



GlaxoSmithKline Investigación y Desarrollo, S.L.
Severo Ochoa 2
28760 Tres Cantos (Madrid)

Dr Henning Gädeke
c/o Dr Michael Makanga
Global Health EDCTP3 Joint Undertaking
56 – 60 Avenue de la Toison d’Or
1060 Brussels
Belgium

2nd September 2025

Letter of endorsement

Dear Sir,

On behalf of GlaxoSmithKline (GSK) Investigación y Desarrollo, S.L., with Registered Address Ochoa 2, 28760 Tres Cantos (Madrid, Spain), VAT number B83326389 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 submit an application to become a contributing partner to the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU).

GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together. We aim to positively impact the health of 2.5 billion people by the end of the decade, as a successful, growing company where people can thrive.

In Global Health, GSK focuses on tackling some of the world's most pressing health challenges by addressing diseases that disproportionately impact underserved populations in lower income countries. Through collaborations with global organizations, partnerships with governments, and support for health system strengthening, GSK advances access to essential medicines and vaccines for diseases such as malaria, tuberculosis, and HIV. The company also invests in innovative solutions to combat emerging health threats, ensuring a sustainable approach to improving health equity worldwide.

GSK, together with 9 partners, is submitting the CUREMAL proposal to the topic *HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02-two-stage: Global collaboration action for research on existing Malaria therapeutics and clinical development of new antimalarial candidates*. In this project, GSK will contribute its activities in-kind and is not claiming EDCTP3 funding. GSK Investigación y Desarrollo, S.L., representing GSK Global Health, is participating into the project as Beneficiary in the meaning of Article 8 of the Horizon Europe model grant agreement.



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CUREMAL's main objective is to evaluate the safety and efficacy of the new antimalarial GSK3772701 (GSK701) in combination with pyronaridine for treating children, adolescents and adults with uncomplicated *P. falciparum* malaria, in two sequential multicentre randomized clinical trials in sub-Saharan Africa malaria endemic regions, with trial-embedded qualitative evaluation of the acceptability of simplified antimalarial regimens. Results generated will be critical to support further studies (Phase 3) of this new treatment.

CUREMAL will conduct comprehensive genetic analyses to monitor established resistance markers and identify novel genetic variants potentially selected by drug treatments, (including GSK3772701 in monotherapy and combination, and standard of care (SoC) used as controls). Additionally, CUREMAL will assess the prevalence of known *Plasmodium falciparum* genetic variants linked to resistance against artemisinin and other standard antimalarial treatments by analysing the genetic profiles of parasites from clinical sites. This will contribute to antimicrobial resistance genomic surveillance efforts in Africa. The project includes a strong capacity building component on genetic surveillance of antimalarial resistance.

GSK will be the project coordinator, leading on legal, administrative, financial and ethics management. GSK will also sponsor the two proposed clinical studies, ensuring compliance with Good Clinical Practice (GCP) guidelines and regulatory requirements.

In addition to GSK's contributions outlined in the CUREMAL work plan, the company will progress the development of GSK701 throughout the project by planning and conducting clinical drug-drug interaction (DDI) studies. As an initial step, GSK will undertake a midazolam CYP3A4 clinical study to assess the potential risk of CYP3A4 induction by GSK3772701. Addressing this risk early in the development process will (a) enable recruitment of a broader patient population for subsequent studies and (b) reduce the risk associated with co-medications that are substrates of CYP3A4. Furthermore, GSK is evaluating the need for additional DDI studies, such as those involving oral contraceptives (OC), should the midazolam study reveal a moderate or strong interaction risk, in accordance with FDA guidelines.

We estimate the total value of performing the activities above to be 14.3M€ in-kind contributions, which represents 62,5% of the project budget. Together with MMV's in-contribution to this topic (0,15M€, described in a separate letter), CUREMAL's in-kind contributions correspond to 63,2% of the total project budget.

Additionally, GSK has supplied 40 kg of GSK701 API drug substance to support the demands of Phase 2 clinical trials. A new formulation, optimized for drug product administration at clinical sites, has already been developed and manufactured. This represents an extra contribution to the project, though it is not included in the in-kind figure mentioned above, as the associated costs were incurred prior to the project's start and are therefore not eligible under the established criteria.



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We confirm the following:

1. 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.
2. We will keep all 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 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 will be based on costs calculated in accordance with Article 6 of the Horizon Europe Model Grant Agreement.

Yours faithfully,

*Electronically signed by: F.
Javier Gamo
Reason: I am signing for
the reasons as stated in
the document.
Date: Sep 1, 2025
15:50:59 GMT+2*

F. Javier Gamo

Francisco Javier Gamo

Director, GSK Global Health Medicines R&D