



PRESS RELEASE

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Schistosomiasis Control Initiative and Pediatric Praziquantel Consortium join forces in the fight against schistosomiasis

Goal is to make a child-friendly treatment for schistosomiasis accessible to children under six years of age in endemic countries

Utrecht, The Netherlands, October 12, 2016 – UK-based Schistosomiasis Control Initiative (SCI), part of Imperial College London, is reinforcing the international non-profit Pediatric Praziquantel Consortium. The aim of the Consortium is to develop, register and make available a new child-friendly praziquantel formulation for the more than 25 million preschool-age children suffering from schistosomiasis, a parasitic disease endemic in most of Sub-Saharan Africa. This age group currently lacks a suitable treatment.

SCI, with their extensive expertise in working with Ministries of Health across sub-Saharan Africa for the control and potential elimination of schistosomiasis, will support the Consortium in preparing and implementing the Access and Delivery plan of the new pediatric formulation in endemic countries. Dr Elly Kourany Lefoll, Program Lead of the pediatric praziquantel development program and Head of Drug Development Neglected Tropical Diseases (NTDs) at Merck KGaA, Darmstadt, Germany, comments: “We are very pleased that SCI joins our Consortium. Over the last four years, we’ve made important progresses across the pediatric praziquantel development program, with a phase II clinical trial currently being conducted in Ivory Coast. This means that we are now testing the new formulation in schistosome-infected pre-school age children to identify the optimal dose.”

If not treated properly, schistosomiasis results in high morbidity, including anemia, stunted growth and reduced learning ability. In some cases, the disease can even be fatal. “As we are advancing in our development program,” Dr Kourany-Lefoll continues, “we have started to develop a plan to make the child-friendly praziquantel formulation accessible to children under six years of age in endemic countries. We are reaching out to access experts, and other key stakeholders, such as the World Health Organization (WHO) and governmental representatives from Sub-Saharan African countries to gain their input and support. SCI will play a crucial role in this endeavor.”

For SCI this partnership opens up different opportunities. SCI’s goal is to reduce the global disease burden of NTDs, including schistosomiasis, in sub-Saharan Africa by 2030 in accordance with the United Nations Sustainable Development Goals. Professor Fenwick, SCI’s founder and director, says, “We have been in contact with the Consortium for many years, and we look forward to this collaboration. We see the pediatric praziquantel formulation as a breakthrough in the battle against schistosomiasis in infected young children, a group lacking suitable treatment until now.” He adds, “Apart from creating awareness, changing perceptions and fostering global support for NTD Programmes, at SCI, we also put great emphasis on ensuring universal access to effective treatment for everyone who suffers from NTDs.”



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The know-how of SCI in deploying preventative and therapeutic tools and strategies to eliminate NTDs complements the existing scientific and regulatory expertise provided by the other six partners of the Consortium. Moreover, SCI has a broad network among policy makers such as the WHO, Ministries of Health, academic institutions, funders and other stakeholders which are key players in the implementation of an effective awareness and sensitization campaign in the coming years.

Schistosomiasis (also known as bilharzia) is one of the most prevalent parasitic diseases in Africa and a very important one in terms of public health burden and economic impact. It is a poverty-related disease that leads to chronic illness. The threat posed by schistosomiasis is substantial, with 78 affected countries, 700 million people at risk and an estimated 258 million people infected. More than 90% of patients live in Africa, where the disease affects a large proportion of children under the age of 14.

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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 need 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 to the current commercial formulation.

The Consortium was established in July 2012 by Merck KGaA, Darmstadt, Germany (Merck KGaA), Astellas Pharma Inc. (Astellas), Swiss Tropical and Public Health Institute (Swiss TPH) and Lygature (formerly TI Pharma). At the beginning of 2014, Farmanguinhos and Simcyp, a Certara company, joined the Consortium as full partners. The Schistosomiasis Control Initiative (SCI), part of Imperial College London, joined in 2016.

Merck KGaA, Darmstadt, Germany leads the program and brings expertise and support related to praziquantel, including resources from different areas (drug product manufacturing, pre-clinical, clinical, regulatory) needed for clinical development and to efficiently execute the project. Astellas contributes by providing its innovative pharmaceutical technologies in the area of pediatric drug formulation development as well as clinical development in children. Swiss TPH brings extensive experience in helminths biological and pharmacological research, epidemiology and clinical research in endemic regions. The governance is facilitated by Lygature, a Dutch non-profit organization and independent party with an extensive portfolio of international public-private partnerships in drug research and development, including in the area of neglected diseases. Farmanguinhos, the federal governmental pharmaceutical laboratory of the Fiocruz Foundation in Brazil, brings unique expertise to produce and distribute the new pediatric formulations product in endemic countries. Simcyp, a Certara company, brings expertise in pharmacokinetic modelling for better predicting the appropriate dosage for use in the pediatric clinical trials. SCI, part of Imperial College London, provides the necessary expertise to define and execute the access strategy and plan as well as to initiate and implement NTD control and elimination programs in Sub-Saharan Africa.

For more information, please visit www.pediatricpraziquantelconsortium.org



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About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients.

For more information, please visit our website at www.astellas.com/en

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2015, Merck KGaA, Darmstadt, Germany generated sales of € 12.85 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

For more information, please visit www.merckgroup.com

About Swiss TPH

The Swiss Tropical and Public Health Institute (Swiss TPH) is a leading institution in the field of global health. Its mandate is to contribute to improving the health of populations through excellence in research, health services and education & training. Swiss TPH focusses on key areas of activity in infectious and neglected diseases such as malaria or schistosomiasis, environmental risk factors, health system strengthening and epidemiology. Swiss TPH is associated institute of the University of Basel. Currently over 700 staff members from 62 nations are organized in two research, three service and one educational department.

For more information, please visit www.swisstph.ch

About Farmanguinhos

Farmanguinhos is a technical-scientific unit of the Oswaldo Cruz Foundation. Bearing in mind the mission of "Acting with environmental responsibility in promoting public health through the production of medicines, research, technological development and general diffusion of knowledge", this unit is the largest public pharmaceutical company under the Brazil's Ministry of Health and are produced medicines for the treatment of diabetes, hypertension, malaria, AIDS, tuberculosis, among others. Farmanguinhos also has an important role in meeting emergency demands of the Ministry of Health.

For more information, please visit www2.far.fiocruz.br/farmanguinhos/



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About Simcyp and Certara

Certara is a leading decision support technology and consulting organization committed to optimizing drug development and improving health outcomes. Certara's solutions, which span drug discovery through patient care, use the most scientifically-advanced modelling and simulation technologies and regulatory strategies to increase the probability of regulatory and commercial success. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions, and key regulatory agencies.

For more information, visit www.certara.com

About Schistosomiasis Control Initiative (SCI)

SCI works with governments to deliver effective school-based and community-based distributions of deworming tablets for schistosomiasis and soil-transmitted helminths, protecting children from these debilitating diseases and improving school attendance, all at a cost of US\$0.50 or less per child.

For more information, visit www.imperial.ac.uk/schistosomiasis-control-initiative

About Lygature

Lygature drives the development of new medical solutions for patients by managing public-private partnerships that bring together academia, industry and society. Every day we pioneer solutions in the areas of medical technology and pharmacotherapy to serve patients worldwide. Lygature is a not-for-profit organization based in the Netherlands. We build upon the legacy of the Center for Translational Molecular Medicine (CTMM) and Top Institute Pharma (TI Pharma).

For more information, visit www.lygature.org