

PRESS RELEASE

GHIT and EDCTP co-invest additional €7.8 million in the Pediatric Praziquantel Consortium's access program for treatment of schistosomiasis in preschool-aged children

- The Pediatric Praziquantel Consortium receives funding for the implementation of the [ADOPT](#) program, paving the way for the introduction of a child-friendly formulation to treat schistosomiasis in preschool-aged children.
- The ADOPT program prepares for large-scale delivery of the new pediatric medication across endemic countries, once registered.

25 February 2021, Utrecht, The Netherlands. The Pediatric Praziquantel Consortium, an international public-private partnership dedicated to the development of a pediatric formulation to treat schistosomiasis in preschool-aged children, today announced that it has been awarded additional funds of €2.1 million from the [Global Health Innovative Technology \(GHIT\)](#) Fund and €5.7 million from the [European & Developing Countries Clinical Trials Partnership \(EDCTP\)](#). Together with continued contributions from Consortium partners, the funding from GHIT and EDCTP will support the ADOPT program – an implementation research program to prepare for the large-scale access and delivery of the Consortium's novel pediatric medication in endemic countries.

Schistosomiasis is a highly prevalent parasitic disease in sub-Saharan Africa and one of the most damaging tropical diseases in terms of public health burden and economic impact. Praziquantel is the current 'standard of care' treatment. The drug is safe, effective, and available for adults and school-aged children. At present, this very vulnerable group of preschool-aged children has been left untreated in public health programs primarily due to the lack of an appropriate child-friendly formulation of the drug. The Consortium has bridged this treatment gap by developing a child-friendly tablet formulation of praziquantel. The tablet is orally dispersible and has improved taste properties. The project is in Phase III, with a pivotal trial being run in Kenya and Ivory Coast to generate confirmatory data for registration.

Through its ADOPT program, the Consortium aims to identify approaches to ensure wide acceptance and equitable access to its treatment for preschool-aged children suffering from schistosomiasis. The five-year program considers aspects ranging from technology transfers and logistics for local manufacturing and distribution of the drug, to social mobilization and acceptance by the population. To that end, the program will support studies in selected African countries, including Kenya and Ivory Coast.

“We are delighted that our funding proposals were favorably evaluated by both the GHIT Fund and EDCTP,” said Dr Jutta Reinhard-Rupp, Chair of the Pediatric Praziquantel Consortium Board and Head of the Global Health Institute at Merck. “There are an estimated 50 million preschool-aged children globally in need of treatment and it is our goal to help fill this treatment gap towards the elimination of this disease. The additional funding is indeed critical to confirm how best to reach very young patients.”

Commenting on their renewed investment in the Consortium, Ms Catherine Ohura, GHIT Fund CEO & Executive Director said: “We are very excited about our partnership with the Consortium since 2013 now entering into the final stage of the project. At GHIT, we believe medicines are invaluable with access and valueless without it. The ADOPT program will be a critical step in bridging R&D and access & delivery and will inform the World Health Organization (WHO)'s and country guidelines on how to have the most impact from this innovation.”

Dr Michael Makanga, Executive Director, EDCTP said: “Following our previous investment in the Consortium’s late-stage clinical development program, we felt it important to support the implementation of the access program. Indeed, successful development and access to a suitable pediatric treatment of schistosomiasis – through this global public-private partnership – will be a tangible contribution towards the Sustainable Development Goals by ensuring that the preschool-age group is not left behind.”

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For the media (not for publication)

For more information and interview requests, please contact Daniela Bonora, Project Communications Manager at Lygature, via: daniela.bonora@lygature.org or +31 6 48 40 13 04

Notes to Editors

1. About schistosomiasis

Schistosomiasis (also known as bilharzia) is one of the most prevalent parasitic diseases in sub-Saharan Africa, caused by parasitic flatworms called schistosomes. It affects almost 240 million people¹, mainly in communities without access to safe drinking water and with poor sanitation, with an estimated number of deaths of about 200,000² per year. The parasites live within freshwater snails and infect humans by penetrating the skin. The disease can lead to chronic inflammation of the organs, which can be fatal but also to anemia, stunted growth, and impaired learning ability with devastating consequences for the lives of the young children.

