BRONJtest
Proprietary Genetic Profile

Novel Genetic Test

for predicting the risk of developing BRONJ

- Intended test for cancer and potentially osteoporosis patients on bisphosphonates (BPs) therapy
- High sensitivity to identify patients at risk of developing bisphosphonate-related osteonecrosis of the jaw (BRONJ)
- Applicable for all clinicians prescribing BPs and for dental surgeons before treating patients using BPs

Micromedic
Life Saving Cancer Diagnostics

BRONJtest

Proprietary Genetic Profile

Micromedic's unique genetic test enables personal treatment of bisphosphonates for cancer patients by predicting the risk of developing BRONJ

The market opportunity

Cancer and osteoporosis are driving a large number of bone-strengthening treatments. In the U.S. alone, more than 15 million prescriptions for oral or intravenous bisphosphonates (BPs) are dispensed each year for the prevention and management of osteoporosis, and are also used to prevent bone complications in metastatic cancer. BRONJ is a severe condition induced by BPs. It is driven by the increased prescribing of BPs primarily for cancer and osteonecrosis patients.

The condition is a significant side effect, adversely impacting quality of life and producing significant morbidity in afflicted patients. Most cases are incurable and treatment strategy includes pain relief and avoidance of infections and new lesions. BRONJ occurs most commonly in multiple myeloma patients with an incidence rate of up to 18%, breast and prostate cancers, and in osteoporosis patients, at a lower percentage. The U.S. FDA acknowledged the risk for BRONJ in 2005 with a black box warning. The American Medical Association recently recognized the condition as drug-induced ONJ with a specific ICD-9 code of 733.45.3. The cost of treatment of the condition ranges between $200 for a doctor's visit to $20,000 for hospitalization and surgery.

The unmet need

In order to avoid this severe adverse condition, the BRONJ risk should be evaluated in all patients prior to BPs administration. In addition, as the inciting event is usually dental surgery, the risk for BRONJ must be evaluated in candidate patients already administrated with BPs. Today, clinicians lack specific predictive tests and are obligated to use tools lacking substantial clinical evidence for BRONJ risk evaluation.

> *A test for identifying patients at risk of developing BRONJ when prescribing BPs can improve the management of these patients and could save the health system significant expenses.*

BRONJtest – the safest way for prescribing BPs

BRONJtest is a unique genetic test relevant to all clinicians who prescribe bisphosphonates to cancer patients. The BRONJtest is designed to help physicians more efficiently and safely match the appropriate therapy for their patients.

- Micromedic has identified a unique genetic profile which characterizes patients at risk of developing BRONJ
- As opposed to bone turnover marker assays, the BRONJtest is specifically designed to evaluate the genetic risk status of cancer patients and potentially osteoporosis patients
- In addition, the BRONJtest is intended to support dentists and oral surgeons in assessing the status of their BP-treated patients before starting dental treatment

> *Micromedic is currently seeking a strategic partner to complete the product development and initiate commercialization.*

Product Development

- Clinical trials identified a unique genetic profile indicative of BRONJ in multiple myeloma patients and in patients with other types of cancer.
- Clinical trial comprised 125 cancer patients. SNPs were discovered by NGS and confirmed by other genotyping methods. SNPs were discovered and tested in two independent sets. SNPs were combined together to an algorithm yielding 93% sensitivity and 68% specificity.
- Commercial product technology of NGS or PCR will be defined together with the partner.
- The test is developed in collaboration with the University of Florida and Sheba Medical Center.

Intellectual Property

- The technology is protected by strong IP portfolio.

References

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Lazarovici et al, J Oral Maxillofac Surg. 2010 68(4):790-6.
Zuzana Janovská, Acta Medica 2012 55: 111–115.

Micromedic Technologies (TASE: MCTC) is engaged in the development and commercialization of unique solutions addressing real needs prevailing in the field of cancer diagnostics and early cancer detection.

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