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Navidea Biopharmaceuticals Announces Presentation of Results from Two Lymphoseek® and Radiolabeled Colloid Studies in Lymphatic Mapping for Breast Cancer at SNMMI

Single center clinical study and meta-analysis demonstrated ability of Lymphoseek to accurately identify tumor-draining lymph nodes

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced results from two separate studies that compared the performance of Lymphoseek® (technetium Tc 99m tilmanocept) Injection, a novel receptor-targeted small-molecule radiopharmaceutical recently approved by the U.S. Food and Drug Administration, with that of radiolabeled sulfur colloid in breast cancer patients undergoing diagnostic evaluation in lymphatic mapping procedures. The studies were presented in oral presentations at the 2013 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in Vancouver, Canada.

Dr. Stephen Povoski, MD, of The Ohio State University, presented meta-analysis results from Phase 3 clinical trials for Lymphoseek compared with published data for radiolabeled colloid. A single center clinical research study was presented by Dr. Jennifer Baker, MD, University of California San Diego, and detailed that institution's direct clinical experience with the two agents. Of note, this abstract, *"Tilmanocept identifies more positive nodes using fewer sentinel lymph nodes compared to [99mTc] sulfur colloid in early stage breast cancer patients,"* received the "Dr. Tapan K. Chaudhuri, MD, FACNM, Award for Best SNM Abstract Involving Breast Cancer Research," awarded by the Education and Research Foundation for Nuclear Medicine and Molecular Imaging. The award was founded by Dr. Chaudhuri with a goal to promote research in breast cancer, and was presented at the SNMMI Annual Meeting to recognize the best paper in breast cancer research.

"We were pleased that these complementary studies of Lymphoseek in lymphatic mapping procedures for patients with breast cancer could be shared at SNMMI, because they highlight performance characteristics of this novel product that are important to clinicians and the patients in their care," said Mark Pykett, V.M.D., Ph.D., CEO of Navidea Biopharmaceuticals. "Locating appropriate tumor-draining lymph nodes, decreasing patient morbidity by removing as few nodes as possible and scheduling procedures efficiently are key concerns for physicians who conduct lymphatic mapping procedures, and we believe these data further demonstrate the clinical benefit of Lymphoseek in addressing these specific needs."

“Results of our single institution study at UCSD in breast cancer demonstrate the potential that receptor-targeted imaging agents may have in reliably localizing tumor-draining lymph nodes, enhancing efficiencies, and in optimizing patient management post-surgery,” said Anne Wallace, M.D., Chief, Division of Plastic Surgery; Professor of Surgery, UC San Diego School of Medicine; Director of the Breast Care Unit; UC San Diego Moores Cancer Center. “Appropriate lymphatic mapping and lymph node biopsy can benefit certain patients by sparing them removal of unnecessary lymphoid tissue and preventing side effects such as lymphedema or swelling, pain and sensory changes, scarring or disfigurement, and extended recovery times.”

Abstract Highlights:
"Tilmanocept identifies more positive nodes using fewer sentinel lymph nodes compared to [99mTc] sulfur colloid in early stage breast cancer patients (Baker et al, University California San Diego)

The independent, retrospective study conducted by UCSD compared the performance of Lymphoseek and radiolabeled sulfur colloid in breast cancer patients at a single institution. Results demonstrated statistically significant results for Lymphoseek in the accurate identification of tumor-draining lymph nodes. Lymphoseek detected 73% of tumor-positive nodes whereas radiolabeled sulfur colloid detected 49%, and Lymphoseek demonstrated a 98% early imaging success rate (the ability of the agent to be imaged in less than 10 minutes). The late imaging failure rate (the ability of the agent to be imaged within 2 hours) was 0% with Lymphoseek and 11.3% with radiolabeled colloid.

Comparison of key sentinel node biopsy parameters for 99m Tc-tilmanocept (TcTM) and 99mTc-sulfur colloid (TcSC) in breast cancer (Povoski et al, The Ohio State University)
This meta-analysis analyzed the efficacy of Lymphoseek with that of radiolabeled sulfur colloid by using data from Phase 3 clinical trials of Lymphoseek in breast cancer in comparison to published data for radiolabeled sulfur colloid. The study examined the endpoints of localization rate (the percentage of patients with a “hot,” or radioactive, node found), and the degree of localization (the number of “hot” nodes found per patient). The localization rate for Lymphoseek was 99.9% (n=148), which was statistically significant ($p<0.001$) against that for radiolabeled sulfur colloid with a localization rate of 94%, (n=9,213). Lymphoseek located 2.08 nodes per patient, as compared to 1.6 for radiolabeled sulfur colloid, which was statistically significant ($p<0.001$)

Full abstracts from SNMMI can be found through the Annual Meeting website at http://interactive.snm.org/index.cfm?pageID=12252.

About Lymphoseek®
Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek was approved by the U.S. Food and Drug Administration in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. The Company anticipates continuing development of Lymphoseek into other solid tumor areas that may include head and neck

cancers, prostate cancer, thyroid cancer, lung/bronchus cancers, colorectal cancer and others.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, approximately 232,000 new cases of breast cancer, 77,000 new cases of melanoma and 67,000 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2013.

U.S. Indication and Important Safety Information About Lymphoseek
Indication
Lymphoseek (technetium Tc 99m tilmanocept) Injection is a lymphatic mapping agent indicated for use with a hand-held gamma counter to assist in the localization of lymph nodes draining a primary tumor site in patients with 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.

The most common adverse reactions are 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 actively developing four radiopharmaceutical agent platforms – Lymphoseek®, NAV4694, NAV5001 and RIGScan™ – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. 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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