MEDIA RELEASE

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Video available at: http://vimeo.com/100211905

SAMBA II offers on-the-spot HIV testing to millions living with HIV in Africa

Cambridge, UK and Melbourne, Australia

A new transformative point-of-care diagnostic which gives instant results for the detection of genetic material of the HIV virus is being rolled out across Africa.

The small, highly portable machine - known as SAMBA II - will help transform the lives of millions, especially HIV exposed infants who have a one in two chance of early death if HIV infection is not diagnosed within the first six weeks of life and if they are not immediately initiated on treatment.

Already available in Uganda and Malawi, SAMBA II has just received product approval in Kenya, making available for the first time rapid, accurate and cost-effective DNA point-of-care diagnosis in even the most environmentally challenging and resource-limited settings.
Developed by Diagnostics for the Real World, a spin-out company from the University of Cambridge, the new SAMBA II instrument and chemistry has been a decade in the making.

SAMBA II makes use of innovative technology to offer an effective sample-in-results-out test without the need for centralised laboratories or specialist technicians. It integrates the whole testing process within a single instrument using ready-made disposable cartridges. Easy to read results are obtained in less than two hours and indicated by a simple blue line similar to a pregnancy test.

Until now nucleic acid based HIV tests have taken many hours to perform and required specialist facilities and highly-trained personnel. The necessity of transporting samples over long distances to centralised laboratories creates numerous logistical problems including long delays. In the meantime, many patients may be lost before they can be initiated on treatment. By bringing rapid testing to the point-of-care, SAMBA II solves these difficulties.
Dr Helen Lee, Director of Research in the Department of Haematology at Cambridge University and CEO of Diagnostics for the Real World said, “The beauty of these tests is that they are simple, accurate and have a fast turn-around time.”

In addition to delivering accurate Early Infant Diagnosis from a small “pin-prick” blood sample, SAMBA II is also designed to measure the level of HIV in the blood. Often described as the “holy grail” of HIV diagnostics, rapid

decentralised testing of HIV genetic materials has proven elusive but is vital in early detection of resistance to treatment.

The development of SAMBA is a remarkable story of triumph over adversity and the pursuit of a single goal by a determined team of scientists and engineers. Speaking as SAMBA II machines were being prepared for their journey to Zimbabwe, Dr. Lee said: *"*Throughout the development of SAMBA we have maintained a purity of purpose, concentrating always on the problems of how to carry out a highly sophisticated test in a hostile environment of dust, high heat and humidity. More often than not, things were stacked against us, but we never gave up."

Finding organisations willing to support such a long-term project - particularly one uncompromisingly focused on resource-limited settings where profit could never be a reality - was essential to the project. The Wellcome Trust agreed to fund the early development of SAMBA chemistry, bridging the gap between fundamental research and the design of a fully operational assay. The project then received follow-on funding from the National Institutes of Health (NIH), the Children's Investment Fund Foundation (CIFF) and more recently, the UK Technology Strategy Board as well as UNITAID, a global health initiative which has invested to accelerate the product's market entry through supporting regulatory approvals and field studies in seven countries. Another vital partner is Médecins sans Frontières who provided access to their African sites for early SAMBA field-testing. Dr Elisabeth Szumillin, Advisor HIV Medical Department, Medecins Sans Frontieres (France) said: "The one-stop visit means that the patient can be tested close to home. Having results available immediately also helps us to simplify the treatment programme."

The Department of Health in Zimbabwe is currently undertaking a "task shifting" study involving 40 health care workers with varying levels of qualification to demonstrate that almost anyone can use SAMBA II. *"*A major feature of SAMBA II is that it is so easy to operate that anyone who can cook can do it.*"* Dr Lee explained.

Ted Bianco, Director of Innovations at the Wellcome Trust said: *"*There is an urgent need for high-quality and affordable HIV-diagnostic tests in developing countries, where currently available tests are neither affordable nor accessible. The SAMBA test is able to provide results quickly and on-site, thereby helping patients to get appropriate clinical support."

Peter McDermott, Executive Director of Health at CIFF said: "Since 2009, the number of children receiving HIV treatment has increased, but it still falls woefully short, with only 3 out of 10 eligible children having access. This is in part due to the lack of point of care testing. SAMBA II provides, for the first time, a transformational platform to address this critical barrier. To close the treatment gap, we therefore call for urgent and increased financing to support innovative point-of-care diagnostics like SAMBA and to address other critical issues such as loss to follow-up of children initiated but not then sustained on treatment."

Philippe Duneton, Executive Director of UNITAID said: “Accelerating access to new innovative technologies and increasing their affordability through stimulating competition between developers is an important part of our role in global health to help transform the management of disease.”

ENDS

Notes for editors

Dr Helen Lee, Peter McDermott and The Honorable Sarah Achieng Opendi (State Minister for Primary Care, Ministry of Health, Uganda) will be presenting SAMBA II at a press briefing at the IAS conference in Melbourne, Australia on 22 July at 12 noon local time.

Aspects of SAMBA II implementation in Uganda, Kenya and Zimbabwe will be also be presented on 20 July 2014 at a Symposium at the World Aids Conference 2014 in Melbourne. SAMBA II instruments can be seen at the Diagnostics for the Real World stand throughout the course of the Conference.

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About Diagnostics for the Real World

DIAGNOSTICS FOR THE REAL WORLD LTD [DRW], founded in 2002, is a spinout company based on breakthrough technologies developed at the University of Cambridge. DRW's mission is to provide rapid, simple, accurate and cost-effective diagnostic assays for resource-poor settings thereby enabling "test and treat" at the point-of-care. http://www.drw-ltd.com

About the Wellcome Trust

The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health, spending over£700

million each year on realising this ambition. We support bright minds in biomedical research and the medical humanities, including public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.
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