March 25, 2015

Navidea Biopharmaceuticals Announces Presentation of Lymphoseek® Data at Society of Surgical Oncology Meeting

High concordance between preoperative and intraoperative findings noted in data from patients with head and neck oral cavity squamous cell carcinoma

Outcome analysis from melanoma and breast cancer patients using Lymphoseek indicates accurate sentinel node detection

DUBLIN, OHIO--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB), today announced that data from its Lymphoseek® (technetium Tc 99m tilmanocept) injection studies in melanoma, breast and oral cavity squamous cell cancers (SCC) will be presented at the *68th Annual Cancer Symposium of the Society of Surgical Oncology (SSO) meeting held in Houston, TX, March 25-28, 2015.*

An oral presentation by Douglas Chepeha, M.D. of the University of Toronto-Princess Margaret Hospital reveals that analysis from Phase 3 data for detection of sentinel lymph nodes (SLN) in head and neck oral cavity squamous cell carcinoma patients demonstrated high concordance between preoperative lymphoscintigraphy and intraoperative SLN biopsy findings. Notably, 95.2% of patients had agreement between their preoperative (by imaging) and intraoperative (by handheld gamma-probe) findings. This high concordance when using Lymphoseek confirms its role in the utility of preoperative lymphoscintigraphy imaging for planning and conducting SLN biopsy.

Results of a follow-up outcome study presented as a poster by Julian Kim, M.D. of the University Hospitals Seidman Cancer Center indicated that in patients who were confirmed to be node-negative (N0) after sentinel lymph node biopsy (n=89; 57 breast cancer, 32 melanoma) the regional recurrence-free rate (RRFR) was 98.8% (100% in breast cancer; 97.4% in melanoma) at three years. An overall false negative rate (FNR) for the two tumor types was 5.6% and the negative predictive value (NPV) was 98.6% (100% in breast cancer; 96.4% in melanoma). These results demonstrate that Lymphoseek accurately identified SLNs and is likely predictive of pathological staging.

Presentation Details

Date:	March 28, 2015
Type:	Oral
Title:	Lymphoscintigraphy Concordance with Intraoperative Findings from Sentinel Lymph Node (SLN) Biopsy with [99mTc] Tilmanocept in Clinically Node-negative (cN0) Head and Neck Squamous Cell Carcinoma Patients (HNSCC)

Authors:

D. Chepeha,(1) A. Agrawal,(2) F.J. Civantos,(3) S.Y. Lai,(4.) 1. Otolaryngology, University of Toronto - Princess Margaret Hospital, Toronto, ON, Canada; 2. The Ohio State University, Columbus, OH; 3. University of Miami Hospitals and Clinics, Miami, FL; 4. MD Anderson Cancer Center, Houston, TX.

Date: March 26, 2015
Type: Poster
Title:

False Negative Rate (FNR) and Negative Predictive Value (NPV) from 3-year Outcome Study after Sentinel Lymph Node Biopsy (SLNB) with [99mTc] Tilmanocept in Clinically Node-negative (cN0) Breast Cancer and Melanoma Patients

Authors: *J. Kim, J.K. O'Donnell, Division of Surgical Oncology, Department of Surgery, Case Western Reserve University, Cleveland, Ohio*

About ILM and Lymphoscintigraphy

To date, Lymphoseek is the first and only receptor-targeted agent developed specifically for Intraoperative Lymphatic Mapping (ILM). ILM is a surgical oncology procedure in which lymph nodes draining the area around a tumor are identified and biopsied to determine if cancer has spread to the lymph nodes. Lymphoscintigraphy is an imaging procedure routinely performed pre-operatively to provide surgeons with guidance on the relative location of lymph nodes to be biopsied. ILM with a radiopharmaceutical is specifically intended to identify for the surgeon the first lymph node(s), called Sentinel Lymph Nodes (SLN), to receive lymphatic flow from the primary tumor site. SLNs are removed and analyzed for the presence of malignant cells. By identifying the SLNs prior to surgery, a small incision and focused dissection can be used to remove the node. This technique provides an accurate staging procedure that spares patients who are negative for lymph node metastasis by SLN biopsy the morbidity of a complete lymph node dissection.

About Lymphoseek

Lymphoseek® (technetium Tc 99m tilmanocept) injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Lymphoseek has also received European approval in imaging and intraoperative detection of sentinel lymph nodes in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. Overall in the U.S., solid tumor cancers may represent up to 1.2 million cases per year. The sentinel node label in the U.S. and Europe may address approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer in the U.S., and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and

55,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

Lymphoseek Indication and Important Safety Information

Lymphoseek is a radioactive diagnostic agent indicated with or without scintigraphic imaging for:

- Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management.
- Guiding sentinel lymph node biopsy using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity, breast cancer or melanoma.

Important Safety Information

In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers.

In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:

WWW.LYMPHOSEEK.COM

About Navidea Biopharmaceuticals Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB) is a commercial stage precision medicine company focused on the development and commercialization of precision diagnostics, therapeutics and radiopharmaceutical agents. Navidea is developing multiple precision-targeted products and platforms including Manocept™, NAV4694, and NAV5001, to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013 and by the EMA in November 2014. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and therapeutics, and advancing the Company's pipeline through global partnering and commercialization efforts. For more

information, please visit www.navidea.com.

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

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Source: Navidea Biopharmaceuticals, Inc.