

MEDIA UPDATE

Novartis and Medicines for Malaria Venture report positive results for Phase 2b study of novel ganaplacide/lumefantrine combination in children with malaria

- *Novartis and Medicines for Malaria Venture (MMV) report positive Phase 2b study results for novel non-artemisinin combination to treat uncomplicated malaria*
- *In the Phase 2b study conducted in children less than 12 years of age, ganaplacide/lumefantrine met the primary study objective*
- *The positive Phase 2b results for the next generation antimalarial therapy support continued development of the combination*

Basel, September 29, 2021 — As the threat of resistance to current malaria treatment grows, Novartis and MMV have reported positive results of a new non-artemisinin combination in a Phase 2b study.

The study tested ganaplacide, a novel agent with an entirely new mechanism of action, in combination with a new formulation of lumefantrine that is optimised for once daily dosing. This combination has the potential not only to clear malaria infection, including artemisinin resistant strains, but also to block the transmission of the malaria parasite.

This Phase 2b study was an open label randomized controlled study conducted in two parts and which enrolled more than 500 patients with acute uncomplicated malaria due to *Plasmodium falciparum* infection. After successful evaluation of the treatment in 349 patients older than 12 years in Part A of the study, Part B enrolled 175 patients under 12 years of age in seven countries that suffer from endemic malaria (Burkina Faso, Côte d'Ivoire, Gabon, Kenya, Mali, Uganda and India).

The ganaplacide/lumefantrine solid dispersion formulation combination met the primary objective in Part B of the study in children with acute uncomplicated malaria. The primary objective of adequate clinical and parasitological response (ACPR) at Day 29 with polymerase chain reaction (PCR) correction was considered to be met if the lower limit of the 2-sided 95% exact confidence interval for PCR corrected ACPR) rate was greater than 80%.

In children with acute uncomplicated malaria, response to treatment with ganaplacide/lumefantrine was similar to the rate observed in patients who received

artemether-lumefantrine control therapy. Ganaplacide/lumefantrine also demonstrated similar median parasite-clearing times compared to the control therapy. The combination of ganaplacide/lumefantrine solid dispersion formulation was generally well tolerated in the children.

“The world needs a diversified pipeline of anti-malarial medicines, especially as we are faced with emerging resistance to current treatments,” said Sujata Vaidyanathan, Head Global Health Development Unit, Novartis. “These results are definitely good news, but much more work remains. In a world where a child dies of malaria every two minutes¹, we must continue to accelerate the progress in the development of new tools to save lives.”

“This is a truly exciting step forward in the development of next-generation antimalarials,” said Dr David Reddy, CEO of MMV. “With this phase 2b data we remain cautiously optimistic that ganaplacide/lumefantrine could one day be saving the lives of those at greatest risk of malaria – young children. MMV is proud to have partnered with Novartis in this project right from the discovery of the compound through to its clinical development and look forward to the next steps. We congratulate Novartis for the timely completion of this study given the additional challenges posed by COVID-19, and also would particularly like to thank the investigators, caregivers, patients and their families.”

The study was led by Novartis with scientific and financial support from MMV and their donors. The ganaplacide/lumefantrine solid dispersion formulation is also included in the WANECAM2 consortium activities funded by the European & Developing Countries Clinical Trials Partnership (EDCTP) that supports capacity building in Africa.

These positive results support the future progression of the combination in patients with acute uncomplicated malaria.

The results are timely given the recent publication of a study in the *New England Journal of Medicine*² that found decreased sensitivity to artemisinin in Uganda, a year after the publication of similar research in Rwanda.

Plasmodium falciparum malaria is primarily treated with artemisinin combination therapies (ACTs) such as artemether-lumefantrine. ACTs are still highly effective and well tolerated. Novartis introduced the first fixed-dose combination ACT in 1999 and has since delivered more than 1 billion courses of antimalarial treatment, largely at no profit. However, the increased observation of parasites with a slower response to artemisinin in Africa points to an increasingly urgent need to develop a new non-artemisinin class of anti-malarials to avoid a return to the high levels of childhood mortality last seen in the 1990s.

Notes for editors

Ganaplacide, discovered at the Novartis Institute for Tropical Disease, is the result of a Wellcome Trust, Medicines for Malaria Venture and Singapore Economic Development Board supported joint research programme with the Novartis Institute for Tropical Diseases, the Genomics Institute of the Novartis Research Foundation, and the Swiss Tropical and Public Health Institute. The research program aimed to discover the next generation of antimalarial drugs.

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Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world’s top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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About MMV

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, have brought forward eleven new medicines and have assumed the access stewardship of a further two. An estimated 2.7 million lives have been saved by these MMV co-developed medicines. MMV's success is based on its extensive partnership network of around 150 active partners including from the pharmaceutical industry, academia and endemic 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.

MMV is grateful for the funding received from its donors that make this work possible: Australian Department of Foreign Affairs and Trade, Bill & Melinda Gates Foundation, European & Developing Countries Clinical Trials Partnership, German Federal Ministry of Education and Research, Global Health Innovative Technology Fund, Global Disease Eradication Fund Korea, Government of the Principality of Monaco, Irish Aid, Ministry of Foreign Affairs of the Netherlands, Newcrest, Research Investment for Global Health Technology Fund, Swiss Agency for Development and Cooperation, the UK Foreign Commonwealth & Development Office, Unitaid and USAID.

For more information, please visit <http://www.mmv.org>

References

¹ World Health Organization, World Malaria Report 2020. Available at: <https://www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2020>

² <https://www.nejm.org/doi/full/10.1056/NEJMoa2101746>

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