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Results from world-first clinical trial support early treatment for HIV

SYDNEY, AUSTRALIA (28 May 2015) – A major international HIV treatment trial co-ordinated by the Kirby Institute at UNSW in partnership with three other international research centres has been terminated ahead of schedule after interim results provided conclusive evidence that immediate treatment of HIV is clinically superior compared with deferred treatment among people with HIV infection and early disease.

Interim results of the Strategic Timing of AntiRetroviral Treatment (START) study have shown that there is significant benefit from initiating antiretroviral therapy (ART) before CD4+ T-cell counts (an important indicator of immune function) drop from the normal range (above 500 cells/mm^3) to 350 cells/mm^3. Current international guidelines generally recommend initiating treatment when CD4+ count is less than 500 cells/mm^3. Until now, there has been a lack of robust evidence to justify treatment at higher CD4+ counts.

The recommendation to stop the study was based on an interim analysis that showed the following:

- Risk of serious AIDS events, and deaths due to non-AIDS events including major cardiovascular events, renal and liver disease and cancer was reduced by more than 50% among those in the early treatment group compared to those in the deferred group.
- Reductions due to early treatment were seen in both serious AIDS and serious non-AIDS events; the effect of early treatment on AIDS was greater than non-AIDS events.
- Safety outcomes (e.g., serious adverse event) were similar in the two groups.
- Findings were consistent across a number of pre-specified subgroups, including

geographic region.

“These findings have global implications for the treatment of people living with HIV,” said Professor Sean Emery, co-ordinating investigator of the START study from the Kirby Institute at UNSW Australia. “As a result of this trial, we now know that treatment at all stages of disease extends survival and prevents serious disease complications in people with HIV infection. Together with data from previous studies showing reduced risk of HIV transmission among people on ART, these new findings support treatment for everyone with HIV,” said Professor Emery.

All study participants will be informed of these results and offered treatment if they are not already taking it. Participants will continue to be followed in the next stage of the study that is expected to conclude in late 2016.

“We would like to thank the thousands of HIV-positive participants in the study who have contributed to a finding that will impact treatment guidelines around the world,” said Professor Emery.

The START study was the first randomised clinical trial to examine the initiation of antiretroviral treatment for HIV-positive individuals with CD4+ cell counts greater than 500 cells/mm^3.

The study, which was carried out by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), enrolled 4,685 individuals who had never taken antiretroviral therapy with a CD4+ count in the normal range (above 500 cells/mm^3). One-half of the participants were randomised to initiate antiretroviral treatment immediately (early treatment) and one-half were randomised to receive treatment once their CD4+ count declined to 350 cells/mm^3. Participants were enrolled at 215 sites in 35 countries, including Australia.

Four international centres coordinated the work of sites in START:

- The Kirby Institute at UNSW Australia.
- The Medical Research Council (MRC) Clinical Trials Unit at University College London.
- The Copenhagen HIV Programme at the Rigshospitalet, University of Copenhagen in Denmark.

- The Veterans Affairs Medical Center affiliated with George Washington University in Washington, DC.

The University of Minnesota served as the statistical and data management centre and trial sponsor.

Funding for the START trial was provided by the National Institutes for Health (NIH), the National Health and Medical Research Council of Australia (NHMRC), and a number of government organisations based in Europe.

The HIV medicines used in the trial are approved medications donated by AbbVie, Inc., Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline/ViiV Healthcare, Janssen Scientific Affairs, LLC, and Merck Sharp and Dohme Corp.

For more information about the START trial, see the Questions and Answers or visit ClinicalTrials.gov using study identifier NCT00867048.

Media Requests:

Laurie Legere
Media and Communications Manager
The Kirby Institute, UNSW Australia
Llegere@kirby.unsw.edu.au
(02) 9385 9987