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TB trial carried out in South Africa finds new once-weekly treatment

Research carried out by the **Aurum Institute** in Johannesburg, and the **South African Tuberculosis Vaccine Initiative**, **Institute of Infectious Disease and Molecular Medicine** (University of Cape Town), has found an alternative way to treat tuberculosis with fewer tablets than today's recommended course of treatment. The novel drug combination makes it easier for patients to complete their course of treatment.

TB is a major health problem in South Africa. In 2012 there were 530,000 new cases of the disease, and 31,000 people died from it (excluding HIV deaths).

Most cases of TB are curable if treated effectively and promptly. The standard treatment is four drugs daily for two months followed by two drugs daily for four months –around 360 tablets over a six-month period.

The RIFAQUIN trial results show that a combination of the drugs Rifapentine and Moxifloxacin could reduce the number of tablets in a course of treatment to around 140 over the same six month period. Trial participants took Ethambutol, Moxifloxacin, Rifampicin, and Pyrazinamide daily during the first two months of treatment and then Rifapentine and Moxifloxacin once a week during the last four months.

The trial was carried out in Botswana, South Africa, Zambia and Zimbabwe, and led by St George's, University of London together with the Medical Research Council Clinical Trials Unit at UCL. A total of 827 people took part in the trial, 464 of whom were from South Africa.

The results showed 96 percent of patients taking the six-month Rifapentine and Moxifloxacin combination were cured, which was as good as the standard treatment. Study participants were assessed 12 months after they had finished their treatment.

Associate Professor Mark Hatherill, lead investigator for the trial in Cape Town, said:

"The burden of taking tablets is huge for TB patients. Consequently, even with the best will in the world, patients sometimes stop their treatment once they begin to feel better. Over a long period of time this has led to more drug resistant strains."

Dr Salome Charalambous, lead investigator for the trial in Johannesburg, said:

"Less tablets means there is a higher chance of the patient completing their treatment. It also makes it easier for clinics to supervise treatment. This is particularly important for

countries like South Africa, where clinics are very busy, and where it is not uncommon for patients to travel many miles to receive each treatment."

The drug combination could also be used in patients with drug resistant strains because it doesn't contain isoniazid, the drug that patients are most likely to be resistant to.

The trial was also designed to test whether the length of treatment could be reduced from six months to four months. The results showed that the combination of Rifapentine and Moxifloxacin after the first two months of treatment does not allow shortening of treatment from six to four months. Patients still need to take their treatment for six months, but the new once-weekly drug combination could make that easier.

SATVI Investigator, Doctor Hennie Geldenhuys, said that "A large and complex trial like this is challenging but it shows that important research such as this can be performed to high standards in the developing world. The results make it worth the hard work."

Research Nurse, Danelle Van As, said that "This study was very exciting because of the possibility that TB patients may take less tablets daily and that the time of treating TB could be shortened.

RIFAQUIN is a unique TB trial, as it investigated both shortening and simplifying treatment, and used higher doses of Rifapentine than other studies that have looked at shortening TB treatment using Fluroquinolones.

The findings, which were funded by the European and Developing Countries Clinical Trials Partnership, are published in the *New England Journal of Medicine Today* of 23 October 2014.

The researchers point out that a number of considerations need further investigation before health services could prescribe the once-weekly treatment combination. These include the cost effectiveness of the new regimen, and more data on the effectiveness of the proposed regimen in HIV-positive patients, who are particularly at risk of TB.

For further information, please contact:

Associate Professor Mark Hatherill

South African Tuberculosis Vaccine Initiative (SATVI) University of Cape Town

Tel: +27 21 406 6791 **Email:** **mark.hatherill@uct.ac.za**

Doctor Hennie Geldenhuys

South African Tuberculosis Vaccine Initiative (SATVI)

University of Cape Town

Tel: 023- 346 5400 Email: hennie.geldenhuys@uct.ac.za

FOR ASSISTANCE WITH MEDIA LIAISON:

Mr Kelvin Vollenhoven- Communications Manager

South African Tuberculosis Vaccine Initiative

Tel: 023-346 5400/021-406 6013 **Cell:** 074 585 2858