



Micromedic Reports Positive Clinical Study Results for Identifying New Genetic Markers to Predict Risk of Developing BRONJ

TEL AVIV (August 31, 2015) Micromedic Technologies Ltd. (TASE: MCTC), a company engaged in the development and commercialization of innovative solutions for cancer diagnostics, today announced that it has identified several new genetic markers with high potential to predict necrosis of the jawbone in patients treated with bisphosphonate drugs, and was able to repeat findings from a previous study for one significant marker in a larger and more diversified group tested in a second trial.

The findings are based upon a trial that was designed to validate findings from a previous study conducted at the Tel Hashomer Medical Center, Israel, and reported in May 2014. The previous study was designed to identify the unique genetic profile that enables the assessment of risk among cancer patients to develop bisphosphonate-related osteonecrosis of the jaw, or BRONJ. The current trial was performed at the Florida University, USA, and at the Tel Hashomer Medical Center, Israel, using diverse patient populations from the U.S., Europe and Israel. The trial involved 125 samples, of which 108 were multiple myeloma patients, 13 were breast cancer patients, and four were patients suffering from other cancers, that were treated with bisphosphonate drugs. The trial included 69 cancer patients that developed BRONJ and a control group of 56 cancer patients that did not develop BRONJ. The trial included paving the genes by using full exome sequencing, and bioinformatics analysis method was applied for identifying genetic markers.

Statistical model, with the use of six gene markers for the 125 trial subjects, provided 93% sensitivity among cancer patients that developed BRONJ, and 68% specificity among cancer patients that did not develop BRONJ. It should be noted that the underlying statistical method that was primarily used for these results is based on a threshold value calculated on the basis of a single set of data that contains an element of overestimation. In order to validate these statistical results, an alternative method, leave-one-out cross validation, was applied and resulted in sensitivity of 84% and specificity of 68%.

“We believe that these study results represent a significant milestone in the ongoing development of Micromedic’s assay for identifying risk in patients to develop BRONJ,” commented Steven Eitan, CEO of Micromedic. “Based on these positive results, we intend to pursue strategic partnership opportunities for continuing the clinical and commercial development of the BRONJ assay.”

“The approach taken in this study is unique” said Dr. Noam Shomron, Head of the Functional Genomics Laboratory at the Faculty of Medicine, Tel Aviv University. “Employing an algorithm based on a small subset of genes allowed reaching a risk predictor for developing BRONJ. Eventually, using a relatively simple genetic test will allow categorizing the risk of cancer treated patients to develop BRONJ and thus lead to personalized cancer treatment.”



Dr. Noam Yarom, Director of the Oral Medicine Clinic at the Sheba Medical Center, Tel-Hashomer, commented, “The study results are highly encouraging as no reliable test for predicting BRONJ exists in the market today. BRONJ is a devastating side effect of bisphosphonates, which often leads to both functional and aesthetical problems that may last for many months, or even years. Currently, there is no effective treatment for this condition and, in many cases, it ultimately leads to jaw surgery. Due to the lack of an appropriate predictive test, all cancer patients that need to be treated with bisphosphonates are required to undergo tooth extraction prior to the initiation of therapy. Moreover, there is a contra-indication for dental implant placement in cancer patients receiving bisphosphonates during the term of the therapy and for a few years post-treatment. Thus, a test that could stratify the risk for BRONJ is expected to substantially improve the quality of life for patients requiring bisphosphonates therapy.”

About BRONJ

The BRONJ side-effect appears in cancer patients who receive intravenous therapy (approximately 500,000 patients each year) with a prevalence rate of up to 18.6% among multiple myeloma patients, 1.2%-12% among breast cancer patients, 6.5%-7% among prostate cancer patients, and up to 0.1% among osteoporosis patients who receive orally administered treatment (approximately 200 million patients worldwide).

About Micromedic Technologies Ltd.

Micromedic is engaged in the development and commercialization of unique solutions addressing real unmet needs prevailing in the field of cancer diagnostics. The company's technologies include proprietary tests for early cancer detection and personalized cancer management.

For more information please visit the Company's website at www.m-medic.com.

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