

Breast Cancer-Targeted Probe Set for Improved Detection of Lymph Node Metastases



Novel fluorescent probes have been developed that selectively target breast cancer metastases in lymph nodes with high sensitivity. The probe set binds proteins that are collectively expressed in 100% of breast cancer cells that have metastasized to lymph nodes. Standard procedures in diagnosing lymph node metastases involve surgeries that prove unnecessary for a majority of breast cancer patients. Our probes, currently in preclinical development, would be effective for non-invasive cancer cell detection, eliminating the cost, side effects, and misdiagnoses associated with lymph node biopsies.

COMMERCIAL OPPORTUNITY

- Currently sentinel lymph node mapping and biopsy is the preferred procedure for detecting lymph node metastases in breast cancer patients. It relies on non-specific imaging of lymph nodes near the primary tumor, their surgical removal and subsequent biopsy for diagnosis.
- Sentinel lymph node biopsies prove to be unnecessary for 74% of breast cancer patients who have this operation to diagnose metastases; their lymph nodes test negative upon biopsy. The surgeries are ineffective for up to an additional 10% of patients whose metastases are missed due to their size or migration to undetected lymph nodes. Our breast cancer-targeted probe set could allow this large market of patients to avoid sentinel lymph node biopsies.
- Our cancer-targeted probes sensitively and specifically detect metastatic breast cancer cells directly in preclinical mouse models, and could allow non-invasive diagnosis of lymph node metastases and elimination of diagnostic surgeries and biopsies.
- The market potential would be estimated to exceed the projected sales of Lymphoseek® (Navidea Biopharmaceuticals, Inc.), a new oncology diagnostic imaging agent for improved detection of sentinel lymph nodes. Lymphoseek® is projected to earn \$238M worldwide in breast cancer patients after its anticipated FDA approval in early 2013.

TECHNOLOGY

Together, carbonic anhydrase IX (CA9) and carbonic anhydrase XII (CA12) are expressed in 100% of breast cancer lymph node metastases. The probe set consists of monoclonal antibodies targeting CA9 and CA12 with each antibody conjugated to a near infrared fluorophore, VivoTag-S 680®. Specificity of the CA12 probe was tested in mouse mammary tumor xenograft studies, where fluorescence intensity was 7.0-fold higher in CA12+ tumors versus their negative counterparts ($p < 0.001$). Strong fluorescent signals in metastatic lymph nodes were observed 48 hrs. post-injection of each probe. An orthotopic model of lymph node metastasis showed that CA9 targeted probe was sensitive enough to detect 1,000 cells, while the CA12 probe could detect as few as 500 cells.

PUBLICATION/PATENT

- N.K. Tafreshi et al., (2012) *Clin. Cancer Res.* 18:207-219
- PCT application filed in August 2011 for Drs. Morse, Gillies, Bui, and Enkemann

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LICENSING OPPORTUNITY

