



MDxHealth Epigenetic Marker as Companion Diagnostic for Irinotecan based Therapy in Colorectal Cancer

Data Presented at ASCO

IRVINE, CA, and LIEGE, BELGIUM – 8:00 AM, June 3, 2013 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment, today announced data showing that methylation of the Decoy Receptor 1 (DCR1) gene may help guide oncologists in selecting metastatic colorectal cancer (CRC) patients to receive irinotecan-based therapy. The data, presented on June 2nd at the 49th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, USA, showed that CRC patients with methylated DCR1 did not benefit from the addition of irinotecan to capecitabine therapy.

Identification of DCR1 as a novel hypermethylated gene associated with a lack of benefit in adding irinotecan to capecitabine when treating metastatic colorectal cancer was performed in the pathology department of Prof. Gerrit Meijer (VUmc, Amsterdam) as part of the CTMM public-private partnership DeCoDe (Decrease Colorectal Cancer Death) project. Commenting on the discovery, Prof. Gerrit Meijer said “As part of a concerted effort to reduce the enormous impact of colorectal cancer on patients and healthcare systems, all 14 partners in the DeCoDe project have worked tirelessly to identify novel biomarkers that will aid in the diagnosis and treatment of the disease.”

Prof. Wim Van Criekinge, CSO at MDxHealth added, “Predictive molecular biomarkers can help guide the selection of patients that are likely to respond to a given treatment, or in the case of DCR1, identify patients who are unlikely to respond to specific therapy, potentially sparing unnecessary toxicity and allowing treatment with more effective, alternative therapies earlier.”

“The innovative use of advanced bioinformatics, combined with several *Next Generation* molecular profiling methods, and integrated with pharmacological data is one the key missions of NXTGNT and enables the highly efficient identification of specific predictive biomarkers, such as DCR1,” stated Prof. Dieter Deforce, Head of the Laboratory of Pharmaceutical Biotechnology at NXTGNT Center in Pharmaco (Epi)genomics, a joint collaboration between MDxHealth and the Ghent University.

Study Details

The presence of DNA methylation for a selected panel of 22 genes was assessed on primary tumors of 185 patients with metastatic CRC treated with first-line capecitabine (CAP, n=90) or a combination of capecitabine and

irinotecan (CAPIRI, n=95) in the phase 3 CAIRO trial. Methylation status of each gene was correlated to progression free survival (PFS) by treatment regimen. Genes for which methylation status was associated with response to irinotecan were validated in 166 patients treated with first-line CAP (n=78) or CAPIRI (n=88). In CAPIRI treated patients, DCR1 methylation was correlated to a shorter PFS compared to patients with unmethylated DCR1 (hazard ratio [HR]=0.4, p = 0.0009). In patients with methylated DCR1 PFS did not improve with CAPIRI treatment, compared to treatment with CAP (discovery set: HR=0.8 p=0.4; validation set: HR=1.1, p=0.6, in contrast to patients with unmethylated DCR1 (discovery set: HR=2.5, p=0.00004; validation set: HR=1.7, p=0.004).

About CTMM

The CTMM (Center for Translational Molecular Medicine) is a Netherlands-based public-private partnership. It is dedicated to the development of technologies in molecular medicine that enable early diagnosis and personalized treatment for main areas of disease causing mortality and diminished quality of life in the western world. Focus lies on oncology, cardiovascular, neurodegenerative and infectious/auto-immune disease. CTMM operates by inviting, assessing, and funding multidisciplinary projects that involve active participation by Netherlands-based academia and industry. All CTMM projects are judged by an independent International Advisory Board and approved by a Supervisory Board based on their significant potential to translate research knowledge into clinical practice. The CTMM is funded by the Dutch government (50%), academia (25%) and industry (25%). Additional funding is provided by supporting foundations on behalf of patients.

DeCoDe (Decrease Colorectal Cancer Death) is one of the CTMM projects, with 14 partners and a project budget of 18.6 M Euro. Key figures CTMM: 119 partners, M€ 302.7 allocated budget until the end of 2015, 22 projects/consortia, www.ctmm.nl.

About MDxHealth®

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. The company's first commercial product, ConfirmMDx™ for Prostate Cancer, has been shown to help distinguish patients who have a true-negative biopsy from those who may have undetected cancer. MDxHealth helps to address a large and growing unmet medical need for better cancer diagnosis and treatment information. The company has a proprietary platform and a strong epigenetic product pipeline focused on the development of products for prostate, brain, lung and colon cancers. The company is based in Irvine, California with a European headquarters in Liege, Belgium. For more information visit MDxHealth's website at www.mdxhealth.com.

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