2. About the Pediatric Praziquantel Consortium

The Pediatric Praziquantel Consortium is an international not-for-profit partnership that aims to reduce the global disease burden of schistosomiasis by addressing the medical needs of infected preschool-age children. Its mission is to develop, register and provide access to a suitable pediatric praziquantel formulation for treating schistosomiasis in this age group. The pediatric formulation under investigation has been designed to be smaller, exhibit an improved palatability and be orally dispersible compared with the current commercial formulation. For more information, visit the Consortium website:

www.pediatricpraziquantelconsortium.org

3. Consortium Partners

- **Merck** (Germany) leads the clinical development program and provides expertise and support from different areas: preclinical, clinical, drug substance/drug product development and manufacturing, regulatory and access. Merck is the sponsor of the clinical trials. www.merckgroup.com
- **Astellas Pharma Inc.** (Japan) has developed the new pediatric PZQ formulations, and provides expert advice on clinical development in children, and pharmacokinetic modeling. www.astellas.com
- **The Swiss Tropical and Public Health Institute (Swiss TPH)** (Switzerland) is a world-leading institute in global health with a particular focus on low- and middle-income countries. Swiss TPH uniquely combines research, education and services at local, national and international level, and has extensive experience in helminths biological and pharmacological research; epidemiology; and clinical research in endemic regions. Besides its role in the clinical development program, Swiss TPH is co-leading the ADOPT program. www.swisstph.ch/en
- **Lygature** (The Netherlands), a not-for-profit foundation, acts as the independent coordinator of the Consortium, providing governance in terms of progress, finance and collaboration. Since 2006, Lygature has supported close to 100 public-private partnerships in the field of life sciences & health, including poverty-related diseases. www.lygature.org

¹ <http://www.who.int/schistosomiasis/disease/en/>

² <https://www.who.int/en/news-room/fact-sheets/detail/schistosomiasis>



- **Farmanguinhos** (Brazil), the federal governmental pharmaceutical laboratory of the Fiocruz Foundation in Brazil, brings unique expertise to producing and distributing the new pediatric formulation product in endemic countries. www.far.fiocruz.br
- **The SCI Foundation** (United Kingdom) is a non-profit organisation that works in partnership with Ministries of Health in sub-Saharan African countries supporting and facilitating sustainable public health programmes that reduce the impact of preventable diseases like schistosomiasis and soil-transmitted helminthiasis. SCI Foundation is co-leading the ADOPT program. www.schistosomiasiscontrolinitiative.org
- **Kenya Medical Research Institute** (Kenya) provides expertise on local disease epidemiology, clinical trials and clinical care and is responsible for conducting the clinical phase III trial in Kenya according to Good Clinical Practice and national and local regulatory and ethics standards. www.kemri.org
- **Université Félix Houphouët-Boigny** (Ivory Coast) was involved in the clinical phase II trial of the pediatric praziquantel formulation. It provides expertise on local disease epidemiology, clinical trials and clinical care and is responsible for the clinical phase III trial in Ivory Coast according to Good Clinical Practice and national and local regulatory and ethics standards. www.univ-fhb.edu.ci
- **Klinikum rechts der Isar der Technischen Universität München (TUM)** (Germany) represented by the Center for Global Health provides multidisciplinary expertise and partnership in the field of Neglected Tropical Diseases in several countries of the global South. www.tum.de

4. Acknowledgement of support

The Consortium is financially supported by Merck; in-kind contributions from the Consortium's partners; and grants from the Bill and Melinda Gates Foundation (2012), the Global Health Innovative Technology Fund (GHIT) (2013, 2014, 2016, 2019 & 2021), and the European & Developing Countries Clinical Trials Partnership (EDCTP), under its second program supported by the European Union (2018 & 2021).

5. The ADOPT program and funding

The ADOPT program stands for "Adoption of Levo-Praziquantel 150 mg for schistosomiasis by endemic countries". The additional investment of €2.1 million from GHIT will run for two years (2021-2023), while the investment of €5.7 million from EDCTP will run for five years (2021-2025).