



Global Health Innovative Technology Fund

E D C T P

EDCTP and Global Health Innovative Technology Fund partnership for the development of a paediatric formulation for schistosomiasis

The European & Developing Countries Clinical Trials Partnership (EDCTP) and The Global Health Innovative Technology Fund (GHIT) announced a new partnership today, 8 December 2017, to support product development research. The partners' first action will be co-funding the PZQ4PSAC phase III clinical study, which is sponsored by Merck KGaA and conducted by the Pediatric Praziquantel Consortium. This study will provide clinical data and support for registration of a new praziquantel (PZQ) tablet formulation to treat schistosomiasis in preschool-aged children (PSAC). EDCTP will be contributing €1,99M¹ and GHIT €3,22M² to the study consortium for a total project value of €12,10M including in-kind and cash contributions by all related parties.

"The joint investment in this project reflects the true value of global partnership with a noble goal of creating local solutions in disease endemic countries. Moreover, this pivotal study aims to generate valuable evidence and support for registration of a paediatric formulation for preschool-aged children against schistosomiasis, thus addressing a neglected population and disease - the EDCTP programme embraces populations often excluded from clinical studies but with major unmet medical needs.

Dr Michael Makanga, EDCTP Executive Director

GHIT is proud to support this important partnership that has, in a short time, made incredible strides toward developing a pediatric formulation of the gold standard medication for schistosomiasis—a disease that devastates millions of children in low and middle income countries around the world. This co-investment with EDTCP highlights our strategy to work in partnership to leverage our capital and accelerate R&D for global health with Japanese innovation.

Dr BT Slingsby, GHIT Fund CEO

Schistosomiasis is a highly prevalent parasitic disease in sub-Saharan Africa, which may cause disabling conditions such as anaemia, malnutrition, and impaired childhood development. Although an effective treatment—praziquantel tablets—is available, these are difficult for young children to swallow, have an unpleasant bitter taste, and cannot be administered by crushing the tablet. The Pediatric Praziquantel Consortium was established with the aim of developing, registering and making accessible a new paediatric orally disintegrating tablet praziquantel formulation. The study, titled "Phase III clinical trials and registration of a new praziquantel orally disintegrating tablet formulation suitable for preschool-aged children with schistosomiasis", has the following objectives:

¹ EDCTP is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.

² GHIT has already announced their funding for this clinical study in March 2017.

<https://www.ghitfund.org/about/mediacenter/pressdetail/detail/172>. Since 2014 GHIT has invested a total amount of ¥1,14B in the Pediatric Praziquantel Consortium (~ €8.63M)



EDCTP

- to conduct Phase III clinical trials in Kenya and Cote d'Ivoire to demonstrate the efficacy and safety of a single dose of PZQ orally disintegrating tablets in children age 3 months to 6 years infected with *Schistosoma mansoni* and *Schistosoma haematobium*;
- to establish the final commercial process for the Active Pharmaceutical Ingredient and the Drug Product at the respective final manufacturing sites;
- to prepare the core registration dossier for submission to EMA (Article 58) and WHO prequalification; and
- to foster awareness of the project and to further refine the Product Delivery & Access plan and seek its endorsement by key stakeholders.

EDCTP and GHIT are looking forward to future collaboration to co-fund research of mutual interest. EDCTP and GHIT share a common funding scope covering HIV/AIDS, malaria, tuberculosis and poverty-related infectious diseases.

About GHIT

The [GHIT](#) is a Japanese public-private partnership dedicated to facilitating international partnerships that bring Japanese innovation, investment and leadership to the global fight against infectious diseases and poverty in the developing world.

European Union

The European Union supports the EDCTP2 programme under Horizon 2020, its Framework Programme for Research and Innovation.

About EDCTP

The European & Developing Countries Clinical Trials Partnership ([EDCTP](#)) is a public-public partnership funding collaborative clinical research against poverty-related infectious diseases affecting sub-Saharan Africa.