

PRESS RELEASE

Novartis receives approval for first malaria medicine for newborn babies and young infants

- *Coartem® (artemether-lumefantrine) Baby becomes first malaria treatment approved for newborn babies and young infants*
- *Rapid approvals in eight African countries now expected under a special global health scheme run by Swiss agency for therapeutic products (Swissmedic)*
- *Novartis plans to introduce infant-friendly Coartem Baby on largely not-for-profit basis to increase access in areas where malaria is endemic*

Basel, July 8, 2025 – Novartis today announced Coartem® (artemether-lumefantrine) Baby has been approved by Swissmedic as the first malaria medicine for newborns and young infants. The new treatment, also known as Riamet® Baby in some countries, was developed in collaboration with Medicines for Malaria Venture (MMV) to treat the potentially deadly mosquito-borne disease.

Eight African countries also participated in the assessment and are now expected to issue rapid approvals under the Swiss agency's Marketing Authorization for Global Health Products procedure.¹ Novartis plans to introduce the infant-friendly treatment on a largely not-for-profit basis to increase access in areas where malaria is endemic.

"For more than three decades, we have stayed the course in the fight against malaria, working relentlessly to deliver scientific breakthroughs where they are needed most," said Vas Narasimhan, CEO of Novartis. "Together with our partners, we are proud to have gone further to develop the first clinically proven malaria treatment for newborns and young babies, ensuring even the smallest and most vulnerable can finally receive the care they deserve."

Until now, there has been no approved malaria treatment for infants weighing less than 4.5 kilograms, leaving a treatment gap. They have instead been treated with formulations intended for use in older children, which may increase the risk of overdose and toxicity. Malaria vaccines are also not approved for the youngest babies.²

Some 30 million babies are born in areas of malaria risk in Africa every year,³ with one large survey across West Africa reporting infections ranging between 3.4% and 18.4% in infants younger than 6 months old.⁴ However, current data on malaria in young babies is extremely limited as they are rarely included in clinical trials of antimalarial agents.^{5,6}

"The available malaria treatments have only been properly tested in children aged at least 6 months because smaller infants are usually excluded from treatment trials," said Professor Umberto D'Alessandro, Director of the MRC Unit, The Gambia at the London School of

Hygiene and Tropical Medicine. “That matters because neonates and young infants have immature liver function and metabolize some medicines differently, so the dose for older children may not be appropriate for small babies.”

The new dose strength designed for young infants 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](#). The treatment is dissolvable, including in breast milk, and has a sweet cherry flavor to make it easier to administer.

“Malaria is one of the world’s deadliest diseases, particularly among children. But with the right resources and focus, it can be eliminated,” said Martin Fitchet, CEO of MMV. “The approval of Coartem Baby provides a necessary medicine with an optimized dose to treat an otherwise neglected group of patients and offers a valuable addition to the antimalarial toolbox.”

About the CALINA study

The Swissmedic approval is based on the Phase II/III [CALINA](#) study, which investigated a new ratio and dose of Coartem (artemether-lumefantrine) to account for metabolic differences in babies under 5 kilograms. It is indicated for the treatment of infants and neonates weighing between 2 and less than 5 kilograms with acute, uncomplicated infections due to *Plasmodium falciparum* or mixed infections including *P. falciparum*. Coartem is known by the brand name Riamet in Switzerland and some other countries.

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 were 263 million cases of malaria and 597,000 deaths in 2023, almost all of them in Africa. Children under 5 years old accounted for about three in four malaria deaths in the region.⁷

About Novartis in malaria innovation

Novartis finds breakthroughs for diseases neglected by science and brings innovative medicines to communities on the margins of healthcare, building on 85 years of innovation in global health. Novartis has built the industry’s largest pipeline of treatments to control or eliminate malaria and neglected tropical diseases, backed by nearly USD 490 million in funding for global health R&D since 2021. This includes four new antimalarial compounds with the potential to combat rising drug resistance, one of which is just completing Phase III trials, and another which is a potential single-dose cure. Since 1999, Novartis has delivered more than 1.1 billion treatment courses of antimalarials, mostly at no profit, including 500 million treatments of a child-friendly formulation for babies weighing at least 5 kilograms.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions

or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with 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 contained in this press release 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 nearly 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](#).

About MMV

MMV is a Swiss not-for-profit working to deliver a portfolio of accessible medicines with the power to treat, prevent and eliminate malaria. Born in 1999 to drive health equity, MMV closes critical gaps in research, development and access – to expand the use of existing antimalarials and innovate new compounds. This starts with women and children. As of 2024, MMV-supported products have effectively treated more than 711 million patients.

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

References

1. Eight African countries participated in Swissmedic's [Marketing Authorization for Global Health Products \(MAGHP\) procedure](#) for Coartem Baby – Burkina Faso, Cote d'Ivoire, Kenya, Malawi, Mozambique, Nigeria, Tanzania and Uganda -- and are expected to approve the medicine following approval by Swissmedic. These eight countries account for 47% of estimated cases in 2023, according to the WHO's [Global Health Observatory](#)
2. WHO. [Malaria vaccines \(RTS,S and R21\)](#)
3. Reddy, Valentina et al. Global estimates of the number of pregnancies at risk of malaria from 2007 to 2020: a demographic study. The Lancet Global Health, Volume 11, Issue 1, e40 - e47
4. Ceesay SJ et al. Malaria Prevalence among Young Infants in Different Transmission Settings, Africa. Emerg Infect Dis. 2015 Jul;21(7):1114-21. doi: 10.3201/eid2107.142036. PMID: 26079062; PMCID: PMC4480393.
5. D'Alessandro U, et al. Malaria in infants aged less than six months - is it an area of unmet medical need? Malar J. 2012 Dec 2;11:400. doi: 10.1186/1475-2875-11-400. PMID: 23198986; PMCID: PMC3529680.
6. Dobbs, et al. Plasmodium malaria and antimalarial antibodies in the first year of life. *Parasitology*. 2016;143(2):129-138. doi:10.1017/S0031182015001626
7. WHO. [Malaria](#).

#

Novartis Media Relations

E-mail: media.relations@novartis.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com