October 30, 2014

Navidea Announces Scientific Presentations of Results from Lymphoseek® Studies at the European Association of Nuclear Medicine and European Society of Surgical Oncology Meetings

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) today announced that data and results from its Lymphoseek® (technetium Tc 99m tilmanocept) injection studies in breast cancer, melanoma or head and neck cancer were recently presented at the European Association of Nuclear Medicine Congress in Gothenberg, Sweden and will be presented this week at the European Society of Surgical Oncology-British Association of Surgical Oncology Congress from October 29-31, 2014 in Liverpool, UK.

“Following our recent positive opinion by the Committee for Medicinal Products for Human Use (CHMP) and the anticipated approval by the European Commission later this year, we are pleased to share these exciting Lymphoseek results with the European medical community,” said Rick Gonzalez, Navidea Chief Executive Officer. “We believe the targeted technology of Lymphoseek is an advance in the reliable and accurate location of sentinel lymph nodes aiding more effective cancer staging and better informing post-surgical treatment. Taken together with this month’s U.S. FDA approval for lymphatic mapping in all solid tumors, momentum continues to build toward our primary goal of making Lymphoseek the global standard of care in lymphatic mapping.”

Details of the presentations by Navidea and its collaborators are listed below.

European Society of Nuclear Medicine

Oral Title:	*99mTc-tilmanocept provides precise correlation of lymphoscintigraphy with in vivo lymph node findings in a meta-analysis of [breast cancer (BC), melanoma (ME), head/neck SCC (HNSCC)]*
Presenter:	Cornelia Reininger MD PhD, Navidea Biopharmaceuticals, Dublin, OH
Poster Title:	*Tc Tilmanocept Accurately Detects Sentinel Lymph Nodes and Predicts Pathologic Nodal Status in Patients with Squamous Cell Carcinoma of the Head and Neck: Results of a Phase 3 Multi-Institutional Trial*

Authors: Stephen Y Lai, MD, PhD, FACS[1], Amit Agrawal, MD[2], Frank Civantos, MD, FACS[3], [1]M.D. Anderson Cancer Center, Houston, TX; [2]The Ohio State University Wexner Medical Center, Columbus, OH; [3]University of Miami Hospital, Miami, FL

European Society of Surgical Oncology – British Association of Surgical Oncology

Date: October 31, 2014

Oral Title: *^{99m}Tc-Tilmanocept provides stably localised detection of lymph nodes (LN) in melanoma across all anatomic locations regardless of body mass index (BMI), or day of surgery*

Presenter: Frederick Cope PhD, FACN, CNS, Navidea Biopharmaceuticals, Dublin, OH

Oral Title: *The false negative rate (FNR) for ^{99m}Tc-tilmanocept is crucially low across breast cancer (BC), melanoma (ME), and head/neck squamous cell carcinoma (HNSCC), portending good patient outcome*

Presenter: Frederick Cope, PhD, FACN, CNS, Navidea Biopharmaceuticals, Dublin, OH

The presentations showed positive and consistent results from Lymphoseek's three pivotal prospective Phase 3 studies in melanoma, breast cancer, and certain head and neck cancers and included associated analysis of the combined data from more than 500 subjects. All three studies showed positive diagnostic performance of Lymphoseek across the solid tumor types studied. To date, no clinically significant drug-related adverse reactions have been reported. Lymphoseek has no contraindications and the most common adverse reactions were injection site irritation and/or pain (<1%).

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 been recommended by CHMP for European approval for the following indication:

- Radiolabelled Lymphoseek is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity.

- External imaging and intraoperative evaluation may be performed using a gamma detection device

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.

U.S. 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 biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is developing multiple precision diagnostic products and platforms including Manocept™, NAV4694, NAV5001, and NAV1800 (RIGScan™), to help identify the sites and pathways of undetected disease and enable better diagnostic

accuracy, clinical decision-making 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. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, 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.