THE IMPACT OF SCHISTOSOMIASIS

- More than 700 million people at risk
- At least 258 million people require treatment
- Nearly half are school-age children
- 120 million people with morbidity
- Many chronically disabled children
- High infection rates in young children
- No suitable treatment for preschool-age children

Merck leads the program and provides expertise and support relating to PZQ, including internal resources from different areas needed for clinical development – drug product manufacturing; preclinical; clinical and regulatory. Also responsible for the development and manufacturing of the L-PZQ Active Pharmaceutical Ingredient (API).

Astellas Pharma Inc. (Japan) has developed the new pediatric PZQ formulations, and provides expert advice on clinical development in children, and pharmacokinetic modeling.

Swiss Tropical & Public Health Institute is a not-for-profit institute internationally renowned for its research, services, teaching and training in global health. It contributes with extensive experience in helminths biological and pharmacological research; epidemiology; and clinical research in endemic regions.

Lygature, a Dutch 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 a hundred public-private partnerships in the field of life sciences & health, including poverty-related diseases.

Farmanguinhos, the federal governmental pharmaceutical laboratory of the Fiocruz Foundation in Brazil, brings unique expertise to addressing the production and distribution of new pediatric formulations in endemic countries.

SimCYP, a UK-based research company, provides pharmacokinetics modeling capabilities and expertise.

The Schistosomiasis Control Initiative at Imperial College London, works to provide treatments against schistosomiasis and three soil-transmitted helminths to the rural poor in Sub-Saharan Africa and Yemen. SCI will facilitate preparation and implementation of the Access and Delivery plan.

www.pediatricpraziquantelconsortium.org
Schistosomiasis is one of the most prevalent parasitic diseases in Africa, and is a very important one in terms of public health burden and economic impact. Left untreated, this poverty-related disease can lead to anemia, stunted growth and impaired learning ability, and chronic inflammation of the organs, which can be fatal in the most serious cases.

As efforts focus on morbidity control and elimination, there is a pressing need to treat preschool children (under 6 years old). No suitable drug formulation is available for this high-risk group, which accounts for about 10% of the 258 million people already infected.

THE GOLD STANDARD

The existing gold standard treatment for schistosomiasis is praziquantel (PZQ), which was developed in the 1970s. This oral anthelmintic is available as a generic drug and currently donated through the Merck Praziquantel Donation Program, via the World Health Organization (WHO), to fight schistosomiasis in Africa. It is safe and effective, and a tablet formulation is available for adults and school-age children but not for those below 6 years old.

The Pediatric Praziquantel Consortium is developing a PZQ formulation that is more suitable for younger children, including infants and toddlers. The formulation should be smaller, orodispersible, and have improved taste properties compared to the approved PZQ Cesol® 600 mg tablet.

THE NEW PZQ FORMULATION CANDIDATES

The existing PZQ formulation is a racemic mixture of levopraziquantel (L-PZQ) and dextropraziquantel (D-PZQ). Only one of these components is pharmacologically active: the L-PZQ enantiomer. The other component, D-PZQ has been shown to be inactive and significantly contributes to the taste that makes treating young children difficult.

Two novel PZQ formulation candidates have been developed by the Consortium: a racemic mixture and an enantiopure version, both with improved taste properties. The new formulation candidates are a quarter of the size of the current approved PZQ Cesol® 600 mg tablet. Because they are orodispersible, they can be dispersed in water and administered to younger children, infants and toddlers. Both formulation candidates are in clinical testing. This allows the Consortium to select the final formulation, and to acquire the clinical data required for its registration in endemic countries where the medication is urgently needed.