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Novartis and Medicines for Malaria Venture launch patient trial in Africa for KAF156, a novel compound against multidrug-resistant malaria

- *Compound has potential to be a game-changer in malaria elimination, rapidly clearing malaria infection, including resistant strains, and blocking parasite transmission*
- *KAF156 is first compound from the imidazolopiperazines, a novel class of antimalarials, to enter phase IIb combination studies*
- *Clinical trial has started early August in adults with malaria and is planned to expand to adolescents and children in a total of nine countries in Africa and Asia*

Basel and Geneva, August 21, 2017 – Novartis and Medicines for Malaria Venture (MMV) have launched a patient trial for KAF156, a next-generation antimalarial compound with the potential to treat drug-resistant strains of the malaria parasite. The trial will test the efficacy of KAF156 in combination with a new, improved formulation of the existing antimalarial lumefantrine. The first trial center is operational in Mali and will be followed by sixteen additional centers across a total of nine countries in Africa and Asia over the next few months.

“This new milestone underscores our company’s long-standing commitment to the fight against malaria,” said Vas Narasimhan, Global Head of Drug Development and Chief Medical Officer, Novartis. “With nearly half of the world’s population at risk, malaria continues to be a major public health challenge. Developing new antimalarial medicines is critical to achieving malaria elimination. Innovative science continues to be our best weapon against the disease.”

KAF156 belongs to a novel class of antimalarial compounds called imidazolopiperazines. It has the potential to clear malaria infection, including resistant strains, as well as to block the transmission of the malaria parasite. As demonstrated in a phase IIa proof-of-concept trial, the compound is fast-acting and potent across multiple stages of the parasite’s lifecycle, rapidly clearing both *P. falciparum* and *P. vivax* parasites.

Next-generation antimalarials are urgently needed to tackle rising parasite resistance to current therapies. Emergence of resistance to both artemisinin and many partner drugs has been reported in Asia¹ and reduced sensitivity to artemisinin has also been sporadically reported in Africa².

The phase IIb study will test multiple dosing combinations and dosing schedules of KAF156 and lumefantrine, including the feasibility of a single dose therapy in adults, adolescents and children. As children are the most vulnerable to malaria, the goal is to include them in the clinical trial as quickly as possible, following safety review of the data generated in adults, thereby potentially accelerating the development of a pediatric formulation.

“To build on the gains made against malaria since the turn of the century, we need new medicines that are effective across all types of resistance patterns and geographies, and that

are easy to administer, especially to children,” said Dr David Reddy, CEO of MMV. “With the phase IIb trial of KAF156-lumefantrine now underway, the MMV–Novartis partnership is drawing closer to the exciting prospect of such a new medicine that would be a powerful tool to fight the disease.”

It is important to test new drug candidates in the settings where they will be used. Conducted in state-of-the-art centers across Africa and Asia, the KAF156 trial is particularly complex given that multiple dosing combinations and dosing schedules are being tested in parallel in three different age groups.

“Malaria is a major public health concern in Mali – especially for children. Thus, the need for novel antimalarials is urgent,” said Dr. Bakary Fofana, clinical trial investigator at the Malaria Research and Training Center in Bougoula-Hameau. “Because it is a new compound with the potential to treat malaria including strains resistant to currently used antimalarials, we are particularly motivated to run the KAF156 patient trial at our site in Mali.”

KAF156 is the result of a Wellcome Trust, MMV and Singapore Economic Development Board supported joint research program with the Novartis Institute for Tropical Diseases, the Genomics Institute of the Novartis Research Foundation, and the Swiss Tropical and Public Health Institute.

Novartis is developing KAF156 with scientific and financial support from MMV (in collaboration with the Bill & Melinda Gates Foundation).

The partnership between MMV and Novartis builds on a long-standing successful collaboration in antimalarial drug development, which led to the launch in 2009 of the first high-quality artemisinin combination therapy for children. Since 2001, Novartis has delivered more than 300 million dispersible pediatric treatments without profit to malaria-endemic countries.

About the Novartis Malaria Initiative

The Novartis Malaria Initiative drives research, development and access to novel treatments to eliminate malaria. It is one of the pharmaceutical industry’s largest access-to-medicine programs. Since 2001, the initiative has delivered more than 800 million treatments without profit, mostly to the public sector of malaria-endemic countries.

The Novartis Malaria Initiative is integrated in Novartis Social Business, a unit which includes Novartis Access, SMS for Life and the Novartis Healthy Family programs.

For more information visit www.malaria.novartis.com

About 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 delivering 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 ultimately help to eradicate this terrible disease.

For more information visit www.mmv.org

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About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 119,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com>.

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References

1. <https://thedevelopmentset.com/the-unrelenting-specter-of-drug-resistant-malaria-da11f736c973>
2. <http://www.nejm.org/doi/pdf/10.1056/NEJMc1612765> or
<http://www.sciencedirect.com/science/article/pii/S1471492217300041?via%3Dihub>
3. <http://www.nejm.org/doi/full/10.1056/NEJMc1612765#t=article>

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Novartis Media Relations

Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Emma Stoetzel
Novartis Social Business
+41 61 324 1590 (direct)
+41 79 618 1290 (mobile)
emmanuelle.stoetzel@novartis.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Richard Pulik +1 212 830 2448
Cory Twining +1 212 830 2417

Medicines for Malaria Venture Communications

Jaya Banerji
T: +41 22 555 0327 (direct)
M: +41 79 707 71 81 (mobile)
banerjij@mmv.org