

PRESS RELEASE

Novartis malaria treatment Coartem® Baby receives WHO prequalification, paving way for greater access for newborns and young infants

- *Coartem® (artemether-lumefantrine) Baby is the first and only malaria treatment for newborns and young infants, closing long-standing treatment gap*
- *WHO prequalification key milestone for donor-funded and public sector purchasing by UN and other procurement agencies*
- *Novartis making treatment available on largely not-for-profit basis in areas where malaria is endemic*

Basel, April 24, 2026 – Novartis today announced that the World Health Organization (WHO) has prequalified Coartem® (artemether-lumefantrine) Baby, the first and only antimalarial developed specifically for newborns and young infants weighing from 2 to 5 kilograms. The decision is a key step towards enabling widespread access through public sector procurement. Coartem Baby is also known as Riamet® Baby in some countries and was developed in collaboration with Medicines for Malaria Venture (MMV).

“This new formulation of artemether-lumefantrine represents an innovation as there are no antimalarial medicines specifically developed for the treatment of uncomplicated malaria in children from 2 to 5 kilograms body weight,” said Dr Daniel Ngamije Madandi, Director, Malaria and Neglected Tropical Diseases at the WHO.

Prequalification is a process run by the WHO to assess the quality, safety and efficacy of treatments for diseases like malaria, HIV/AIDS and tuberculosis. Prequalification outputs, including lists of prequalified products, are used by United Nations and other procurement agencies to inform funding and purchasing decisions for the public sector.¹

Novartis is making the treatment available on largely not-for-profit basis in malaria-endemic regions.

“This decision takes us one step closer to ensuring that the tiniest babies have access to the first antimalarial designed specifically for them,” said Dr Lutz Hegemann, President of Global Health at Novartis. “We have already introduced the treatment in Ghana and are pleased to now be going further together with our partners to reach even more of the smallest malaria patients.”

Until recently, there has been no approved malaria treatment for infants weighing less than 4.5 kilograms, leaving a treatment gap. The smallest infants with malaria have instead been treated with formulations intended for use in older children, which may increase the risk of side effects and toxicity.

“As doctors we’ve tended to look for malaria in older children, but when newborn babies got sick nobody seemed to know what to do,” said Dr Emmanuel Aidoo, a pediatrician at Methodist Hospital in Ankaase, Ghana. “Having a new treatment tailor-made for infants that is well tolerated gives us confidence.”

Coartem Baby was developed by Novartis with the scientific and financial support of MMV, and as part of the [PAMAfrica consortium](#), which is co-funded by the [European & Developing Countries Clinical Trials Partnership](#) and the [Swedish International Development Cooperation Agency](#).

“For too long, newborns and young infants with malaria have fallen through the cracks because existing treatments were not designed with them in mind,” said Dr Martin Fitchet, CEO of MMV. “WHO prequalification of Coartem Baby is a major public health milestone and reflects MMV’s commitment to ensuring that even the smallest and most vulnerable patients are not left behind. This achievement shows what is possible when partners come together to translate scientific innovation into real-world impact.”

About malaria

Malaria is a life-threatening disease caused by a parasite and spread to humans by some types of mosquitoes. According to the most recent WHO data, there 282 million cases and 610,000 deaths in 2024 – roughly 9 million more cases than the previous year – almost all of them in Africa. Children under 5 years old accounted for about three in four malaria deaths in the region.² However, current data on malaria in the youngest babies is extremely limited as they are rarely included in clinical trials of antimalarial agents.^{3,4} Some 30 million babies are born in areas of malaria risk in Africa every year,⁵ with one large survey across West Africa reporting infections ranging between 3.4% and 18.4% in infants younger than 6 months old.⁶

About Novartis in malaria innovation

Novartis has built the industry’s largest pipeline of treatments to control or eliminate malaria and neglected tropical diseases,⁷ backed by more than USD 500 million in funding for global health R&D since 2021. This includes four new non-artemisinin antimalarial compounds with the potential to combat rising drug resistance. Novartis has delivered more than 1.1 billion treatment courses of its antimalarial Coartem since 1999, largely at no profit.

About MMV

MMV is a Swiss non-profit product development partnership. MMV works “end-to-end” to discover, develop and deliver affordable and accessible medicines to treat, prevent and eliminate malaria. Since 1999, over 1.3 billion people have benefited from MMV’s co-developed medicines. With malaria still killing 600,000 each year, MMV brings partners together to close the remaining gaps in antimalarial access and innovation.

For more information, visit www.mmv.org. Follow MMV on social media: [X](#), [LinkedIn](#), [YouTube](#) and [Facebook](#)

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efficiencies or opportunities expected from our external business opportunities; the development or adoption of new technologies, including artificial intelligence, and new business models; the implementation of our new IT projects and systems; potential significant breaches of information security or disruptions of our information technology systems; actual or potential legal proceedings, including regulatory actions or delays or government regulation related to the products and pipeline products described in this press release; safety, quality, data integrity, or manufacturing issues; major macroeconomic and geo- and socio-political developments, including the impact of any potential tariffs on our products or the impact of war in certain parts of the world; future global exchange rates; future demand for our products; and other risks and factors referred to in Novartis AG's most recently filed Form 20-F and in subsequent reports filed with, or furnished to, the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

About Novartis

Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 300 million people worldwide.

Reimagine medicine with us: Visit us at <https://www.novartis.com> and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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