

FOR IMMEDIATE RELEASE**STREAM CLINICAL STUDY FIRST TO INCLUDE BEDAQUILINE TO TEST
SHORTENED TREATMENT REGIMENS FOR MULTIDRUG-RESISTANT TB IN
PHASE III TRIAL**

Stage 2 of trial aims to reduce MDR-TB treatment from 24 months to 6 or 9 months

Paris, France | 13 April 2016 — Today, the International Union Against Tuberculosis and Lung Disease (The Union) and its affiliate Vital Strategies, announced that the STREAM Stage 2 clinical study has begun, with the first patients participating enrolled at a clinical trial site in Mongolia.

STREAM Stage 2 is based on a shared interest to evaluate simpler and shorter treatment regimens for patients with multidrug-resistant tuberculosis (MDR-TB). The current treatment standard for this airborne disease involves a complex regimen¹ that can last up to 24 months, and involves frequent and painful injections. This poses a significant burden both for patients and the health systems tasked with administering treatment.

This study will include bedaquiline, produced by Janssen Therapeutics, Division of Janssen Products, LP, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, as part of two additional experimental treatment arms. This is the first phase III clinical trial to test the effectiveness of bedaquiline within a shortened MDR-TB treatment regimen.

The Union, sponsors of the trial, and in collaboration with Janssen, amended the original STREAM study protocol to include an all-oral 9-month regimen and a 6-month regimen, both of which include bedaquiline. The trial's principal investigators are from the United Kingdom's Medical Research Council (MRC) and the collaboration is supported by the United States Agency for International Development (USAID).

STREAM is the first clinical trial of its kind in Mongolia and several other STREAM countries.

“We hope this study will mark a crucial turning point in the fight against drug-resistant TB,” said I.D. Rusen, Senior Vice President for Research and Development and Union lead for the STREAM Trial. “If successful, the results from Stage 2 will provide further evidence for adopting shorter and more simplified treatment regimens – an essential step in the worldwide effort to confront MDR-TB.”

“Standardised, simpler and shorter treatment regimens to address MDR-TB are critical if we are to achieve our goal of eliminating MDR-TB deaths,” said Wim Parys, M.D., Global Head of R&D, Global Public Health, Janssen. “The STREAM study represents our continuing research efforts in addressing this unmet need for patients with MDR-TB.”

Currently STREAM is in its first stage, having opened for recruitment in July 2012 with Stage 1 results expected in late 2017. Stage 1 does not include bedaquiline-containing arms. Building on the success of Stage 1, Stage 2 has started in Mongolia and will eventually enrol a total of 1,155 patients in at least 10 countries.

About The Union and Vital Strategies

Since its founding as a global scientific organisation in 1920, The Union has drawn from the best evidence and expertise to advance solutions to public health challenges affecting people living in poverty. The Union is currently progressing solutions for tuberculosis, HIV, tobacco-related diseases and other lung and non-communicable diseases. With close to 17,000 members and subscribers from 156 countries, The Union has its headquarters in Paris and 11 offices in Africa, the Asia Pacific, Europe, Latin America, North America and South-East Asia.

Vital Strategies, an affiliate of The Union, was formed from the joining of the Union North America and World Lung Foundation earlier this year. Vital Strategies combines evidence-based strategies with innovation to help build stronger health systems and workforces, develop sound public health policies, manage global programs, undertake epidemiology and research and design strategic communication campaigns for policy and behaviour change.

For more information, visit www.theunion.org and www.vitalstrategies.org.

About STREAM

The STREAM trial is a multi-centre international randomised controlled trial sponsored by The Union to evaluate standardised treatment regimens of anti-tuberculosis drugs for patients with MDR-TB.

STREAM Stage 2 has been approved to be the Phase III trial of bedaquiline, and is part of the post-approval commitment for bedaquiline from both the United States (U.S.) Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About bedaquiline

Bedaquiline, is a diarylquinoline antimycobacterial agent developed by Janssen for the treatment of MDR-TB as part of a combination therapy. Bedaquiline is registered in more than 40 countries (including US, all EU member states, South-Africa, India and Russia). It works by inhibiting adenosine 5'-triphosphate (ATP) synthase, an enzyme essential for the generation of energy in *Mycobacterium tuberculosis*.

About MDR-TB

In 2014, just over 6.3 million people were newly diagnosed with TB, and there were an estimated 480,000 new cases of MDR-TB¹, a particularly complicated form of TB characterised by resistance to at least two of the standard four-drug, anti-TB drug regimen.² MDR-TB is estimated to have killed 190,000 people worldwide in 2014¹, but one economic analysis projects that it could claim a further 2.6 million lives per year by 2050 if left unchecked.³

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