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Lymphoseek® Technically Successful in Evaluation of Sentinel Lymph Node Biopsy in Patients Undergoing Neoadjuvant Chemotherapy

- Data from Study Presented at San Antonio Breast Cancer Conference-

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) today announced that results from an investigator-initiated retrospective analysis demonstrated Lymphoseek® (technetium Tc 99m tilmanocept) injection was successful in lymph node identification rate, node-positivity rate, and number of total nodes evaluated in sentinel lymph node biopsy (SLNB) procedures in clinically node-negative breast cancer patients undergoing neoadjuvant chemotherapy (NAT) compared to patients undergoing initial surgical treatment. These findings suggest that Lymphoseek offers breast surgeons the confidence to specifically identify and remove sentinel lymph nodes in this patient population. Results of the study conducted at the University of California, San Diego, School of Medicine, led by Anne Wallace M.D., professor of surgery, and Jonathan Unkart, M.D., Department of Surgery, UC San Diego Health, were presented today at the San Antonio Breast Cancer Conference in San Antonio, Texas.

“Prior thinking suggests that neoadjuvant chemotherapy may induce fibrosis and inflammation that alters lymphatic drainage of axillary lymph nodes in breast cancer and may obscure lymphatic mapping procedures,” said Dr. Wallace, who is also director of the Comprehensive Breast Health Center at UC San Diego Moores Cancer Center. “This analysis provides compelling evidence that Lymphoseek was successfully used for SLNB in the breast cancer neoadjuvant chemotherapy population and could potentially reduce the necessity for unnecessary and morbid axillary dissections, and improve the quality of life for patients.

“One of the most frequently asked questions we encounter from physicians is on the effectiveness of Lymphoseek in NAT patients,” commented Michael Tomblyn, M.D., Navidea’s Chief Medical Officer. “These findings show Lymphoseek’s usefulness in the complicated NAT population and that the outcomes are not different from the standard breast cancer population.”

The aim of the study was to compare identification rate, node-positivity rate and total number of nodes evaluated during SLNB with Lymphoseek and vital blue dye (VBD) in clinically node-negative patients receiving neoadjuvant endocrine or chemotherapy versus initial surgical treatment. A retrospective review of patients undergoing SLNB with Lymphoseek plus VBD from May 2013-2015 at UCSD was conducted. Of the 417 total sentinel lymph node (SLN) cases identified, 72 (17.2%) cases were in patients who had received NAT (61-

chemo, 11- endocrine). The SLN identification rate was 100% in both groups (p=1.0). Overall, there were 68 (16.3%) cases of SLN-positivity, 14 (19.4%) in the NAT group versus 54 (15.7%) in the non-NAT group (p= 0.54). The median number of identified nodes was 3 in both groups. In the a zero-truncated negative binomial count model, age, surgeon and evaluating pathologist were significant predictors of the total number of SLNs evaluated. The use of NAT did not significantly affect the number SLNs evaluated.

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), with or without scintigraphic imaging, 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

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immuno-diagnostic agents and immuno-therapeutics. Navidea is developing multiple precision-targeted products and platforms including Manocept™ and NAV4694 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 in Europe in November 2014. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products 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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