Colorectal cancer is one of the most common causes of cancer diagnosed in the United States and the world. In 2012, over one million new cases were diagnosed, resulting in almost 700,000 annual deaths. Proper screening and early detection are keys to preventing the disease. But not all precancerous cells can be seen with standard screening techniques—in particular, those that are “flat” in architecture.

The Solution

Thomas Wang, M.D., has developed a technique at the University of Michigan that uses a peptide labeled with optical contrast agents (dyes) that bind specifically to biological molecules on the cell surface of abnormal tissues. These provide a “red flag” to help the physician guide tissue biopsy and result in earlier detection of difficult-to-identify pre-cancerous and cancerous lesions, especially in high-risk patients. In addition, a higher diagnostic yield may either reduce the need for additional exams or extend the times between exams.

Suspicious lesions are spotted using a special microscope that fits through a standard medical endoscope. The advanced imaging is sensitive to flat lesions and gross polyps and allows doctors to look at molecular targets rather than structural changes.
An innovative fluorescent-labeled peptide screening technique targets molecules on the surface of abnormal tissues. This results in earlier detection of hard-to-identify pre-cancerous and cancerous lesions in patients.

**Significant Need**
A higher diagnostic yield may either reduce the need for additional exams or extend the times between exams. Patients would be able to minimize the physical discomfort associated with taking the prep and the inconvenience of undergoing sedation for the procedure.

**Compelling Science**
A novel imaging agent for early detection of flat, colorectal lesions that cannot otherwise be seen on conventional white light endoscopy.

**Competitive Advantage**
This advanced imaging may improve detection and prevention of colorectal cancer because it is sensitive to flat lesions and gross polyps and allows doctors to look at molecular targets rather than structural changes. Standard screening techniques have a significant miss rate of hard-to-detect lesions.

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“MTRAC funding and guidance gives us the resources we need as we complete our clinical studies and go through the process of moving the product to market.”

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**MTRAC Project Key Milestones**

- Obtain FDA and IRB approval for Phase 1B clinical studies to collect fluorescence images
- Quantify fluorescence images and measure target-to-background ratios for dysplasia detection
- Collect fluorescence images of colonic dysplasia in n=25 subjects for Phase 1B study
- Evaluate performance (sensitivity, specificity, predictive value) for detection of colonic dysplasia

**Overall Commercialization**

- **Commercialization Strategy**
  - Plan is to license Intellectual Property rights

- **Intellectual Property**
  - Patent filed with the United States Patent and Trademark Office

- **Product Launch Strategy**
  - To be determined by licensee

- **Engage Investors**
  - Interest should increase with results of Phase 1 clinical study—MTRAC funds are being used to support the initial clinical trial, which will be complete by mid-2015

- **Regulatory Pathway**
  - Investigational New Drug (IND) and amendment to IND submitted to FDA, PI trial is underway

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**Thomas Wang, M.D.**

04/2015

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[Image of Thomas Wang, M.D.]