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Navidea Biopharmaceuticals Announces Results from Lymphoseek® Study on Accuracy of Lymph Node Detection from Injection Time to Surgery

- Lymphoseek demonstrated reliable identification of lymph nodes over 15 minutes to 30 hours, typical timeframes for lymphatic mapping in clinical setting -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced positive results from a meta-analysis study of Lymphoseek® (technetium Tc 99m tilmanocept) Injection that compared the performance of Lymphoseek, a novel, receptor-targeted radiopharmaceutical recently approved by the U.S. Food and Drug Administration, against a commonly used agent, vital blue dye (VBD), in identifying lymph nodes likely to harbor cancer cells over a period of time after injection.

Study results indicated that Lymphoseek demonstrated reliable histopathological detection of lymph nodes in lymphatic mapping across the likely time range of the procedure from injection to surgery: 15 minutes to 30 hours. The data were presented in an oral presentation by James O'Donnell, MD, of Case Western University Hospitals, Cleveland, Ohio, at the 2013 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in Vancouver, Canada.

"As a synthetic, small-sized molecule, Lymphoseek clears the injection site quickly and reliably," said Frederick O. Cope, PhD, Senior Vice President, Pharmaceutical Research and CSO at Navidea Biopharmaceuticals. "The unique receptor-targeting characteristics of Lymphoseek allow for effective and durable identification of tumor-draining lymph nodes, as was clearly demonstrated by this study. This intentionally designed mechanism of action allows Lymphoseek to tightly bind to those lymph nodes that drain from a tumor, where they are retained and can be detected, rather than passively flowing through them as is the case with other agents. As evidenced in this study, Lymphoseek demonstrated the ability to be utilized across time ranges that may be encountered in the clinical setting, from as early as 15 minutes up to 30 hours."

"The ability to reliably schedule lymphatic mapping procedures is important for physicians to efficiently utilize medical resources and staff, and is important for the breast cancer and melanoma patients who want their procedures performed quickly and efficiently during this anxious time," said Dr. O'Donnell, Division Chief, Nuclear Medicine, at UH Case Medical Center. "Dynamics that confront physicians in the clinic revolve around how rapidly a tracing agent clears the injection site, how long it remains in the lymph nodes to enable a lymphatic mapping procedure to be conducted, and most importantly, how accurate the agent may be

in identifying the lymph nodes most likely to harbor tumor metastases. This study was designed to compare the performance of Lymphoseek and VBD with those specific considerations in mind.”

In the study, 332 patients were evaluated in two Phase 3 clinical trials that compared Lymphoseek and VBD in patients with breast cancer and melanoma. A meta-analysis of the rate of agreement (concordance) of Lymphoseek to VBD localization was conducted. The time from injection to surgery was used as a measure to compare efficacy for five discrete time periods (0 to <15 minutes, 15 minutes to < 2 hours, 2 hours to <6 hours, 6 hours to <10 hours and 15 hours to 30 hours), as were pathology findings for combined time window segments relative to VBD. Combined meta-analysis nodal concordance was 99.9%. The overall reverse concordance (radioactive nodes that were also dyed blue) was 65.2%. The failed detection rate for pathology positive patients was 3.7% for Lymphoseek and 22.2% for VBD.

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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