

MDxHealth to Participate in Prospective Clinical Validation Study with AssureMDx for Bladder Cancer

Study to Evaluate Ability to Reduce Invasive Procedures for Bladder Cancer Survivors and Allow Earlier Detection of Recurrence

IRVINE, CA, and HERSTAL, BELGIUM, November XX, 2015 – MDxHealth SA (Euronext: MDXH), announced today that it has entered into an agreement with Erasmus University Medical Center Rotterdam (Erasmus MC) for the inclusion of MDxHealth's AssureMDx for Bladder Cancer, a urine-based, liquid biopsy test, into a prospective clinical study designed to assess the ability of urine-based molecular tests to stratify patients with non-muscle invasive bladder cancer (NMIBC) for recurrence monitoring.

A total of 2,000 urine samples from 435 patients will be collected in a, multi-center, two-arm, prospective randomized clinical trial financed by ZonMw, the Netherlands Organisation for Health Research and Development and Erasmus MC. The study is designed to assess the test's ability to safely reduce the number of invasive cystoscopies performed during follow-up of patients with NMIBC with a low/intermediate risk of recurrence or progression. The study will also examine whether the addition of urine tests to follow-up of patients with higher risk of recurrence and progression leads to earlier detection of potentially dangerous recurrences. All urine samples will be tested using AssureMDx assay.

Prof. Dr. Ellen Zwarthoff, principal investigator at Erasmus MC commented, "Given that current diagnostic tools are invasive and at times costly, the potential for urine-based molecular tests to help reduce the number of invasive cystoscopies for low or intermediate risk patients, while providing earlier detection of possible recurrence for those at high-risk, would be a major advance for patient care. As such, we look forward to collaborating with MDxHealth on this important clinical trial."

About Bladder Cancer

In the US and EU, over 170,000 patients are diagnosed with bladder cancer every year, and over 50,000 patients will die from the disease. Annually in the US alone, it is estimated that over 1 million patients with hematuria (blood in urine) are referred to urologists for fear of bladder cancer. The traditional tools and procedures employed for the detection of bladder cancer have some limitations, not the least of which are cost and invasiveness, but also these methodologies are prone to miss some small bladder tumors, satellite lesions as well as carcinoma in situ. Importantly, bladder cancer is one of the most expensive cancers to treat given more than half of all early stage bladder cancer patients will recur in the three years following treatment.

About Erasmus University Medical Center

Erasmus MC is the largest and most authoritative University Medical Center in the Netherlands. Almost 13,000 staff members work within the core tasks of patient care, education, and scientific research on the continuous improvement and enhancement of individual patient care and social healthcare. They develop high-level knowledge, pass this

on to future professionals, and apply it in everyday patient care.

About MDxHealth

MDxHealth is a multinational healthcare company that provides actionable epigenetic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) technology and assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. For more information visit mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

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