



Europe-Africa partnership spearheads development of next-generation antimalarial drug

- The European & Developing Countries Clinical Trials Partnership (EDCTP) grants €10 million over five years to “WANECAM 2” a unique collaboration between antimalarial drug researchers in Africa and Europe from ten academic institutions, a pharmaceutical company, Novartis, and a not-for-profit product development partnership (PDP), Medicines for Malaria Venture.
- The grant will support African trials of a novel antimalarial combination comprising KAF156 (ganaplacide) and lumefantrine in a new once-daily formulation. KAF156 has demonstrated the potential to treat resistant malaria and to be administered as a single dose.
- The grant will also help to build and strengthen research capabilities in the four participating African countries: Burkina Faso, Gabon, Mali and Niger.

Bamako, Mali / Basel, Switzerland, April 15, 2019. The European & Developing Countries Clinical Trials Partnership (EDCTP) has granted new funding of €10m over five years to support late-stage clinical trials of a next-generation antimalarial combination including KAF156 (ganaplacide). The trials will be conducted in four countries in West and Central Africa: Burkina Faso, Gabon, Mali and Niger.

Led by the WANECAM consortium (West African Network for Clinical Trials of Antimalarial Drugs), ten academic organisations¹ based in Africa and Europe will collaborate with the not-for-profit organization Medicines for Malaria Venture (MMV) and the pharmaceutical company Novartis to develop its compound KAF156 in combination with a new formulation of lumefantrine. The aim is to advance the development of a much-needed new antimalarial therapy while strengthening clinical trial development capabilities in Africa.

Global partnerships have made significant strides in malaria control over the past 20 years, yet the rate of progress has recently diminished². A recent survey of African malaria leaders³ showed high levels of concern around resistance to some of the current gold-standard treatments, artemisinin combination therapies (ACTs), in Asia, and the likelihood that it could spread to Africa, emphasizing the urgent need for novel, easy-to-administer antimalarial medicines.

¹ The full list of partners is attached as an appendix

² <https://www.who.int/malaria/publications/world-malaria-report-2018/en/>

³ <https://www.novartis.com/news/media-library/malaria-futures-for-africa-report>



The Principal Investigator, Professor Abdoulaye Djimdé of the **L'Université des Sciences, des Techniques et des Technologies de Bamako** and coordinator of the WANECAM group, said: “We welcome the generous support from EDCTP and are grateful for their long-term commitment to clinical development in Africa – and specifically supporting clinical research in critical diseases such as malaria. This backing is vital to accelerate the development of this much-needed new compound. African collaboration with a group of international experts on this programme can help ensure the trials are completed rapidly and to the highest quality standards. With reports about parasite resistance to artemisinins and ACTs, it is essential that we have new antimalarials ready and waiting.”

KAF156⁴, the new antimalarial compound that will be studied, holds the potential to be the first new chemical class of compound for the treatment of acute malaria in 20 years which in combination with the new formulation of lumefantrine could be administered as a single-dose treatment. The combination is currently in late-stage clinical trials across 17 centres in nine countries in Africa and Asia. It is being developed by Novartis with scientific and financial support from MMV (in collaboration with the Bill & Melinda Gates Foundation), and is one of seven late-stage antimalarials being developed by MMV partnerships. The EDCTP grant will fund two clinical trials for KAF156 in combination with a new formulation of lumefantrine which will include studying its effectiveness in children, the group most at risk of dying from malaria. If successful, data from these trials will support future submissions to register the medicine with regulatory authorities.

The EDCTP funding will also support efforts to strengthen clinical research infrastructure in Niger, as well as existing clinical research capacities at all other trial sites involved. These efforts will involve exchanging experiences and best practices between the sites and the European academic centres, as well as with Novartis and MMV.

Dr. Michael Makanga, EDCTP Executive Director, said: “We are delighted to broaden the coalition of organisations that EDCTP funds and partners to deliver our malaria strategy. By involving the private sector and a not-for-profit PDP, we have broadened our network of expertise. With all sectors working together, we can build stronger partnerships to defeat malaria.”

By 2017, malaria mortality had more than halved in sub-Saharan Africa compared to the turn of the century, due to better prevention, mainly via bednets, and improved treatment with ACTs. However, over 400,000 people died due to malaria-related causes that year, most of them young children under the age of five. The most recent 2018 World Malaria Report stated that progress in the fight against the disease is flattening for the second year in a row.

⁴ KAF156 (ganaplacide) 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.



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Notes to Editors

Details of trials to be funded

The EDCTP grant will fund two trials of KAF156 in combination with a new formulation of lumefantrine:

- One Phase 2B trial in 3 cohorts of children from 12 years down to 6 months of age – the youngest being the most at risk of dying from the disease
- One Phase 3 trial in adults and infants >0.5 years of age

Recruitment into the first trial is expected to start in early 2020.

Appendix - list of EDCTP-funded partner organizations, their websites and quotes.

