

iTP Biomedica launches BladderPredict™, a state-of-the-art diagnostic to manage early stage Bladder Cancer

iTP Biomedica's molecular technology platform delivers unprecedented insights into the nature of cancer and other complex diseases

TORONTO, July 19, 2016 – iTP Biomedica Corp., a developer of proprietary whole transcriptome-based cancer diagnostics, today announced the launch of BladderPredict, a groundbreaking next-generation sequencing-based test that will for the first time assist uro-pathologists in assigning disease grade in early stage bladder cancer, and urologists and uro-oncologists in managing the disease. The test will be provided in collaboration with iTP's partner, Mount Sinai Services of Toronto, a global provider of customized clinical laboratory and research services.

Prior to BladderPredict, bladder cancer tumours were only evaluated by the human eye, leading to debate amongst pathologists on tumour grade in up to 40% of non-muscle invasive bladder cancer cases. Now, iTP Biomedica's proprietary technology delivers a functional readout of the tumour's entire genome to enable a transcriptome-wide fingerprint of grade. This provides a higher degree of certainty on the aggressiveness of the tumour and allows for a more objective evaluation of tissue biopsies for evidence-based point of care treatment.

"The current course of treatment for bladder cancer is often selected based upon presumed prognosis of the disease type, which is determined by the microscopic appearance of the tumor cells; however these are presumed. Many tumors may appear identical under the microscope but behave dramatically differently in reality," said Mount Sinai Hospital surgeon Dr. Alexandre Zlotta, who leads the hospital's Bladder Cancer Research Program. "Because bladder cancer has a variable course with tumours behaving in very different ways, quite often we treat either too aggressively, or not aggressively enough."

"We believe this is the future of cancer diagnostics and prognostics, as whole transcriptomes provide a deep and comprehensive view of tumour state and potential clinical trajectories", added iTP's Chief Scientific Officer and Lunenfeld-Tanenbaum Research Institute scientist, Dr. Jeff Wrana. "With these technologies we can probe the functions of genes and their protein products. We can also assess how genes might be mutated or rearranged to influence the aggressiveness of cancer."

Research supporting the technology has already been well-received by academic and clinical communities. In recent years, findings were published in the Journal of European Urology, and presented at meetings sponsored by the American Society of Clinical Oncology, the American Urological Association and the European Association of Urology.

"We are extremely pleased to introduce BladderPredict to clinicians and patients as it will greatly assist practitioners in treating patients who are facing such a difficult disease" said Dr. Ken Hughes, iTP's President & CEO. "This is an important milestone for the company as it exemplifies our technology platform and shows its clinical application. We are grateful to our funding partners for empowering us to develop this state-of-the-art technology, and we will be applying it to multiple cancers and other diseases in the coming months".

About Bladder Cancer

An estimated 85,000 North Americans are diagnosed with bladder cancer each year. Although less common in women, it is the fourth most common cancer in men. Due to an 80 per cent recurrence rate, bladder cancer is also the most expensive cancer to treat on a per-patient basis. Despite progress in other areas of cancer treatment, five year survival rates of bladder cancer have not shown any improvement in recent history.

A key obstacle to improving outcomes in bladder cancer is the difficulty in securing reliable diagnoses regarding tumour grade. Highly experienced pathologists may still arrive at separate conclusions about the grade of the same tumour biopsy. In fact, case studies have demonstrated that different pathologists examining the same biopsy may disagree on tumour grade in up to 40 per cent of cases. Since tumour grade is a critical data point to be used in determining disease aggressiveness and providing effective patient care, this lack of diagnostic insight has frustrated clinicians' efforts to manage the disease.

About iTP Biomedica Corp.

iTP Biomedica Corporation ("Integrated Transcriptomics for Personalized medicine") is a Toronto-based company founded to commercialize unique technology developed at Sinai Health System's Lunenfeld-Tanenbaum Research Institute (LTRI). This proprietary whole-genome technology platform is positioned to supersede other molecular approaches to diagnosis/prognosis that have recently been commercialized. Current tests depend on limited numbers of marker genes to predict the behaviour of complex diseases, and therefore are prone to false positive and false negative results. By contrast, iTP Biomedica delivers a functional readout of the entire human genome and its Next-Gen Transcriptomic platform, incorporating a fully-developed Quality System, efficiently handles massive bioinformatics data sets to allow rapid development and commercialization of exquisitely accurate tests for cancer and other diseases. iTP's lead products are diagnostic/prognostics for bladder cancer progression, with pipeline products for multiple cancers and other disease to follow. The company is also developing a portfolio of blood- and urine-based diagnostic tests as part of its R&D pipeline and is oriented to collaborative co-diagnostics development. For information, visit www.itpbiomedica.com.

About Mount Sinai Services, Inc.

Mount Sinai Services is a CAP/CLIA and ISO 15189 certified global provider of customized clinical diagnostic laboratory and research services. Mount Sinai Services works closely with world-renowned clinicians and researchers at Sinai Health System, Lunenfeld-Tanenbaum Research Institute, University of Toronto and other Canadian academic and healthcare providers to offer comprehensive services supporting discovery and innovation in the life sciences, including medical device and diagnostic assay development and validation, clinical trial management and providing customized services to biotech and pharma industry. Mount Sinai Services provides specialized clinical laboratory testing throughout Canada and supports processes to achieve new assay reimbursements. Mount Sinai Services is committed to providing its clients with superior customer service and high-quality results based on a truly collaborative approach. For information, visit www.mountsinaiservices.com.

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