
Landmark VivoSight OCT clinical study published in British Journal of Dermatology

Results demonstrate clinical value of OCT in basal cell carcinoma diagnosis

Maidstone, UK, 29 April 2015 – Michelson Diagnostics, the UK-based medical device company focused on multi-beam Optical Coherence Tomography ('OCT') technology, today announces the publication on-line in the British Journal of Dermatology of the full results from an independent clinical study that demonstrates for the first time the clinical value of OCT in the diagnosis of basal cell carcinoma (BCC)¹. This observational, prospective, multi-centre study was conducted using the Company's VivoSight multi-beam OCT device.

This study highlights that using VivoSight OCT is an efficient, non-invasive way to diagnose BCC and has the potential to reduce avoidable biopsies and surgery, thereby reducing scarring for patients.

In summary, the data clearly show a significant increase in specificity (percentage that test negative when BCC is not present) to 75.3% ($p < 0.0001$) when using OCT in the diagnosis of BCC when compared to clinical assessment alone (specificity 28.6%). In the study, use of dermoscopy in addition to clinical evaluation resulted in an increase in specificity to only 54.3%. The diagnostic sensitivity (percentage that test positive when BCC is present) of clinical evaluation alone for BCC was found to be high (90.0%) and while there was a slight increase in sensitivity when using OCT or dermoscopy in addition to clinical evaluation, it did not reach statistical significance. Importantly, overall, the study showed a sizeable improvement in the accuracy of diagnosis of all lesions from 65.8% for clinical evaluation alone to 87.4% with VivoSight OCT (a secondary endpoint of the study).

VivoSight has CE/TGA regulatory-clearance and FDA 510(k) clearance in the United States and is available for sale in Europe, USA and Australia.

Dr. Martina Ulrich, joint lead investigator for the study, commented: "This study demonstrates the clinical value of multi-beam OCT in the diagnosis of BCC in a typical clinical setting. The results published today suggest that incorporating OCT in the evaluation of suspect lesions can lead to an increase in accuracy of diagnosis and is notable for the greatly improved diagnostic specificity that is achievable over clinical evaluation and dermoscopy."

Andy Hill, CEO of Michelson Diagnostics, added: "We believe that VivoSight, based on our proprietary multi-beam OCT technology, has the potential to become the gold standard for non-invasive diagnosis and monitoring of BCC and other conditions that affect cutaneous and epithelial linings of the body. BCC is the most common non-melanoma skin cancer in humans and affects an estimated 2.8m people in the US alone. The results of the study published today unequivocally show, for the first time, the clinical value of using OCT in the diagnosis of tumours such as BCC and can potentially limit the need for biopsy or surgery and thus subsequent scarring."

The full abstract of the paper can be accessed by following this weblink:

<http://onlinelibrary.wiley.com/doi/10.1111/bjd.13853/abstract>

For further information

Michelson Diagnostics

Andy Hill, Chief Executive Officer

Tel: +44 (0)20 8308 1695

FTI Consulting

Simon Conway / Mo Noonan / Victoria Foster Mitchell

Tel: +44 (0)20 3727 1000

Notes to editors

Study Summary: OCT-assisted diagnosis of BCC

The purpose of the study was to examine the use of OCT in a clinical setting for specificity, sensitive and diagnostic value when compared to clinical and dermoscopic evaluation. The study assessed 164 patients with 256 lesions in a prospective, multi-centre trial across six centres in Germany for the diagnosis of BCC. Patients with Pink lesions² which were clinically suspected of BCC and required a diagnostic biopsy were assessed using VivoSight OCT. Each result was compared with standard clinical evaluation with and without dermoscopy. All results were verified by the gold standard of biopsy and histological analysis. All lesions were examined clinically prior to the start of the trial and only those suspected of BCC were selected.

British Journal of Dermatology

The British Journal of Dermatology is one of the top dermatology journals in the world, and publishes papers on all aspects of the biology and pathology of the skin. Originally the Journal, founded in 1888, was devoted almost exclusively to the interests of the dermatologist in clinical practice. However, the rapid development, since the 1950s, of research on the physiology and experimental pathology of the skin has been reflected in the contents of the Journal, which now provides a vehicle for the publication of both experimental and clinical ethical research and serves equally the laboratory worker and the clinician. (<http://www.bad.org.uk/journal-information>)

Basal Cell Carcinoma

Basal Cell Carcinomas (BCCs) are abnormal, uncontrolled growths or lesions that arise in the skin's basal cells, which line the deepest layer of the epidermis (the outermost layer of the skin). BCCs often look like open sores, red patches, pink growths, shiny bumps, or scars and are usually caused by a combination of cumulative and intense, occasional sun exposure. In 2010, an estimated 2.8 million cases of BCC were diagnosed in the US, and the figures have continued to climb. BCC is the most frequently occurring form of all cancers. More than one out of every three new cancers is a skin cancer, and the vast majority are BCCs. (<http://www.skincancer.org/skin-cancer-information/basal-cell-carcinoma>)

About the VivoSight OCT System and Michelson Diagnostics

Michelson Diagnostics develops, manufactures and markets the VivoSight multi-beam Optical Coherence Tomography ('OCT') scanner; a point-of-care, real-time tissue imaging device. The patented technology, which has CE/TGA regulatory-clearance and FDA 510(k) clearance in the United States, provides clinicians with continuous images of the epidermis and superficial dermis of the skin that can be interpreted by a medical professional. Given the unprecedented image resolution and image quality, VivoSight OCT has many potential clinical applications beyond the initial focus in dermatology.

The Company's vision is for the VivoSight OCT system to become the standard-of-care for the non-invasive diagnosis and treatment monitoring of certain diseases and conditions that affect cutaneous and epithelial linings of the body. Michelson Diagnostics currently generates revenues from the first commercial application of VivoSight, in the diagnosis of non-melanoma skin cancer (NMSC).

VivoSight has regulatory clearance in Europe, the USA and Australia, for use by trained clinicians in their assessment of the patient's medical condition. VivoSight is currently sold in Germany where the scans are reimbursed for patients with private healthcare insurance. Further clinical studies are presently being conducted at leading centres in the United States.

The Company, based in Maidstone, Kent, was founded in 2006 and has 20 employees, and has offices in Germany and USA. It is supported by a syndicate of Venture Capital, corporate and private investors including funds managed by Octopus Investments, Smith and Nephew, Catapult Ventures and Angel Investors.

For more information about Michael Diagnostics and the VivoSight system, see www.michelsondiagnostics.com and www.vivosight.com.

Reference:

1. M. Ulrich, T. Maier, H. Kurzen, T. Dirschka, C. Kellner, E. Sattler, C. Berking, J. Welzel, U. Reinhold; The German Working Group of Diagnostic Methods in Dermatology, *Br J. Dermatol.* 2015 Apr 22. DOI: 10.1111/bjd.13853
2. Pink lesion are unclear erythematous papule or plaque lesions