	<p>Medicines for Malaria Venture, Geneva, Switzerland www.mmv.org</p>	<p>Dr David Reddy, CEO, MMV: “Malaria continues to kill an unacceptable number of people each year and the malaria community continues to seek innovative ways to tackle this burden. The new combination including KAF156 holds much promise as a potential next-generation antimalarial that could help simplify treatment and counter drug resistance. We welcome EDCTP’s critical support to put KAF156 to the test and determine if the compound can deliver on this promise.”</p>
	<p>Novartis, Basel, Switzerland www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/novartis-social-business/malaria-initiative</p>	<p>Dr David Hughes, Senior Global Program Head, Anti-infectives, Novartis: “We sincerely appreciate this far-sighted decision by EDCTP which enables us to work through an innovative public-private collaboration to drive forward both the development of KAF156 and further strengthen the capabilities of participating African sites to run high-quality clinical trials.”</p>
	<p>L'Université des Sciences, des Techniques et des Technologies de Bamako, Mali www.usttb.edu.ml/</p>	<p>Professor Alassane Dicko, MRTC/USTTB: “At the Malaria Research and Training Center, we remain committed to finding ways of preventing and treating malaria especially in Sub-Saharan Africa where 90% of burden of the disease is concentrated. MRTC is honored to coordinate this unique and important network of Public-Private partnership between African and European institutions and Novartis,</p>



		generously funded by EDCTP for the development of KAF156”.
	<p>Groupe de Recherche Action en Santé, Burkina Faso www.gras.bf</p>	<p>Dr Sodiomon B. Sirima, Scientific Director, GRAS: “As one of the pioneer private research institutions based in Africa, GRAS is proud and privileged to be part of this north-south initiative funded by EDCTP which aims to develop a promising new generation antimalarial drug”</p>
	<p>Karolinska Institutet, Stockholm, Sweden www.ki.se/en/mtc/centre-for-malaria-research-at-karolinska-institutet</p>	<p>Prof. Anders Björkman: “To us the WANECAM 2 project is a unique Africa/Europe research initiative/partnership to address one of the most alarming global health threats, drug resistant malaria”</p>
	<p>London School of Hygiene and Tropical Medicine, London, UK www.london.ac.uk/.../london-school-hygiene-tropical-medicine</p>	<p>Colin Sutherland, Professor of Parasitology, LSHTM: “There is nothing more urgent than the continued effort to bring new drugs for malaria into the clinics and pharmacies of Africa. We look forward to working with this brilliant network of scientists, clinicians and experts in drug development to test this important new formulation of KAF156 plus lumefantrine.”</p>
	<p>University of Lyon, Lyon, France www.icbms.fr</p>	<p>Professor Stephane Picot, Head of Malaria Research Unit: “Academic partners from non-endemic countries are highly dedicated to the training and support, with EDCTP, of the clinical trial activities of African key players in the fight against malaria within the WANECAM 1 & 2 projects. This new partnership is a step further toward a long lasting collaborative network.”</p>
	<p>Eberhard Karls Universität, Tübingen, Germany www.medizin.uni-tuebingen.de</p>	<p>Professor Steffen Borrmann, University of Tübingen: “We are delighted to be part of the WANECAM 2 consortium. The combination of KAF156 with lumefantrine has the potential to achieve a longstanding goal in infectious diseases research: a single-dose cure for multi-drug resistant malaria.”</p>
	<p>Abdou Moumouni University, Niamey, Niger</p>	<p>Mr Eric Adehossi, Abdou Moumouni University: “Malaria remains the leading cause of morbidity, mortality and school absenteeism in Niger. The current objective of the fight against malaria in Niger is to reverse trends in malaria incidence and to stop its transmission on the road to elimination by 2025. The fight against malaria passes by early detection of cases and the establishment of effective treatment. Parasite resistance to antimalarials makes the development of</p>



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		<p>new therapeutic combinations critical. The new combination including KAF156 could be an essential weapon to put into the therapeutic arsenal. This study will also enable us to integrate a research group and strengthen our capacity in clinical research”.</p>
	<p>Institut des Sciences et Techniques, Bobo-Dioulasso, Burkina Faso www.instech-bobo.bf</p>	<p>Professor Jean Bosco Ouedraogo, Institut des Sciences et Techniques, Bobo-Dioulasso, Burkina Faso: “The combination of KAF156 with lumefantrine is a promising drug for malaria control; this trial will help in improving the capacity of the WANECAM 2 African sites and reinforce the collaboration North-South and South-South.”</p>
	<p>Centre de Recherches Médicales de Lambaréné, Gabon www.cermel.org</p>	<p>Dr Ghyslain Mombo-Ngoma, CERMEL: “We at CERMEL are committed for the long term to strengthening the capacities in Central Africa and Gabon for the development of new and effective antimalarial drugs in the face of the threat of artemisinin resistance. The WANECAM 2 and the KAF156 trials are all important opportunities for both capacity building and the development of a newly promising antimalarial drug”</p>
	<p>University of Amsterdam, The Netherlands www.uva.nl/en</p>	<p>Professor Martin Grobusch, University of Amsterdam, The Netherlands: “The work ahead to be accomplished by the WANECAM 2 consortium will provide essential data furthering our knowledge of KAF156 as a potentially important novel compound reinforcing our antimalarials armamentarium.”</p>