

THE IMPACT OF SCHISTOSOMIASIS¹

One of the most prevalent parasitic diseases worldwide

More than 700 million people at risk

Approximately 250 million people require treatment

Transmission has been reported from close to 80 countries

Up to 200 thousand deaths per year

Many disabling complications

High infection rates in young children

No suitable treatment for about 50 million preschool-age children

1. WHO, Schistosomiasis Fact Sheet, 1 February 2023. <https://www.who.int/news-room/fact-sheets/detail/schistosomiasis>

FROM CONCEPT...

2012



PRE-CLINICAL PACKAGE COMPLETED
Rac-PZQ and L-PZQ ODTs
November 2013

FORMULATIONS AVAILABLE
Technology transfer from
Astellas to Farmanguinhos
& Merck
Completed in September 2014

**BILL & MELINDA GATES FOUNDATION
GRANTS \$1.15 MILLION**

THE NEW PEDIATRIC TREATMENT OPTION

Is a novel dispersible tablet
containing levopraziquantel
(L-PZQ), the biologically
active praziquantel (PZQ)
enantiomer.

The new 150 mg tablets are
small, allow precise dosing,
and have improved taste
properties for preschool-age
children.



**IMPROVED TASTE OF NEW
DISPERSIBLE CANDIDATES
CONFIRMED**
Swill-and-spit taste study in
Tanzanian children
Completed mid-2015

**PHARMACOKINETIC PROFILE
IDENTIFIED AND GOOD SAFETY IN
ADULT VOLUNTEERS**
Phase I studies in South Africa
Completed in March 2015

THE GHIT FUND GRANTS \$1.86 MILLION

CLINICAL DEVELOPMENT

2016

START DOSE-FINDING TRIAL
Phase II in Côte d'Ivoire

THE GHIT FUND GRANTS \$4.9 MILLION

EDCTP GRANTS \$5.7 MILLION

COMPLETION OF PHASE III TRIAL
in Côte d'Ivoire and Kenya (Nov 2021)

THE GHIT FUND GRANTS \$4.7 MILLION

THE GHIT FUND GRANTS \$2.1 MILLION

EDCTP GRANTS €1,99 MILLION

2018

REGISTRATION & IMPLEMENTATION

2022

**REGULATORY SUBMISSION
EUROPEAN MEDICINES AGENCY**
(EU-M4all procedure)

START CONFIRMATORY TRIAL
Phase III in Côte d'Ivoire and Kenya

**EUROPEAN MEDICINES
AGENCY POSITIVE OPINION**
(EU-M4all procedure)

THE GHIT FUND GRANTS \$4.1 MILLION

**WORLD HEALTH ORGANIZATION
(WHO) INCLUSION INTO LIST OF
PREQUALIFIED MEDICINES**

**L-PZQ FORMULATION AND
DOSE SELECTED**
Phase II in Côte d'Ivoire
Completed in 2018

FUNDING OPPORTUNITIES
Opportunity to invest, procurement
& implementation



2023

2024

... TO PATIENTS

Product available in
Sub-Saharan Africa on a
not-for-profit basis



2025