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Lymphoseek® Reduces Sentinel Lymph Node Biopsy Imaging Time, Facilitating Patient Throughput and Workflow Efficiencies

- Data from Time-Efficiency Study Presented at RSNA2015 -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB) today announced that results from an investigator-initiated imaging study demonstrated Lymphoseek® (technetium Tc 99m tilmanocept) injection reduced imaging time by more than 50% in sentinel lymph node biopsy procedures in malignant melanoma compared to Tc99m sulfur colloid (SC). This finding suggests hospitals and oncology treatment teams can achieve greater patient throughput and workflow efficiencies utilizing Lymphoseek. Results of the study, conducted at the Thomas Jefferson University Hospitals and led by Charles M. Intenzo, M.D., Professor of Radiology, Director, Nuclear Medicine and Molecular Imaging in the Department of Radiology were presented today at the Radiological Society of North America Annual Meeting (RSNA 2015) in Chicago, Illinois.

“This study continues to support our belief in the clinical value of Lymphoseek for physicians and patients and also introduces an operational efficiency that strengthens the value to the hospital and the overall patient experience,” commented Michael Tomblyn, M.D., Navidea’s Chief Medical Officer. “Based on the ability to rapidly clear from the injection site and transit to tumor-draining lymph nodes, we believe that Lymphoseek may facilitate more efficient resource utilization including predictable scheduling of lymphatic mapping procedures, associated personnel and resources.”

A total of 34 consecutive patients with malignant melanoma underwent Sentinel Lymph Node (SLN) mapping with Lymphoseek. Patients received the Lymphoseek dose in 4 intradermal administrations around the tumor site. Images were acquired at intervals up to 40 minutes after injection, which is the department’s standard-of-care protocol used for Tc99m Sulfur Colloid (SC) procedures. This site’s previous experience showed that SC injections required 40 to 45 minutes after injection for visualization of all lymph nodes in patients with malignant melanoma. Using Lymphoseek, the results show that in all 34 patients, all lymph nodes seen in the final 40-minute image were identified in the 20-minute image, providing rapid and stable localization and identification of the sentinel nodes. The study concludes that in malignant melanoma, SLN mapping with Lymphoseek involves a total imaging time of 20 minutes which is one-half of the time required for Tc99m SC. From a clinical perspective, the authors conclude that utilizing Lymphoseek is more time-efficient than SC by facilitating patient throughput and expediting subsequent transport to the operating room.

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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