



Vivacta Initiates Development of Point of Care Test for Vitamin D

Demonstrates that small molecules can be rapidly measured in whole blood using its unique technology

Sittingbourne, Kent, UK, 9th February 2011 -- Vivacta Limited, the medical diagnostics company with a revolutionary system for point-of-care testing, announces it has initiated development of a new rapid diagnostic test for measuring Vitamin D. Diagnosis of Vitamin D deficiencies and regular monitoring of Vitamin D levels and obtaining results rapidly is potentially important in improving management of a range of diseases including osteoporosis, cystic fibrosis and Crohn's disease. The test will enable physicians to determine Vitamin D levels in a pin prick of patient's blood within 10 minutes potentially facilitating community-based diagnosis and therapy. The test is simple to perform and can be used in the physician's office, at a local clinic or other point of care away from the hospital laboratory. Ultimately the test could be performed by patients at home.

The new project demonstrates that the Vivacta system, which uses piezofilm technology to bring the advantages of immunoassays to the point of care, can be used to measure small molecules such as Vitamin D. Vivacta has also developed tests focused on the detection of large molecules, including a fully operational test for thyroid stimulating hormone (TSH) and is currently developing a cardiac test panel.

Immunoassays are very sensitive techniques for measuring small amounts of target substances (analytes) in biological samples. Such techniques must normally be carried out remote from the patient in specialised laboratories, often associated with hospitals, where samples must be sent. Vivacta's innovative piezofilm technology platform avoids the complexities of sample management and enables the development of near-patient diagnostic tests achieving the very high sensitivity and wide dynamic range, equivalent to immunoassays conducted in laboratories.

Dr Tim Carter, Chief Executive Officer of Vivacta and co-inventor of the piezofilm platform technology, said: "We are very pleased to have initiated this new programme which demonstrates the applicability of our technology to small molecules such as vitamins and drugs. A number of potential commercial partners have asked us whether our system can be used to monitor drug levels and we wanted to demonstrate this. We chose Vitamin D because of the significant interest in the medical community for enhanced surveillance of vitamin D levels in the general public and to meet the need of patients whose vitamin D levels require regular monitoring. However, vitamin D is only one example among a wide range of small molecules including many pharmaceuticals which can be monitored using our system".

Vitamin D is a fat-soluble vitamin and is normally absorbed from the intestine like a fat. Vitamin D tests are sometimes used to monitor individuals with diseases that interfere with fat absorption, such as cystic fibrosis and Crohn's disease and in osteoporosis (weak bones), and to ensure that the patients have adequate levels of vitamin D. Vitamin D monitoring is also used to track the effectiveness of treatment with vitamin D, calcium, phosphate, and/or magnesium supplementation.

Vivacta's innovative technology can be used to measure both small and large molecules and the goal ultimately is to measure a wide range of these molecules, as well as nucleic acids. Target applications include diagnosis of disease, companion diagnostics, therapeutic drug monitoring, vaccination status and therapeutic effectiveness monitoring such as the detection of anti-drug antibodies, as well as other personalised medicine applications.

Vivacta collaborates with healthcare companies to develop point of care diagnostics for these applications.

Vivacta's patented cartridge-plus-reader system is simple to use and cost effective.

The piezofilm diagnostic sensor is packaged within a small, self contained cartridge requiring no liquid reagents. The unique cartridge system minimises the amount of patient blood required and removes the need for red cell separation. Single and multiple assay cartridges and readers have been developed. The multiple assay system allows simultaneous testing of several different analytes or the same analyte more than once to further enhance dynamic range and sensitivity.

Cartridges are inserted by the user into a compact reader which provides data rapidly to users at the point of care and simultaneously to remote locations within decentralised healthcare networks. The system is designed to meet the criteria for CLIA waiver.

Vivacta has a validated product development and manufacturing process with a quality system certified to ISO 13485. Its pilot facility for manufacturing cartridges provides partners with a small-scale manufacturing and process development resource. Vivacta has established a strong, independent IP base with a portfolio comprising over 10 patent families.

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About Vivacta

Vivacta Limited is applying its expertise in piezofilm technology to develop a range of new generation high performance POC diagnostics able to deliver quantitative readings within 10 minutes from a single pin prick of blood.

The Company's platform technology exploits the piezoelectric effect by which thermal perturbations on a piezofilm surface cause an electric charge to be produced. The measurement of this electric charge enables monitoring of chemical activity – or rate of binding between antibody and analyte – in an assay. In harnessing this piezofilm platform technology, Vivacta has developed PoC diagnostic products able to produce and present sensitive, precise and fully quantitative results, equivalent to those produced in laboratories.

Vivacta has generated an independent intellectual property position of over 10 patent families protecting the use of piezofilms in diagnostic assays. Vivacta's investors include HBM BioVentures, IDInvest (formerly AGF), Spark Ventures and Viking.

For more information please visit www.vivacta.com

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