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Launch of biggest ever rheumatic heart disease patient programme

Global rheumatic heart disease patient programme launched at World Heart Federation's World Congress of Cardiology and Cardiovascular Health 2016 (WCC 2016)

Cardiovascular experts from South Africa and Canada have today announced plans to perform the largest ever global studies of patients with rheumatic heart disease (RHD), a disease which currently kills approximately 233,000 people¹ per year, despite being almost entirely preventable.

The INVICTUS programme builds upon the REMEDY project², which released the findings of a pilot study in 2014. The pilot study researched 3,343 RHD patients from 14 countries in Africa, India and the Yemen and concluded that RHD, the most common acquired heart disease in children in many countries of the world, was being neglected and poorly treated.

The global burden of RHD, which is caused by rheumatic fever after an untreated strep throat infection, currently falls disproportionately on children and young adults living in the developing world, especially where poverty is widespread, such as Sub-Saharan Africa, India and other parts of Asia.

The programme was announced at the World Congress of Cardiology and Cardiovascular Health, taking place $4^{th} - 7^{th}$ June in Mexico. Researchers from the University of Cape Town and the Population Health Research Institute at McMaster University in Canada, along with the World Heart Federation are now calling on cardiovascular experts from around the world to join the project. The worldwide programme consists of a registry of 20,000 patients and two clinical trials that will examine if rivaroxaban can safely reduce strokes in patients with RHD.*

Professor Bongani M Mayosi, Professor of Medicine and head of the Department of Medicine at Groote Schuur Hospital and University of Cape Town, and one of the lead investigators for INVICTUS commented: "RHD with atrial fibrillation is a major cause of stroke, disability and death in children and young adults living in developing countries. Warfarin is the only effective preventive drug at the moment, but is notoriously difficult to use effectively and safely in many parts of world. INVICTUS will provide definitive information on the effectiveness and safety of the oral Factor Xa inhibitor Xarelto® (rivaroxaban) which is much easier to use than warfarin and less likely to cause fatal bleeding complications. ³"

Professor Stuart Connolly from McMaster University in Canada, and the co-lead investigator commented: "The direct oral anticoagulants such as rivaroxaban have been shown in large clinical trials to be safe and effective in patients with non valvular atrial fibrillation in developed countries, but RHD patients were excluded from those trials.

"It is now time to show that RHD patients also can benefit from a drug like rivaroxaban in preventing strokes and other embolic events in patients with rheumatic valve disease."

¹ <u>http://www.world-heart-federation.org/heart-facts/fact-sheets/rheumatic-heart-disease/</u>

² European Heart Journal (2015) 36, 1115–1122 doi:10.1093/eurheartj/ehu449

³ Patel et al N Engl J Med 2011;365:883-91



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Professor Salim Yusuf, President of the World Heart Federation and Chairman of the Steering Committee of INVICTUS commented: "The launch of the RHD patient registry and trial programme on such a global scale forms a really key part of the international efforts underway to reduce RHD mortality rates and help meet the WHO 25x25 target. The registry of 20,000 patients from across all continents is ambitious but must be fulfilled if real progress is to be made and effective measures developed for those countries most affected to urgently put in place."

The INVICTUS programme is supported by a grant by Bayer AG and endorsed by the World Heart Federation.

For more information about the INVICTUS (<u>INvest</u><u>I</u>gation of rheumati<u>C</u> AF <u>T</u>reatment <u>U</u>sing vitamin K antagonists, rivaroxaban or aspirin <u>Studies</u>) trial, including how to participate, please contact: Bongani Mayosi on <u>bongani.mayosi@uct.ac.za</u> or <u>invictus@phri.ca</u>

ENDS

To sign up to receive press materials or for more information contact the WCC 2016 press office team at 00 44 (0)203 861 3820 / wcc2016@grayling.com. The UK press office will be open 9am – 6pm (British Summer Time) for the duration of the Congress. Alternatively please contact the named team members below:

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Notes to editors

INVICTUS

*The global INVICTUS programme comprises of a registry and two clinical trials. The registry will include 20,000 patients; additionally, with the two clinical trials it will be tested: First, in patients with rheumatic valvular atrial fibrillation or flutter (AF/flutter), whether rivaroxaban is non-inferior to vitamin K antagonists (VKAs) for prevention of stroke or systemic embolism (the Non-inferiority Trial). Second, in patients with RHD, either with AF/flutter but unsuitable for VKA therapy, or with sinus rhythm but with high risk, whether rivaroxaban is superior to aspirin for prevention of stroke or systemic embolism (the Superiority Trial).

About WCC 2016

The World Congress of Cardiology & Cardiovascular Health (WCC) 2016 is taking place in Mexico City, 4-7 June 2016. It is the official congress of the World Heart Federation and is held every two years. It is an international forum, showcasing experts from across the globe and convening the whole cardiovascular community to discuss and implement innovative solutions on heart health and the latest developments in cardiology. For more information about WCC 2016 including the scientific programme and abstract programme visit the website.



World Congress of Cardiology & Cardiovascular Health

Mexico City, Mexico

About the World Heart Federation

The World Heart Federation is dedicated to leading the global fight against cardiovascular disease (CVD), including heart disease and stroke. We are the only global advocacy and leadership organization bringing together the CVD community to drive the CVD agenda and help people live longer, better, more heart-healthy lives. Working with more than 200 member organizations in over 100 countries, we strive for a 25% reduction by 2025 in premature deaths from cardiovascular disease around the world. For more information, please visit: www.worldheart.org; www.facebook.com/worldheartfederation and twitter.com/worldheartfed