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Navidea Biopharmaceuticals Announces Positive Lymphoseek® (technetium Tc 99m tilmanocept) Injection Results on Injection Timing and Surgery Across Multiple Solid Tumor Types

- Data supporting sNDA demonstrate Lymphoseek clinical utility in lymphatic mapping, independent of surgery performed day of or day after injection -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced results from combined analyses of Phase 3 clinical trials that evaluated Lymphoseek® efficacy in lymphatic mapping for identifying pathology-positive lymph nodes across multiple solid tumor types: melanoma, breast cancer and head and neck squamous cell carcinoma. The results indicated that Lymphoseek sensitivity for sentinel lymph node mapping was consistent across the tumor type studies, regardless of whether surgery was conducted on the same day as, or on the day after injection of Lymphoseek. Additionally, for patients with head and neck cancer, Lymphoseek demonstrated a low false negative rate (FNR) of 2.6% (4.6% for same day injection before surgery and 0.0% FNR in patients injected the day prior to surgery). Results from the study comprise part of an sNDA filing for Lymphoseek which is under review by the U.S. Food and Drug Administration.

“Flexibility and the ability to predictably image and schedule lymphatic mapping procedures either the day before or on the same day of surgery enable efficient and economical utilization of staff and healthcare resources,” said James O’Donnell, M.D., Division Chief, Nuclear Medicine, UH Case Medical Center, Cleveland, Ohio. “The convenience of receptor-targeted imaging agents such as Lymphoseek, which can provide diagnostic accuracy, rapid injection site clearance and predictable lymph node uptake, facilitate lymphatic mapping and informed diagnostic evaluation by clinicians for patients who may have breast cancer, melanoma or head and neck cancer.”

“These results clearly demonstrate the clinical adaptability and utility of Lymphoseek in sentinel lymph node lymphatic mapping to reliably identify tumor-draining lymph nodes that may be at high risk of harboring cancer in patients with breast cancer, melanoma or head and neck squamous cell carcinoma,” said Cornelia Reininger, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Navidea. “Our sNDA for Lymphoseek use in sentinel node biopsy in patients with head and neck cancer, based in part on this study, is in Priority Review with the FDA with an approaching PDUFA date of June 16, 2014. Results from this study are also included in a second sNDA for Lymphoseek label expansion currently in review with the FDA, which is designed to support more flexible utilization of Lymphoseek in

lymphatic mapping and lymphoscintigraphy imaging. These applications reflect Navidea's commitment to expanding usage and indications for Lymphoseek and our belief that the product can provide a flexible, reliable and cost-effective solution for lymphatic mapping across a wide range of tumor types."

The study evaluated Lymphoseek sensitivity in 384 evaluable patients from three pivotal Phase 3 clinical studies: two Phase 3 studies in patients with breast cancer and melanoma (melanoma, n=153; breast cancer, n=148) and one Phase 3 study in patients with head and neck squamous cell carcinoma (n=83). Patients were injected before surgery, imaged, and then surgery was conducted up to 30 hours post-injection. Results based on sensitivity for day-of-injection or day-after-injection were compared. Meta-analysis results across tumor types (n=100 pathology-positive patients) indicated per patient sensitivity for Lymphoseek in identifying pathology-positive subjects. Sensitivity for Lymphoseek was 99% in same day injection procedures, and 99% in surgery procedures performed the day after injection. In addition, the FNR for patients with head and neck squamous cell carcinoma was 4.6% (95% CI: 0.1%-22.8%) for same day injection (n=40) and 0.000 (95% CI: 0%-20.6%) for patients who had surgery on the day after injection (n=42). The data were presented by Bonnie Abbruzzese, Director, Clinical Research, MS, RD, CCRA, Navidea Biopharmaceuticals, at the 2014 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in St. Louis, Mo.

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 (FDA) 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 other head and neck cancers such as thyroid cancer, prostate cancer and cancers of the female reproductive system (e.g., cervix, endometrial and vulva cancer). Lymphoseek was granted Fast Track and Priority Review designation for its sNDA for sentinel lymph node detection in patients with head and neck cancer and is currently in review with the FDA.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to publicly available information, approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 69,500 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2014, and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 137,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

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 developing multiple precision diagnostic products and platforms, including NAV4694, NAV5001, Manocept™ and NAV1800 (RIGScan™), to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making 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. 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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