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Dr Henning Gädeke
Global Health EDCTP3 Joint Undertaking
56 – 60 Avenue de la Toison d'Or
1060 Brussels
Belgium

28 August 2025

RE: Letter of endorsement in support of **MIRACLE 101248967-2** under the HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02-two-stage call: Global collaboration action for research on existing Malaria therapeutics and clinical development of new antimalarial candidates.

Dear Dr Gädeke,

On behalf of Novartis Pharma AG (Novartis), Lichtstrasse 35, CH-4056 Basel, Switzerland, and in accordance with Council Regulation (EU) No 2085/2021 of 19th November 2021 establishing the joint undertakings under Horizon Europe and specifically Article 9 therein, I hereby declare a commitment to participate as a consortium member and to provide a cash and in-kind contribution to Stage 2 application **MIRACLE 101248967-2 should** it be successfully evaluated .

Novartis is an innovative medicines company committed to reimagining medicine to improve and extend people's lives. Our work to deliver novel interventions against malaria is strongly aligned with GH EDCTP3 JU's vision to reduce the burden of poverty-related infectious diseases in sub-Saharan Africa.

Novartis has a long history and a strong track record in developing new antimalarial agents. Since 1999, we have delivered more than 1.1 billion treatment courses of our artemether + lumefantrine antimalarial, mostly at no profit. We continue to innovate in the treatment of malaria, backed by nearly USD 490 investment in global health R&D since 2021. Four new antimalarial candidates are in clinical trials, all with the potential to combat rising drug resistance. Our ability to deliver on our innovation is demonstrated by the recent approval, and upcoming launch, of **Coartem Baby**, a product developed for underserved infants with malaria. The Coartem Baby program was supported by **EDCTP via the PAMAfrica** Consortium. Underpinned by strategic partnerships across different sectors, Novartis is committed to bring innovative treatments to communities on the margins of healthcare through community health models.

Our consortium builds on EDCTP investments in previous consortium, PAMAFRICA. The focus of **MIRACLE** is on the execution of **Phase 2 and Phase 3 clinical trials to evaluate novel antimalarial candidates with the capability to deliver new treatment option**, with new mode of action, **for severe malaria**. The new treatment option for severe malaria has the potential to make a huge contribution to alleviating the burden of malaria and advancing the ultimate aim of malaria elimination. **Novartis will contribute to the project by providing the novel antimalarial drugs, executing a clinical development program**, ensuring that the program meets regulatory standards and contributing expertise to develop an access plan in addition to supporting capacity building. Novartis will particularly contribute to



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1. Conduct of Phase 2 and 3 clinical studies (WP3) to evaluate the novel antimalarials in scope of the proposal in collaboration with the consortium partners. In so doing, **Novartis will provide the i.v. drug product of two novel anti-malarial compounds, KAE609 and INE963, and will make the financial contribution outlined below to support trial operations.** Novartis will make a financial contribution within the scope of activities included in MIRACLE.
2. In addition, **Novartis will leverage its organizational expertise and scale to contribute to communication, dissemination and exploitation (WP6) in order to translate the research findings of the consortium into policy and practice, ultimately contributing to improved health outcomes for patients at risk of malaria.**

We estimate the total value of our cash contribution to be **€ 24 750 000** as detailed below.

Novartis Funding (€)	Description of Activities
19 500 000	Cash contribution: beneficiary subcontractors Clinical supply (drug product) Data management Training and QC Patient costs (e.g. clinical staff salaries, fees, outreach etc.) ECGs
5 250 000	Cash contribution: non-beneficiary sub-contractors Central laboratory, evaluation of PK
24 750 000	Total Novartis cash contribution

Novartis will also provide free-of-charge in kind support with respect to all tasks assigned to Novartis in the relevant Work Packages. These in-kind contributions include manufacture and supply of investigational medicinal product to clinical sites in the Phase 2/3 study/ies, operational and oversight activities with respect to the Novartis sponsored study/ies outlined in Work Package 3 and support for the dissemination of results and regulatory strategy as outlined in Work Package 6. The costs of these activities will not be calculated in accordance with Article 6 of the Horizon Europe Model Grant Agreement and are therefore not quantified as a contribution under Global Health EDCTP3 JU.

We confirm the following:

1. In the event that the MIRACLE grant is awarded, we will comply with the Horizon Europe Regulation (EU) No 2021/695; Council Regulation (EU) No 2085/2021 establishing the joint undertakings under Horizon Europe; the Model Grant Agreement for Horizon Europe and applicable Global Health EDCTP3 JU rules, including the relevant work programmes and in particular the call conditions therein.



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- 2. We will keep all confidential information received in the context of our involvement as contributing partner to the Global Health EDCTP3 JU confidential. This confidentiality obligation applies in particular but is not limited to the areas of Global Health EDCTP3 JU call topic preparation and publication, proposal submission and evaluation, and consortium formation. We further understand that this obligation strictly prohibits the release of confidential information to any legal entities save where specifically authorised by Global Health EDCTP3 JU. Internal dissemination of information within our organisation will be done on the basis of the “need-to-know” principle.
- 3. We are confident of our ability to fulfil the above commitments in the event that the MIRACLE grant is awarded and further confirm our understanding that the Global Health EDCTP3 JU will allocate resources to the above topic based on these commitments.
- 4. The value of our contribution to which costs are attributed in this letter will be based on costs calculated in accordance with Article 6 of the Horizon Europe Model Grant Agreement.
- 5. We accept that additional modalities regarding the provision of our contribution may be defined in subsequent agreements or documents, such as a funding agreement and topic text.

Yours faithfully,

Novartis Pharma AG Signed by: Signer Name: Caroline Boulton Signing Reason: I approve this document 29-Sep-2025 10:03:11 GMT Signing Time: 29-Sep-2025 09:03:07 GMT E933AF1B64D84AD298DDF33141024ACF Caroline Boulton Global Program Head	Novartis Pharma AG Signed by: Signer Name: Sabine Pfeffer Signing Reason: I approve this document 29-Sep-2025 10:41:43 GMT Signing Time: 29-Sep-2025 10:41:28 GMT B6D31A64938E48628763FBD345867097 Sabine Pfeffer Global Program Executive Director
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