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Navidea Announces Presentation of Results Demonstrating Performance of Lymphoseek® in Breast Cancer at SNMMI

– Data from three investigator-initiated studies reported at the Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging –

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced results from three investigator-initiated studies that demonstrate beneficial performance characteristics of Lymphoseek® (technetium Tc 99m tilmanocept) injection and positive comparative results versus commonly-used, non-receptor-targeted imaging agents. The data were presented by the investigators this week at the 2016 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in San Diego, CA.

“These data further reinforce the beneficial clinical performance attributes of Lymphoseek® (technetium Tc 99m tilmanocept) Injection. And, in addition, they support Lymphoseek’s rapid adoption in sentinel lymph node biopsy procedures and its pre-surgical imaging utility for other solid tumors,” commented Michael Blue, M.D., Senior Medical Director of Navidea. “We believe results from these and other performance-based studies will encourage surgeon’s to use Lymphoseek as they look to optimize outcome for their patients and improve patient experience.”

Experimental Results

In the presentation entitled, “*Performance of Tc-99m tilmanocept when used alone is as or more effective in localizing sentinel nodes than sulfur colloid plus blue dye*,” Jonathan Unkart and Anne Wallace, M.D., Department of Surgery at the University of California San Diego (UCSD), described a retrospective evaluation of the rate of localization of Lymphoseek when used alone compared to sulfur colloid (SC), blue dye (BD) and SC plus BD. The study included results from 148 breast cancer patients evaluated in two, prospective Phase 3 Lymphoseek clinical trials (data published in Annuls of Surgical Oncology 2013). SC and BD data was derived from a literature search presented at SNMMI 2013 Annual Meeting including treatment groups of 17,814 SC alone, 12,821 BD alone and 19,627 SC+BD patients. Results show the following localization rates: Lymphoseek alone: 0.9865, SC alone: 0.9249, BD alone: 0.8294 and SC+BD: 0.9636. The author’s analysis suggests that Lymphoseek provided superior sentinel lymph node localization in breast cancer patients compared to the other non-targeting agents alone or in combination providing surgeons the option to use just a single agent.

The presentation, “*Use of lymphoscintigraphy with Tc-99m tilmanocept does not affect the number of nodes removed during sentinel node biopsy (SLNB) in breast cancer*,” also presented by Dr. Unkart shows data from a retrospective review evaluating whether there is

a difference in the number of nodes removed using Lymphoseek during SLNB in patients who had a pre-operative imaging procedure called lymphoscintigraphy prior to SLNB versus those who only had intra-operative Sentinel Node (SN) identification. The results indicate that in Breast Cancer, identification and removal of SNs using lymphoscintigraphy (3.0 SNs) did not significantly alter the number of SLNs removed during a SLNB procedure with no imaging (2.7 SNs). Lymphoseek's selective-targeting performance characteristic enables the utilization of only a single dose of Lymphoseek per patient irrespective of whether both lymphoscintigraphy and SLNB are performed. The authors concluded that by using Lymphoseek, lymphoscintigraphy imaging procedures may be eliminated in this patient population and may reduce health care cost without impacting patient outcomes.

The presentation entitled, *"Rate of sentinel lymph node visualization in fatty breasts: Tc-99m Tilmanocept versus Tc-99m filtered sulfur colloid,"* describes results from a study at Emory University School of Medicine using Lymphoseek in patients with fatty breast tissue a population that is known to be more difficult to localize nodes when doing SLNB. The results suggest that Lymphoseek more effectively visualized sentinel lymph nodes (SLN) both on lymphoscintigraphy and during surgery compared to filtered sulfur colloids (Tc-SC) with 100% localization using Lymphoseek intraoperatively. Dr. Maryam Shahrzad, M.D. presented retrospective data compiled from 29 consecutive patients with early stage breast cancer where lymphoscintigraphy was performed using Tc-SC and 28 patients where lymphoscintigraphy was performed using Lymphoseek. Multiple patient variables were recorded. The Tc-SC cohort included 96% of patients with fatty breasts versus 89% in the Lymphoseek group. Statistically significant findings included:

- In lymphoscintigraphy, SLN visualization occurred in 86% of the Lymphoseek group compared to 59% of the TC-SC group. (*p-value: 0.02*)
- At surgery, 100% of patients in the Lymphoseek group showed a "hot" SLN compared to only 79% of patients in the Tc-SC group. (*p-value: 0.01*)

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 results guide therapy decisions and determine 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 600,000 new cases of breast cancer, 160,000 new cases of melanoma and 100,000 new cases of head and neck/oral cancer diagnosed 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%).

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About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. 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. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. 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, our ability to repay our debt, the outcome of the CRG litigation, 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 The Company undertakes no obligation to publicly update or revise any forward-looking statements.

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