Bio Mark **TECHNOLOGIES INC.**



BioMark Technologies, Inc. www.biomarktech.com

Sector **Cancer Diagnostics and Therapeutics**

Team and Medical Key

Advisory Group

Rashid Ahmed – CEO and Founder Brian Cheng – CTO Dr. Daniel Sitar - Inventor Dr. B. Ramjiawan – Regulatory and **Clinical Trial** Dr. J. Schrader – IVD Development Dr. Keith Ly – Clinical Support Dr. G. Reuven and F. Hof - Raman System

Intellectual Property

- Issued: Spermine/spermidine acetyltransferase (SSAT 1)
- Pending: 2 filed in 2011 for monoclonal antibody and new substrates.
- 2 others filed in 2013
- 3 others in process to be filed by end of 2013

Stage of Development DIAGNOSTIC

- Phase III trial commenced at CancerCare Manitoba and SBRC.
- Additional international accredited clinical sites in China and Bangladesh

THERAPEUTICS

- Commencing In vivo to complete proof of principle

Contact

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BIOMARK TECHNOLOGIES SUMMARY

Play: Late Stage Cancer Diagnostic with Strong Anti- Cancer Therapeutic Drug Candidates

Vision and Translational Focus

Our mission is to introduce innovative technologies and products to increase prediction and accuracy in diagnosis, prognosis, and treatment of cancer. BioMark's technology portfolio for oncology comprises three areas: 1) diagnosis, 2) response to treatment / prognosis, and 3) drug therapy.

DIAGNOSIS:

The metabolomics-based diagnostic assay allows early cancer detection. The assay consists of screening for the acetylated form of a drug (Amantadine) given to patients prior to measurement via LC MS in body fluids. This acetylation is performed by the enzyme, Spermine/Spermidine N-Acetyl Transferase (SSAT). It has been documented that elevated levels of SSAT are observed in certain cancers including prostate, breast, prostate, and colon. Clinical trials on both cancer and healthy subjects provided proof of principle. In addition, analysis of SSAT mRNA levels in biopsy tissue samples through recent studies conducted at Manitoba Tumour Bank and has confirmed the elevated levels of SSAT in breast, prostate and lung cancers.

Status of Development:

- Completed phase IIb and control studies (indicated above) in Manitoba
- Completed pK and control / mini cancer test on human patients in China
- Phase III (diagnostics) approval granted by Health Canada: July 2012 120 patient study. This study has also been approved by the University of Manitoba ERB. Study focus is on breast, prostate, lung, GI, and melanoma. Clinical trial centers include CancerCare Manitoba, SBRC Manitoba, other approved centres in China and Bangladesh(NCI).

Product Forms:

- · Hospital / commercial laboratory-based testing via internally developed Standard LC MS – ITA submitted
- POC, IVD rapid diagnostic kit in development. Antibodies have been generated to be used in the kits. Elisa kits are under development and will be used in key partner site for validation
- New IR Surface Enhanced Raman System based detection is currently under development at University of Victoria. This method allows metabolite detection using a patented spectrometry technology.

Benefits / Value of Technology:

- Cost effective
- Non-invasive
- Accurate
- Reproducible
- Reduces false positives and other mistakes in diagnosis as well as providing confirmation
- Sensitive

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RESPONSE TO TREATMENT / PROGNOSIS:

BioMark's detection technology can be used to measure response to treatment. This consists of monitoring the level of metabolite pre- and post-treatment. A protocol for this application has been completed and will be presented to CancerCare Manitoba and other potential cancer centres to test patient reaction to different treatment options. The initial focus is on lung cancer.

Benefits / Value of Technology

- Real time monitoring and detecting early response to treatment allows for potential under treatment with chemotherapeutic agents, thereby increasing quality of life.
- Cost effective
- Simple to use
- Reliable
- Non-invasive

CANCER THERAPEUTICS:

BioMark drug therapies include antibody-based drugs and novel compounds

Status of Development

• Antibody Based Drugs: Development of new antibody based therapeutics for cancer treatment has been completed on 3 human cancer cell lines. These include Lung, Breast and Prostate, and a control. BioMark's antibodies exhibited similar or better anticancer efficacy while demonstrating significantly lower toxicity within the therapeutic range as compared to existing antibody-based cancer therapeutics currently on the market. Recent study indicating the lack of acute cytotoxicity in hepatocytes and lymphocytes during the antibody treatment is highly encouraging toward the proposed use of the antibody as a therapeutic entity.

BioMark is developing an integrated plan for the strategic experiments required to reach in vivo proof-of-principle that supports the use of the antibody as a lead drug candidate for IND-enabling development. Patents have been filed for this discovery.

• Novel compounds: Preclinical tests have been completed in human tumour cell lines and primary tumour cultures. Patents have been filed on the substrates for anti tumour properties.

BioMark is working with an innovative Vancouver based company to test a new targeted delivery method to complement its antibody based drug. BioMark intends to determine the efficiency of the delivery method to leverage the innovation for organ cancer imaging application. BioMark hopes to complete the proof of concept shortly.

Benefits / Value of Technology

- Higher survival rate
- Low cost
- Low drug-drug interactions
- Low toxicity concerns