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First field-based molecular diagnostic test for African sleeping sickness in sight

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The Geneva-based not-for-profit foundation FIND and Japanese diagnostics company Eiken announced today that a next-generation molecular test designed specifically for sleeping sickness – a deadly parasitic disease also known as human African trypanosomiasis (HAT) - is ready to enter accelerated field trials in sites across the Democratic Republic of Congo and Uganda. If all goes well, the LAMP (Loop-mediated Isothermal Amplification) test - which has completed design and development phases - will be available for clinical use in 2012.

The announcement was made at the 31st biennial of the International Scientific Council for Trypanosomiasis Research and Control (ISCTRC), in Bamako, Mali.

Designed to be suitable for use in rural African settings where the disease is most common, the LAMP test promises to dramatically improve the ability to confirm a diagnosis of sleeping sickness - even when parasites are present in low numbers - through detection of the parasite's DNA in patient samples. FIND is also exploring LAMP's utility as a tool to confirm cure after treatment of HAT, which would significantly reduce the follow-up period, and could eliminate the need for repeated lumbar punctures.

If not diagnosed and treated early, sleeping sickness inexorably progresses to a stage where the parasites enter the brain, making treatment more difficult and the likelihood of irreversible neurological damage more likely.

"We are pleased to learn that FIND is accelerating its programme to bring molecular diagnostic tools to the field," said Dr. Jean Jannin, Coordinator in the World Health Organization's Control of Neglected Tropical Diseases Department. "The need for sensitive and specific tools - more user-friendly, stable and cheaper - is growing as we move closer towards the elimination of diseases such as sleeping sickness, in order to sustain an efficient surveillance system at the most peripheral level."

LAMP is a molecular diagnostic platform that detects pathogen DNA from patient samples with very high specificity and sensitivity. Unlike most other such tests, LAMP amplifies target DNA at a constant temperature, which means that it can be carried out with much less laboratory equipment than other molecular tests. The reagents for LAMP can be stored at room temperature, since they are dried down in the cup of the reaction tube. In addition, results can be detected by the naked eye, rather than with the complicated detection equipment required for more conventional methods.

"The LAMP test has tremendous public health potential. As a sophisticated yet practical diagnostic tool, it can be used outside of traditional laboratories by technicians without training in molecular biology and can be brought closer to the remote areas where patients live," said President and CEO of Eiken, Tetsuya Teramoto.

Sleeping sickness is a deadly, neglected tropical disease that affects impoverished rural communities in sub-Saharan Africa. It is transmitted by the bite of the tsetse fly and about 60 million people in 36 countries are thought to be at risk. There are no clinical signs that are characteristic of the disease, which makes it difficult to diagnose. If infected people are not treated, they eventually die. The diagnosis of sleeping sickness currently relies heavily on trained health workers using a screening test to identify suspects, and then using microscopes to detect parasites in the blood and other body fluids.

LAMP could also be used for the simultaneous analysis of large numbers of samples, and it has great potential for the diagnosis of animal trypanosomiasis, or nagana, which causes losses of more than $4.2 billion to African farmers every year.

"I am particularly delighted that this ground-breaking platform will be used to detect sleeping sickness," said Giorgio Roscigno, CEO of FIND. "As this new technology becomes more embedded in health systems in developing countries, we expect to see increased uptake of LAMP for other neglected tropical diseases as well."

FIND and Eiken have been working in partnership over the past six years to develop LAMP for a range of diseases, including TB, HAT and malaria. This is in line with FIND's focus on developing multi-purpose platform technologies that can be used by health workers to detect many diseases with a single instrument.

Acceleration of field testing of LAMP for human African trypanosomiasis paves the way for FIND and partners to collect the evidence necessary for the World Health Organization to make an informed judgment on the global policy implications of this new test.

"With the support of our partners and funders, FIND has already been able to bring 5 new diagnostic technologies through WHO approval," said Roscigno. "This is a testament to the power of uniting the public and private sectors to combat poverty-related diseases. Together, we are helping to bring the world one step closer to freedom from sleeping sickness, and other neglected tropical diseases."

Provided by FIND

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