

# Micromedic Announces Cooperation with Axella Research LLC for the Financing and Execution of Clinical and Regulatory Activities Required for the FDA Approval of the CellDetect® Bladder Cancer Monitoring Test in the United States

Tel-Aviv, Israel, November 29, 2015 – Micromedic Technologies Ltd. (TASE: MCTC) ("Micromedic"), announced today that it has entered into a Collaboration Agreement (the "Agreement") with Axella Research LLC ("Axella"), to advance the clinical and regulatory efforts required to commercialize the CellDetect<sup>®</sup> non-invasive diagnostic test for the monitoring of bladder cancer recurrence in the United States.

Under terms of the Agreement, Axella will contribute over US\$1 million in funding the delivery of key clinical research organization ("CRO") services, including the management and execution of a clinical trial, in order to obtain regulatory approval for the sales and marketing of CellDetect® in the United States. In exchange for financing and CRO services, Axella will be entitled to royalties from future U.S.-based sales of CellDetect®.

"We are thrilled to announce this strategic partnership with Axella, which will yield meaningful progress towards regulatory approval of CellDetect® in the United States, and accelerate the commercialization of this novel technology" commented Steven Eitan, Micromedic's Chief Executive Officer. "With the highest recurrence rate of all cancers worldwide, there is a pressing need for improved diagnostic technologies to combat bladder cancer. CellDetect® bladder cancer fills that void by delivering an accurate and reliable non-invasive test, offering significant commercial potential in the largest cancer diagnostics market in the world."

Micromedic is currently developing the CellDetect<sup>®</sup> technology, which allows an accurate diagnosis of cancerous cells based on a unique combination of color differentiation and morphology, by utilizing a proprietary kit containing unique extract and dyes.

Earlier this year, Micromedic announced that CellDetect<sup>®</sup> bladder cancer monitoring has obtained CE Mark, enabling the product to be marketed and sold in Europe. This followed the successful completion of a blinded, multi-center clinical study of CellDetect<sup>®</sup> in February 2015, which achieved the study's primary endpoint for effectively detecting the recurrence of bladder cancer in subjects with a history of the disease. The CellDetect<sup>®</sup> bladder cancer test successfully identified cancerous cells in urine samples in patients with a history of the disease, with reported sensitivity of 84.4% and specificity of 82.7% for the study's primary endpoint.

Micromedic plans to submit a Pre-IDE for the Product to the U.S. Food and Drug Administration in H1/2016.



#### **About Bladder Cancer**

Bladder cancer is the fourth most prevalent cancer among males in the U.S. and the seventh most prevalent among males worldwide, with nearly 430,000 new cases of the disease diagnosed globally in 2012. The rate of recurrence is the highest of all cancers and ranges from 50% to 80%. According to U.S. clinical guidelines, patients with a history of urinary bladder cancer are required to undergo three to four tests per year to monitor disease recurrence in the first two years immediately following treatment, and one test annually in the years that follow. Because of high recurrence rates, the cost of diagnosing and treating bladder cancer is among the highest of all cancers.

## About CellDetect®

Micromedic's CellDetect<sup>®</sup> technology allows an accurate diagnosis of cancerous and precancerous cells, based on unique combination of color and morphology. The technology may be implemented in screening tests and monitoring tests of disease recurrence in cancer patients after being treated. Micromedic has proven the product's efficacy in diagnosing cervical cancer and bladder cancer in the framework of clinical trials, and estimates that the technology underlying the products may be implemented for use in additional cancer indications. The cervical cancer detection screening diagnostic test kit is in the initial commercial stage and Micromedic recently completed a clinical trial to prove its ability to monitor bladder cancer recurrence. Micromedic believes that the underlying technology may be adapted for other types of cancer as well.

# 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.

#### About Axella Research LLC.

Axella Research, LLC is a full service specialty focused CRO, operating under the umbrella Axella BioVentures, a venture company offering a unique research model for companies exploring options to further develop their technology for clinical applications and/or regulatory approval through mitigating the financial burden and navigating the regulatory environment. Axella serves as a strategic partner to assist in expediting clinical research utilizing its SMO/CRO services with both a traditional fee for service model as well as innovative equity driven model. Axella has a robust clinical network and a dynamic clinical and scientific advisory board comprised of practicing physicians who understand the practical



application and economics of medical devices and drugs that can guide a company with strategic, clinical and regulatory pathways for commercialization of their product. The additional advantage of this model allows to generate data and qualify proof of concept in new technologies and enables Axella to engage its group of potential investors for second round financing.

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

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