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Navidea Reports Publication of Lymphoseek® Comparative Results in Injection Site Pain Study in Breast Cancer

- Results published in the Annals of Surgical Oncology -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals (NYSE MKT: NAVB), announces publication of the results from an investigator-initiated, comparative study of Lymphoseek® (technetium Tc 99m tilmanocept) injection versus filtered Tc-99m Sulfur Colloid (fTcSC) measuring injection site pain in patients with breast cancer undergoing lymphoscintigraphy. The paper titled, *"Comparison of Post-injection Site Pain Between Technetium Sulfur Colloid and Technetium Tilmanocept in Breast Cancer Patients Undergoing Sentinel Lymph Node Biopsy,"* was published online in the Annals of Surgical Oncology [DOI - 10.1245/s10434-015-4802-y] and indicated, with patient-reported data, a statistically significant reduction in the level of post-injection associated pain using Lymphoseek compared with use of an fTcSC tracer.

"The publication of these investigator-initiated study findings affirms the value that surgeons place on minimizing pain and discomfort for their patients and continues to reinforce the clinical importance of Lymphoseek," said Michael Tomblyn, M.D., Navidea's Chief Medical Officer. "We believe that these results will enhance the visibility and awareness of Lymphoseek with surgical oncologists and illustrate both the clinical utility and clear benefits for patients."

"As surgeons who perform sentinel lymph node (SLN) biopsy procedures in breast cancer patients, one of our key focuses is optimizing a patient's overall experience," said Dr. Anne Wallace, M.D., professor of surgery, UC San Diego School of Medicine, director of the Comprehensive Breast Health Center at UC San Diego Moores Cancer Center and the study's lead investigator. "We designed this study to understand if Lymphoseek injection is less painful and could improve the patient experience. The results demonstrated that Lymphoseek, in fact, minimizes patient discomfort while allowing for effective SLN mapping."

The publication included results of the randomized, double-blind clinical trial comparing post-injection site pain using fTcSC versus Lymphoseek in 52 [(27) fTcSC and (25) Lymphoseek] breast cancer patients undergoing lymphoscintigraphy. Pain was evaluated with a visual analogue scale and short form McGill Pain Questionnaire at 1, 2, 3, 4, 5, 15 and 30 minutes post-injection. Analysis of the data indicated baseline pain scores were similar between groups. At one minute post-injection, patients receiving fTcSC experienced a mean change in pain of 16.8mm (standard deviation (SD) 19.5) compared to 0.2mm (SD 7.3) in the Lymphoseek group (p =0.0002). Overall, patients receiving Lymphoseek experienced statistically significant less change in pain scores compared to patients receiving fTcSC at 1-3 minutes post-injection.

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

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical 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™ 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 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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