDA "Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review": [www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm#breakthrough](http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm#breakthrough)

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### Medicines for Malaria Venture (MMV)

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 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 and the United States of America, as well as the Wellcome Trust, the ExxonMobil Foundation and Newcrest Mining Ltd, whose support make this vital work possible.

### GSK enquiries:

UK Media enquiries:	David Mawdsley	+44 (0) 20 8047 5502	(London)
	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Stephen Rea	+1 215 751 4394	(Philadelphia)
	Melinda Stubbee	+1 919 483 2510	(North Carolina)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Sarah Alspach	+1 202 715 1048	(Washington, DC)
	Jennifer Armstrong	+1 215 751 5664	(Philadelphia)
Analyst/Investor enquiries:	Sally Jackson	+44 20 8047 5543	(London)
	Kirsty Collins (SRI & CG)	+44 20 8047 5534	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+ 44 (0) 20 8047 5503	(London)
	James Dodwell	+ 44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+ 1 215 751 7002	(Philadelphia)
	Ziba Shamsi	+ 44 (0) 20 8047 3289	(London)
	Lucy Singah	+44 (0) 20 8047 2248	(London)

### Medicines for Malaria Venture enquiries:

[Jaya Banerji](#)

Tel: +41 22 799 4071; Mob: +41 79 707 7181

**Cautionary statement regarding forward-looking statements**

## **PRESS RELEASE**

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. Factors that may affect GSK's operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

**Registered in England & Wales:**  
No. 3888792

**Registered Office:**  
980 Great West Road  
Brentford, Middlesex  
TW8 9GS