

International Union Against Tuberculosis and Lung Disease



Health solutions for the poor

Technology, Research, Education, and Technical Assistance for Tuberculosis

PRESS RELEASE

CONTACT : Dr. I.D. Rusen, Project Director press@theunion.org (+1) 519 271 4078

CLINICAL TRIAL OF 9-MONTH REGIMEN FOR MDR-TB BEGINS IN AFRICA AND ASIA

22 May 2013, Paris, France – A clinical trial to assess a nine-month standardised treatment regimen for multidrug-resistant tuberculosis (MDR-TB) has begun in South Africa, Ethiopia and Vietnam. The trial is being conducted by **TREAT-TB**, an initiative managed by the **International Union Against Tuberculosis and Lung Disease (The Union)**, and will eventually involve 400 patients in Africa and Asia.

The regimen to be tested is modeled on one used in a non-randomised observational study in Bangladesh, which demonstrated excellent outcomes, including an 87% cure rate.

The UK Medical Research Council Clinical Trials Unit (MRC CTU) is the main partner working with The Union to implement STREAM, with the Institute of Tropical Medicine (ITM), Antwerp, Belgium providing laboratory support.

"Our trial is designed to determine whether comparable results can be achieved in different settings", says Dr I.D. Rusen, Project Director for TREAT TB. "The aim is to show that this shorter treatment regimen is at least as effective as the current lengthier treatments used throughout the world to treat MDR-TB".

Identifying improved regimens for MDR-TB is a public health priority, because of the steady increase in the number of cases, now estimated at 600,000 worldwide. MDR-TB is typically much harder to diagnose and treat than drug-susceptible TB and more frequently fatal; in addition, failure to treat the disease effectively has led to further mutations of *Mycobacterium tuberculosis* into extensively drug-resistant strains (XDR-TB), which are nearly incurable.

According to Dr Rusen, the outcomes of this clinical trial are expected to provide important evidence to inform MDR-TB treatment recommendations from global technical agencies, including the World Health Organization (WHO) and The Union, and national policy and guidelines for MDR-TB treatment in high-burden countries.

The TREAT TB clinical trial, which has been dubbed STREAM (Standardised Treatment Regimen of Anti-Tuberculosis Drugs for Patients with MDR-TB), began enrolling patients at King George V Hospital in Durban, South Africa in July 2012. Since then additional sites have been initiated for the trial, including Sizwe Tropical Diseases Hospital in Johannesburg, South Africa; St. Peter's Hospital; the Armauer Hansen Research Institute in Addis Ababa, Ethiopia; and Pham Ngoc Thach Hospital in Ho Chi Minh City, Viet Nam. As of 21 May 2013, 86 patients had already been enrolled into the trial. The participating countries were selected based on their disease burden, as well as other criteria, such as their ability to provide close supervision



of patients, the quality of their laboratory facilities and the support of their national tuberculosis programmes.

Patients treated with the STREAM regimen will receive moxifloxacin, clofazimine, ethambutol and pyrazinamide for nine months, supplemented by prothionamide, kanamycin and isoniazid during an intensive phase of four months. Once the full complement of patients has been enrolled, the trial is expected to run for two years, with results available in 2016.

Funding for TREAT TB (Technology, Research, Education and Technical Assistance for TB) is provided by the US Agency for International Development (USAID).

Additional Contacts

Dr I.D. Rusen, Project Director for TREAT TB, <u>irusen@theunion.org</u> Dr Sarah Meredith, Co-Principal Investigator for STREAM, <u>sm@ctu.mrc.ac.uk</u> Dr Francesca Conradie, Primary Investigator at Sizwe Hospital, <u>fconradie@witshealth.co.za</u>

About TREAT TB

Through funding support from USAID, The Union is managing an ambitious initiative called Technology, Research, Education and Technical Assistance for TB (TREAT TB). Through TREAT TB, The Union aims to build a successful research partnership model that has every potential to stimulate changes in international standards and practice in ways that serve country needs.

Since the initiative's launch in October 2008, TREAT TB has worked to contribute to new knowledge through field evaluations of diagnostic tools, clinical trials of priority research questions and targeted operational research benefitting global, regional and country TB control efforts. TREAT TB projects include the Standardised Treatment Regimen of Anti-TB Drugs for Patients with MDR-TB (STREAM) trial; the Policy Relevant Outcomes from Validating Evidence on ImpacT) PROVE IT studies; and the virtual implementation of new diagnostic tools project, among others. More information about these and other TREAT TB activities can found on the initiative's website here: http://treattb.org/

About The Union

The mission of the International Union Against Tuberculosis and Lung Disease (The Union) is to bring innovation, expertise, solutions and support to address health challenges in low- and middle-income populations. With nearly 15,000 members and subscribers from 152 countries, The Union has its headquarters in Paris and offices serving the Africa, Asia Pacific, Europe, Latin America, Middle East, North America and South-East Asia regions. Its scientific departments focus on tuberculosis and HIV, lung health and non-communicable diseases, tobacco control and research. For more information, please visit our website at www.theunion.org.

